BioLineRx Reports Year-End 2021 Financial Results and Provides Corporate Update

March 16, 2022

- Commercial assessment commissioned indicating US stem-cell mobilization opportunity of ~$360m
- Successful pre-NDA meeting with FDA; NDA submission anticipated in mid-2022
- Announced highly positive results from additional pharmacoeconomic study indirectly comparing Motixafortide plus G-CSF versus plerixafor plus G-CSF
- Cash and cash equivalents at December 31, 2021 of $57.1 million
- Management to hold conference call today, March 16, at 10:00 am EDT

TEL AVIV, Israel, March 16, 2022 /PRNewswire/ -- BioLineRx Ltd. (NASDAQ: BLRX) (TASE: BLRX), a late clinical-stage biopharmaceutical company focused on oncology, today reports its financial results for the fourth quarter and year ended December 31, 2021 and provides a corporate update.

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

- Commissioned a comprehensive third-party market assessment of the US stem cell mobilization market, which identified a commercial opportunity in the US of ~$360 million;
- Completed a successful pre-NDA meeting with the FDA, at which the FDA agreed that the Company's proposed regulatory data package is sufficient to support an NDA submission in stem cell mobilization. To that end, the Company intends to submit its NDA in this indication in mid-2022;
- Announced significantly positive and commercially relevant results from a pharmacoeconomic cost effectiveness study comparing Motixafortide + G-CSF versus G-CSF alone and indirectly comparing Motixafortide + G-CSF versus plerixafor + G-CSF. Both analyses demonstrated substantial cost savings from using Motixafortide and further strengthened the case for use of Motixafortide as a primary mobilization agent for all multiple myeloma patients undergoing autologous stem cell transplantation (ASCT);
    - Versus plerixafor + G-CSF, the study found that the addition of Motixafortide to G-CSF is associated with a net cost savings of ~$30,000 per patient (not including the cost of Motixafortide).
    - Versus G-CSF alone, the study found that the addition of Motixafortide to G-CSF is associated with a net cost savings of ~$19,000 per patient (not including the cost of Motixafortide).
- Delivered one oral and three poster presentations at the 63rd American Society of Hematology (ASH) Annual Meeting & Exposition, which was held December 11-14, 2021. The oral presentation highlighted the successful GENESIS Phase 3 pivotal trial;
- Announced formation of Immuno-Oncology Scientific Advisory Board comprised of recognized leaders in the fields of cancer immunology, intra-tumoral injections and clinical development. The SAB will provide guidance on the Company's ongoing AGI-134 anti-cancer vaccine program and other potential immuno-oncology initiatives;
- Completed recruitment of part 2 of ongoing Phase 1/2a trial of AGI-134 in solid tumors;
- Ended the fourth quarter on solid financial footing, with cash and cash equivalents of $57.1 million.

"The opportunity for Motixafortide in stem-cell mobilization is significant," stated Philip Serlin, Chief Executive Officer of BioLineRx. "We recently commissioned a comprehensive third-party market assessment which identified a $360 million addressable annual opportunity in the US. We continue to maintain optionality among a number of commercialization alternatives, as we believe the very concentrated end market, where approximately 80 transplant centers in the US conduct the vast majority of stem cell transplant procedures, would require a limited commercialization footprint. In the meantime, in order to ensure that Motixafortide is well positioned for a timely and robust US launch that will maximize the value of the asset, we have initiated a number of pre-commercialization launch activities.

At the same time, we are very pleased with the additional results of our pharmacoeconomic study, which demonstrate a significant cost benefit for Motixafotide plus G-CSF as compared to plerixafor plus G-CSF, one of the main current treatment options. These results, together with the overwhelmingly positive results from our GENESIS Phase 3 study, give us tremendous optimism for the potential of Motixafortide to become the new standard of care mobilization agent for multiple myeloma patients – the first true advancement in stem cell mobilization since the approval of plerixafor in 2008.

Following our very productive pre-NDA meeting with FDA that we completed in December, we are diligently working to submit the NDA and position the product for commercialization. We anticipate the NDA submission will occur in mid-2022."

"With over $57 million in cash, we believe we are well financed to extract maximum value from Motixafortide in SCM while at the same time advancing our other pipeline programs," concluded Mr. Serlin.

Upcoming Expected Milestones:

- Submission of NDA to FDA for Motixafortide as novel mobilization agent for multiple myeloma patients undergoing autologous stem cell transplantation in mid-2022;
- Announce initial results for Part 2 of Phase 1/2a trial of AGI-134 in solid tumors in H2 2022;
- Initiate Phase 2 study of AGI-134 in 2023;

- Potential FDA approval of Motixafortide in 2023;
- Potential US launch of Motixafortide in SCM in 2023.

