BioLineRx Reports Year-End 2020 Financial Results and Provides Corporate Update

February 23, 2021

- Phase 3 GENESIS study in stem-cell mobilization (SCM) showed statistically significant positive results for primary endpoint in interim analysis; enrollment ceased early; top-line data expected early Q2 2021 -

- Final results from Phase 2a COMBAT/KEYNOTE-202 study of motixafortide in pancreatic ductal adenocarcinoma (PDAC) showed substantial improvement as compared to historical results across all study endpoints -

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

TEL AVIV, Israel, Feb. 23, 2021 /PRNewswire/ -- BioLineRx Ltd. (NASDAQ: BLRX) (TASE: BLRX), a late clinical-stage biopharmaceutical company focused on oncology, today reports its financial results for the year ended December 31, 2020 and provides a corporate update.

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

- Announced positive results from an interim analysis of its GENESIS Phase 3 trial of motixafortide in stem-cell mobilization (SCM). The interim analysis found statistically significant evidence for the primary endpoint favoring treatment with motixafortide. Based on a recommendation from the independent Data Monitoring Committee (DMC), enrollment was ceased early at 122 patients (instead of 177 originally planned), and top-line data, including full primary and secondary efficacy endpoints, is anticipated in early second quarter of 2021. In parallel, the Company is proceeding with all activities in support of an NDA submission in this indication anticipated in the first half of 2022, including a pre-NDA meeting with the FDA planned for the second half of 2021.
- Reported positive final results from the triple combination arm of the Company's COMBAT/KEYNOTE-202 study evaluating motixafortide in combination with KEYTRUDA® (pembrolizumab) and chemotherapy in patients with second-line stage IV pancreatic ductal adenocarcinoma (PDAC). The results of the study showed substantial improvement as compared to historical results across all study endpoints. The Company is currently planning next development steps for this program, including discussions with potential collaboration partners and development of a protocol for a randomized controlled study.
- Announced initiation of a Phase 2 investigator-initiated clinical trial evaluating motixafortide in combination with LIBTAYO® and chemotherapy in first-line metastatic PDAC. The study is led by Columbia University.
- Announced initiation of a Phase 1b investigator-initiated clinical trial evaluating motixafortide in patients suffering from acute respiratory distress syndrome (ARDS) secondary to COVID-19 and other respiratory viral infections.
- Completed underwritten public offering with gross proceeds of $34.5 million.

"The fourth quarter 2020 was perhaps our most significant so far, having achieved positive data milestones in two programs with significant unmet medical needs – stem-cell mobilization and PDAC," stated Philip Serlin, Chief Executive Officer of BioLineRx. "The Phase 3 SCM interim data that we reported in October were overwhelmingly positive, and based on the DMC's recommendation, we ceased enrollment at 122 out of the originally planned 177 patients. We now look forward to presenting full top-line results from the study, including data related to 100 days of post-transplantation follow-up, by early second quarter of this year. SCM remains our most expeditious path to registration, and we therefore view these data as potentially transformational for our company. In parallel, we are moving forward very aggressively with all activities in support of an NDA submission, which we expect in the first half of next year.

"We are equally excited about the final results from our Phase 2a COMBAT/KEYNOTE-202 PDAC study that we announced in December last year. The data demonstrated that the triple combination of motixafortide, KEYTRUDA and chemotherapy outperformed historical data across all endpoints, including median overall survival, median progression free survival, confirmed and overall response rates and disease control rate. In a cancer population as difficult to treat as second-line metastatic PDAC, and even more specifically those patients initially diagnosed with unresectable stage IV disease, we view these results as highly encouraging and are planning our next development steps forward in this program, likely in collaboration with a biopharmaceutical partner.

"Finally, subsequent to the end of the year, we strengthened our balance sheet through a financing that resulted in gross proceeds of $34.5 million. These funds will allow us to continue to execute on our strategy for motixafortide in both SCM and PDAC, while in parallel advancing our second clinical candidate, the anti-cancer immunotherapy AGI-134, through clinical development. In summary, we exited 2020 on a very positive note, with two data sets that demonstrate both the effectiveness and versatility of motixafortide across multiple indications, and we plan to build upon these successes this year," concluded Mr. Serlin.

Upcoming Significant Expected Milestones

- Top-line results from the Phase 3 GENESIS trial in SCM in early Q2 2021.
- Initial results from Part 2 of the Phase 1/2a trial of AGI-134 in solid tumors in the second half of 2021.
- Pre-NDA meeting with the FDA for SCM in the second half of 2021
- NDA submission for SCM in the first half of 2022

Financial Results for the Year Ended December 31, 2020

Research and development expenses for the year ended December 31, 2020 were $18.2 million, a decrease of $5.2 million, or 22.5%, compared to $23.4 million for the year ended December 31, 2019. The decrease resulted primarily from termination of the BATTLE clinical study for motixafortide in

2019, from lower expenses associated with the motixafortide COMBAT clinical trial and from lower expenses associated with the AGI-134 study, as well as a decrease in share-based compensation and payroll due to a company-wide salary reduction related to the COVID-19 pandemic.