Financial Results for the Year Ended December 31, 2021:

Research and development expenses for the year ended December 31, 2021 were $19.5 million, an increase of $1.3 million, or 7.1%, compared to $18.2 million for the year ended December 31, 2020. The increase resulted primarily from an increase in expenses associated with the AGI-134 phase 1/2a 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 year ended December 31, 2021 were $1.0 million, an increase of $0.2 million, or 19.4% compared to $0.8 million for the year ended December 31, 2020. The increase resulted primarily from an increase in consultancy services related to Motixafortide.

General and administrative expenses for the year ended December 31, 2021 were $4.3 million, an increase of $0.4, or 10.0% compared to $3.9 million for the year ended December 31, 2020. The increase resulted primarily from an increase in directors' and officers' insurance expenses.

The Company's operating loss for the year ended December 31, 2021 amounted to $24.8 million, compared to an operating loss of $22.9 million for the year ended December 31, 2020.

Non-operating expenses amounted to $1.8 million for the year ended December 31, 2021, compared to non-operating expenses of $5.7 million for the year ended December 31, 2020. Non-operating expenses for both periods primarily relate to fair-value adjustments of warrant liabilities and issuance expenses related to the ATM.

Net financial expenses amounted to $0.4 million for the year ended December 31, 2021, compared to net financial expenses of $1.4 million for the year ended December 31, 2020. 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, 2021 amounted to $27.1 million, compared with a net loss of $30.0 million for the year ended December 31, 2020.

The Company held $57.1 million in cash, cash equivalents and short-term bank deposits as of December 31, 2021.

Net cash used in operating activities for the year ended December 31, 2021 was $23.6 million, compared to $23.2 million for the year ended December 31, 2020. The $0.4 million increase in 2021 was primarily the result of an increase in research and development expenses.

Net cash used in investing activities for the year ended December 31, 2021 was $38.2 million, compared to net cash provided by investing activities of $16.7 million for the year ended December 31, 2020. The changes in cash flows from investing activities relate primarily to investments in, and maturities of, short-term bank deposits during the respective periods.

Net cash provided by financing activities for the year ended December 31, 2021 was $57.7 million, compared to $17.9 million for the year ended December 31, 2020. The cash flows in 2021 primarily reflect the underwritten public offering of the Company's 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 the registered direct offerings of ADSs in May and June 2020, as well as 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, Wednesday, March 16 at 10:00 a.m. EDT. 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 March 18, 2022; please dial +1-888-295-2634 from the US or +972-3-925-5904 internationally.

A copy of the Company's annual report on Form 20-F for the year ended December 31, 2021 has been filed with the U.S. Securities and Exchange Commission at https://www.sec.gov/ and posted on the Company's investor relations website at https://ir.biolinerx.com/. The Company will deliver a hard copy of its annual report, including its complete audited consolidated financial statements, free of charge, to its shareholders upon request to Mali Ze'evi, Chief Financial Officer, at maliz@biolinerx.com.

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, has successfully completed a pre-NDA meeting with the FDA, 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 "anticipates," "believes," "could," "estimates," "expects," "intends," "may," "plans," "potential," "predicts," "projects," "should," "will," and "would," and describe opinions about future events. These forward-looking statements involve known and unknown risks, uncertainties and other factors 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 and ability to access sufficient 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; statements as to the impact of the political and security situation in Israel on BioLineRx's business; and the impact of the COVID-19 pandemic and the Russian invasion of Ukraine, which may exacerbate the magnitude of the factors discussed above. 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 16, 2022. 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.

Contact:

Tim McCarthy
LifeSci Advisors, LLC
+1-917-679-9282
tim@lifesciadvisors.com

or

Moran Meir
LifeSci Advisors, LLC
+972-54-476-4945
moran@lifesciadvisors.com

BioLineRx Ltd.

CONSOLIDATED STATEMENTS OF FINANCIAL POSITION

	December 31,	
	2020	2021
	in USD thousands	
Assets		
CURRENT ASSETS		
Cash and cash equivalents	16,831	12,990
Short-term bank deposits	5,756	44,145
Prepaid expenses	152	127
Other receivables	141	142
Total current assets	22,880	57,404
NON-CURRENT ASSETS		
Property and equipment, net	1,341	952
Right-of-use assets, net	1,355	1,331
Intangible assets, net	21,714	21,704
Total non-current assets	24,410	23,987
Total assets	47,290	81,391
Liabilities and equity		
CURRENT LIABILITIES		
Current maturities of long-term loan	3,092	2,757
Accounts payable and accruals:		
Trade	5,918	5,567
Other	1,440	1,227

Current maturities of lease liabilities	191	168
Total current liabilities	10,641	9,719
NON-CURRENT LIABILITIES		
Warrants	10,218	1,859
Long-term loan, net of current maturities	2,740	-
Lease liabilities	1,661	1,726
Total non-current liabilities	14,619	3,585
COMMITMENTS AND CONTINGENT LIABILITIES		
Total liabilities	25,260	13,304
EQUITY		
Ordinary shares	9,870	21,066
Share premium	279,241	339,346
Warrants	-	975
Capital reserve	12,322	13,157
Other comprehensive loss	(1,416)	(1,416)
Accumulated deficit	(277,987)	(305,041)
Total equity	22,030	68,087
Total liabilities and equity	47,290	81,391

CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

	Year ended December 31,		
	2019	**2020**	**2021**
	in USD thousands		
RESEARCH AND DEVELOPMENT EXPENSES	(23,438)	(18,173)	(19,466)
SALES AND MARKETING EXPENSES	(857)	(840)	(1,003)
GENERAL AND ADMINISTRATIVE EXPENSES	(3,816)	(3,914)	(4,308)
OPERATING LOSS	(28,111)	(22,927)	(24,777)
NON-OPERATING INCOME (EXPENSES), NET	4,165	(5,701)	(1,830)
FINANCIAL INCOME	777	236	559
FINANCIAL EXPENSES	(2,277)	(1,629)	(1,006)
LOSS AND COMPREHENSIVE LOSS	(25,446)	(30,021)	(27,054)
	in USD		
LOSS PER ORDINARY SHARE – BASIC AND DILUTED	(0.17)	(0.12)	(0.04)
WEIGHTED AVERAGE NUMBER OF SHARES USED IN CALCULATION OF LOSS PER ORDINARY SHARE	146,407,055	252,844,394	662,933,695

STATEMENTS OF CHANGES IN EQUITY

	Ordinary shares	**Share premium**	**Warrants**	**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 IN 2019:							
Issuance of share capital and warrants, 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 and warrants, 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
CHANGES IN 2021:							
Issuance of share capital and warrants, net	8,956	40,476	975	-	-	-	50,407
Warrants exercised	2,235	18,967	-	-	-	-	21,202
Employee stock options exercised	5	41	-	(39)	-	-	7
Employee stock options forfeited and expired	-	621	-	(621)	-	-	-
Share-based compensation	-	-	-	1,495	-	-	1,495
Comprehensive loss for the year	-	-	-		-	(27,054)	(27,054)
BALANCE AT DECEMBER 31, 2021	21,066	339,346	975	13,157	(1,416)	(305,041)	68,087

CONSOLIDATED STATEMENTS OF CASH FLOWS

	Year ended December 31,		
	2019	**2020**	**2021**
	in USD thousands		
CASH FLOWS - OPERATING ACTIVITIES			
Loss	(25,446)	(30,021)	(27,054)
Adjustments required to reflect net cash used in operating activities (see appendix below)	2,780	6,815	3,481
Net cash used in operating activities	(22,666)	(23,206)	(23,573)
CASH FLOWS - INVESTING ACTIVITIES			
Investments in short-term deposits	(43,545)	(33,500)	(78,000)
Maturities of short-term deposits	48,875	50,168	39,873
Purchase of property and equipment	(67)	-	(97)
Purchase of intangible assets	(6)	-	-
Net cash provided by (used in) investing activities	5,257	16,668	(38,224)
CASH FLOWS - FINANCING ACTIVITIES			
Issuance of share capital and warrants, net of issuance costs	20,297	19,246	50,407
Exercise of warrants	-	1,969	10,907
Employee stock options exercised	1	8	7
Repayments of loans	(889)	(3,133)	(3,376)
Repayments of lease liabilities	(215)	(224)	(196)
Net cash provided by financing activities	19,194	17,866	57,749
INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	1,785	11,328	(4,048)
CASH AND CASH EQUIVALENTS - BEGINNING OF YEAR	3,404	5,297	16,831
EXCHANGE DIFFERENCES ON CASH AND CASH EQUIVALENTS	108	206	207
CASH AND CASH EQUIVALENTS - END OF YEAR	5,297	16,831	12,990

CONSOLIDATED STATEMENTS OF CASH FLOWS

	Year ended December 31,		
	2019	**2020**	**2021**
	in USD thousands		

APPENDIX

Adjustments required to reflect net cash used in operating activities:

Income and expenses not involving cash flows:			
Depreciation and amortization	940	934	703
Long-term prepaid expenses	56	-	
Exchange differences on cash and cash equivalents	(108)	(206)	(207)
Fair value adjustments of warrants	(4,634)	5,142	1,936
Share-based compensation	1,759	1,272	1,495
Interest on short-term deposits	(775)	(232)	(262)
Interest on loans	647	474	301
Warrant issuance costs	417	594	-
Exchange differences on lease liabilities	154	125	55
	(1,544)	8,103	4,021
Changes in operating asset and liability items:			
Decrease in prepaid expenses and other receivables	1,106	428	24
Increase (decrease) in accounts payable and accruals	3,218	(1,716)	(564)
	4,324	(1,288)	(540)
	2,780	6,815	3,481
Supplemental information on interest received in cash	868	381	138
Supplemental information on interest paid in cash	1,198	994	682
Supplemental information on non-cash transactions	147	1,251	10,112

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