Sales and marketing expenses for the year ended December 31, 2020 were $0.8 million, similar to sales and marketing expenses for the year ended December 31, 2019.

General and administrative expenses for the year ended December 31, 2020 were $3.9 million, an increase of $0.1 million, or 2.6% compared to $3.8 million for the year ended December 31, 2019. The increase resulted primarily from an increase in D&O insurance expenses and share-based compensation, offset by small decreases in a number of G&A expenses.

The Company's operating loss for the year ended December 31, 2020 amounted to $22.9 million, compared to an operating loss of $28.1 million for the year ended December 31, 2019.

Non-operating expenses amounted to $5.7 million for the year ended December 31, 2020, compared to non-operating income of $4.2 million for the year ended December 31, 2019. Non-operating expenses for the year ended December 31, 2020 primarily relate to fair-value adjustments of warrant liabilities on the Company's balance sheet, warrant offering expenses and ATM issuance expenses. Non-operating income for the year ended December 31, 2019 primarily relates to fair-value adjustments of warrant liabilities on the Company's balance sheet, offset by warrant offering expenses.

Net financial expenses amounted to $1.4 million for the year ended December 31, 2020, compared to net financial expenses of $1.5 million for the year ended December 31, 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 year ended December 31, 2020 amounted to $30.0 million, compared with a net loss of $25.5 million for the year ended December 31, 2019.

The Company held $22.6 million in cash, cash equivalents and short-term bank deposits as of December 31, 2020. Subsequent to year end, the Company raised gross proceeds of $34.5 million in an underwritten public offering, and received another $9.8 million in gross proceeds from the exercise of outstanding warrants.

Net cash used in operating activities for the year ended December 31, 2020 was $23.2 million, compared to $22.7 million for the year ended December 31, 2019. The $0.5 million increase in 2020 was primarily the result of a decrease in accounts payable and accruals.

Net cash provided by investing activities for the year ended December 31, 2020 was $16.7 million, compared to $5.3 million for the year ended December 31, 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 for the year ended December 31, 2020 was $17.9 million, compared to $19.2 million for the year ended December 31, 2019. The cash flows in 2020 primarily reflect the registered direct offerings of the Company's ADSs in May and June 2020, as well as net proceeds from the ATM program, offset by repayments of the loan from Kreos Capital. The cash flows in 2019 primarily reflect the underwritten public offering of the Company's ADSs in February 2019, as well as net proceeds from the ATM program.

Conference Call and Webcast Information

BioLineRx will hold a conference call today, Thursday, February 23, 2021 at 10:00 a.m. EST. To access the conference call, please dial +1-866-744-5399 from the US or +972-3-918-0610 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 February 25, 2021; please dial +1-888-782-4291 from the US or +972-3-925-5904 internationally.

(Tables follow)

About BioLineRx

BioLineRx Ltd. (NASDAQ: BLRX) (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. 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 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.
CONSOLIDATED STATEMENTS OF FINANCIAL POSITION

	December 31,	
	2019	2020
	in USD thousands	
Assets		
CURRENT ASSETS		
Cash and cash equivalents	5,297	16,831
Short-term bank deposits	22,192	5,756
Prepaid expenses	108	152
Other receivables	613	141
Total current assets	28,210	22,880
NON-CURRENT ASSETS		
Property and equipment, net	1,816	1,341
Right-of-use assets, net	1,650	1,355
Intangible assets, net	21,891	21,714
Total non-current assets	25,357	24,410
Total assets	53,567	47,290
Liabilities and equity		
CURRENT LIABILITIES		
Current maturities of long-term loans	2,692	3,092
Accounts payable and accruals:		
Trade	7,794	5,918
Other	1,280	1,440
Lease liabilities	202	191
Total current liabilities	11,968	10,641
NON-CURRENT LIABILITIES		
Warrants	658	10,218
Long-term loans, net of current maturities	5,799	2,740
Lease liabilities	1,762	1,661
Total non-current liabilities	8,219	14,619
COMMITMENTS AND CONTINGENT LIABILITIES		
Total liabilities	20,187	25,260

EQUITY		
Ordinary shares	4,692	9,870
Share premium	265,938	279,241
Capital reserve	12,132	12,322
Other comprehensive loss	(1,416)	(1,416)
Accumulated deficit	(247,966)	(277,987)
Total equity	33,380	22,030
Total liabilities and equity	53,567	47,290

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CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

	Year ended December 31,		
	2018	**2019**	**2020**
	in USD thousands		
RESEARCH AND DEVELOPMENT EXPENSES	(19,808)	(23,438)	(18,173)
SALES AND MARKETING EXPENSES	(1,362)	(857)	(840)
GENERAL AND ADMINISTRATIVE EXPENSES	(4,435)	(3,816)	(3,914)
OPERATING LOSS	(25,605)	(28,111)	(22,927)
NON-OPERATING INCOME (EXPENSES), NET	2,397	4,165	(5,701)
FINANCIAL INCOME	719	777	236
FINANCIAL EXPENSES	(473)	(2,277)	(1,629)
NET LOSS AND COMPREHENSIVE LOSS	(22,962)	(25,446)	(30,021)
	in USD		
LOSS PER ORDINARY SHARE – BASIC AND DILUTED	(0.21)	(0.17)	(0.12)
WEIGHTED AVERAGE NUMBER OF SHARES USED IN CALCULATION OF LOSS PER ORDINARY SHARE	108,595,702	146,407,055	252,844,394

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STATEMENTS OF CHANGES IN EQUITY

	Ordinary shares	**Share premium**	**Capital reserve**	**Other comprehensive loss**	**Accumulated deficit**	**Total**
	in USD thousands					
BALANCE AT JANUARY 1, 2018	2,836	240,682	10,337	(1,416)	(199,558)	52,881
CHANGES IN 2018:						
Issuance of share capital, net	263	8,567	-	-	-	8,830
Employee stock options exercised	11	415	(380)	-	-	46
Employee stock options forfeited and expired	-	528	(528)	-	-	-
Share-based compensation	-	-	2,526	-	-	2,526
Comprehensive loss for the year	-	-	-	-	(22,962)	(22,962)
BALANCE AT DECEMBER 31, 2018	3,110	250,192	11,955	(1,416)	(222,520)	41,321
CHANGES IN 2019:						
Issuance of share capital, net	1,580	14,165	-	-	-	15,745
Employee stock options exercised	2	83	(84)	-	-	1
Employee stock options forfeited and expired	-	1,498	(1,498)	-	-	-
Share-based compensation	-	-	1,759	-	-	1,759
Comprehensive loss for the year	-	-	-	-	(25,446)	(25,446)
BALANCE AT DECEMBER 31, 2019	4,692	265,938	12,132	(1,416)	(247,966)	33,380

CHANGES IN 2020:						
Issuance of share capital, net	4,777	9,395	-	-	-	14,172
Warrants exercised	393	2,826	-	-	-	3,219
Employee stock options exercised	8	228	(228)	-	-	8
Employee stock options forfeited and expired	-	854	(854)	-	-	-
Share-based compensation	-	-	1,272	-	-	1,272
Comprehensive loss for the year	-	-	-	-	(30,021)	(30,021)
BALANCE AT DECEMBER 31, 2020	9,870	279,241	12,322	(1,416)	(277,987)	22,030

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CONSOLIDATED CASH FLOW STATEMENTS

	Year ended December 31,		
	2018	**2019**	**2020**
	in USD thousands		
CASH FLOWS - OPERATING ACTIVITIES			
Net loss	(22,962)	(25,446)	(30,021)
Adjustments required to reflect net cash used in operating activities (see appendix below)	(1,230)	2,780	6,815
Net cash used in operating activities	(24,192)	(22,666)	(23,206)
CASH FLOWS - INVESTING ACTIVITIES			
Realization of long-term investment	1,500	-	-
Investments in short-term deposits	(26,500)	(43,545)	(33,500)
Maturities of short-term deposits	44,771	48,875	50,168
Purchase of property and equipment	(173)	(67)	-
Purchase of intangible assets	(10,043)	(6)	-
Net cash provided by investing activities	9,555	5,257	16,668
CASH FLOWS - FINANCING ACTIVITIES			
Issuance of share capital and warrants, net of issuance cost	3,830	20,297	21,215
Employee stock options exercised	46	1	8
Proceeds of long-term loan and warrants, net of issuance costs	9,632	-	-
Repayment of loans	(411)	(889)	(3,133)
Repayments of lease liabilities	-	(215)	(224)
Net cash provided by financing activities	13,097	19,194	17,866
INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	(1,540)	1,785	11,328
CASH AND CASH EQUIVALENTS - BEGINNING OF YEAR	5,110	3,404	5,297
EXCHANGE DIFFERENCES ON CASH AND CASH EQUIVALENTS	(166)	108	206
CASH AND CASH EQUIVALENTS - END OF YEAR	3,404	5,297	16,831

BioLineRx Ltd.

CONSOLIDATED CASH FLOW STATEMENTS

	Year ended December 31,		
	2018	**2019**	**2020**
	in USD thousands		
APPENDIX			
Adjustments required to reflect net cash used in operating activities:			
Income and expenses not involving cash flows:			
Depreciation and amortization	545	940	934
Long-term prepaid expenses	5	56	-
Exchange differences on cash and cash equivalents	166	(108)	(206)
Fair value adjustments of warrants	(1,743)	(4,634)	5,142
Share-based compensation	2,526	1,759	1,272
Interest and exchange differences on short-term deposits	(645)	(775)	(232)

Interest on loans	123	647	474
Gain on realization of long-term investment	(500)	-	-
Warrant issuance costs	-	417	594
Exchange differences on lease liability	-	154	125
	477	(1,544)	8,103
Changes in operating asset and liability items:			
Decrease (increase) in prepaid expenses and other receivables	(934)	1,106	428
Increase (decrease) in accounts payable and accruals	(773)	3,218	(1,716)
	(1,707)	4,324	(1,288)
	(1,230)	2,780	6,815
Supplemental information on interest received in cash	834	868	381
Supplemental information on interest paid in cash	165	1,198	994
Supplemental information on non-cash transactions	5,000	147	1,251

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