BioLineRx Reports First Quarter 2021 Financial Results and Provides Corporate Update

May 26, 2021

- Phase 3 GENESIS study in stem-cell mobilization (SCM) demonstrated highly statistically significant positive results across all primary and secondary endpoints -

- ~90% of patients in treatment arm underwent transplantation following only one dose of Motixafortide and only one apheresis session; potentially positions Motixafortide + G-CSF to become new standard of care in this indication -

- Company proceeding with activities in support of NDA submission targeted for H1 2022 -

- Management to hold conference call today, May 26, at 10:00 am EST -

TEL AVIV, Israel, May 26, 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 March 31, 2021 and provides a corporate update.

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

- Announced positive topline results from GENESIS Phase 3 trial of Motixafortide in stem-cell mobilization (SCM). The data demonstrate that the study successfully met all primary and secondary endpoints with an exceptionally high level of statistical significance ($p<0.0001$).
- 88.3% of patients receiving Motixafortide + G-CSF underwent transplantation after only ONE administration of Motixafortide and in only ONE apheresis session, compared to 10.8% for G-CSF alone; potentially supports Motixafortide on top of G-CSF as new standard-of-care mobilization agent in autologous bone-marrow transplantation.
- The Company is proceeding with 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 this year.
- Presented data at the 2021 American Association for Cancer Research (AACR) Annual Meeting analyzing results by liver metastasis status from the Company's Phase 2a COMBAT/KEYNOTE-202 triple combination study testing Motixafortide in metastatic pancreatic cancer. The analysis further strengthened the results reported from the study in December 2020, since not only were substantially all patients initially diagnosed with stage 4 disease, but the vast majority (~80%) of the patients had liver metastases, emphasizing the extremely difficult patient population in this study.
- Strengthened balance sheet with underwritten public offering resulting in gross proceeds of $34.5 million.

"Subsequent to the end of the first quarter, we were extremely excited to announce positive topline results from our GENESIS Phase 3 trial of Motixafortide in stem-cell mobilization for autologous bone marrow transplantation in multiple myeloma patients," stated Philip Serlin, Chief Executive Officer of BioLineRx. "The results demonstrated, with a high degree of statistical significance, a meaningful clinical benefit from adding Motixafortide to the current standard of care, G-CSF, for the mobilization of the targeted number of stem cells required for transplantation. While this was not a head-to-head study, our results compare very favorably to the registrational study of plerixafor.

"Importantly, almost 90% of patients in the treatment cohort underwent transplantation after only one administration of Motixafortide and in only one apheresis session, compared to 10.8% for G-CSF alone. We believe this positions Motixafortide to become the new standard of care in this indication, with a clear clinical benefit of 'one dose, one apheresis, 90% mobilization success rate.' We are working diligently to submit a New Drug Application to the FDA in the first half of next year. If approved, this would be transformative for BioLineRx, and a huge milestone in the Company's history.

"Regarding our PDAC program, the compelling liver metastases data that we recently presented at AACR further strengthen an already robust case for continued development in this very challenging indication. We continue to engage in discussions with potential partners regarding future development.

"To support these and other initiatives, including continued advancement of our second clinical candidate, the anti-cancer vaccine AGI-134, we raised $34.5 million in January that we believe will finance the Company through multiple potentially value-creating milestones," concluded Mr. Serlin.

Upcoming Significant Expected Milestones:

- 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 Quarter Ended March 31, 2021

Research and development expenses for the quarter ended March 31, 2021 were $4.3 million, a decrease of $1.1 million, or 21.1%, compared to $5.4 million for the quarter ended March 31, 2020. The decrease resulted primarily from lower expenses associated with the Motixafortide COMBAT clinical trial, as well as lower expenses associated with the AGI-134 study.

Sales and marketing expenses for the quarter ended March 31, 2021 were $0.2 million, similar to sales and marketing expenses for the quarter ended March 31, 2020.

General and administrative expenses for the quarter ended March 31, 2021 were $1.0 million, a decrease of $0.2 million, or 18.2% compared to $1.2 million for the quarter ended March 31, 2020. The decrease resulted primarily from a decrease in share-based compensation.

The Company's operating loss for the quarter ended March 31, 2021 amounted to $5.5 million, compared to an operating loss of $6.8 million for the quarter ended March 31, 2020.

Non-operating expenses amounted to $4.6 million for the quarter ended March 31, 2021, compared to non-operating income of $0.5 million for the quarter ended March 31, 2020. Non-operating income (expenses) for both periods primarily relate to fair-value adjustments of warrant liabilities on the Company's balance sheet.

Net financial expenses amounted to $0.2 million for the quarter ended March 31, 2021, compared to net financial expenses of $0.3 million for the quarter ended March 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 quarter ended March 31, 2021 amounted to $10.2 million, compared with a net loss of $6.6 million for the quarter ended March 31, 2020.

The Company held $58.1 million in cash, cash equivalents and short-term bank deposits as of March 31, 2021.

Net cash used in operating activities was $6.2 million for the quarter ended March 31, 2021, compared with net cash used in operating activities of $6.7 million for the quarter ended March 31, 2020. The $0.5 million decrease in net cash used in operating activities between the two periods was primarily the result of a decrease in research and development expenses.

Net cash used in investing activities was $36.3 million for the quarter ended March 31, 2021, compared to net cash provided by investing activities of $6.2 million for the quarter ended March 31, 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 $41.9 million for the quarter ended March 31, 2021, compared to net cash provided by financing activities of $0.4 million for the quarter ended March 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 an ATM facility, offset by repayments of a loan from Kreos Capital. The cash flows in 2020 primarily reflect the net proceeds from an ATM facility, offset by repayments of a loan from Kreos Capital.

Conference Call and Webcast Information

BioLineRx will hold a conference call today, Wednesday, May 26, 2021 at 10:00 a.m. EDT. 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 May 28, 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. 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	March 31, 2021
	in USD thousands	
Assets		
CURRENT ASSETS		
Cash and cash equivalents	16,831	16,047
Short-term bank deposits	5,756	42,036
Prepaid expenses	152	1,079
Other receivables	141	190
Total current assets	22,880	59,352
NON-CURRENT ASSETS		
Property and equipment, net	1,341	1,243
Right-of-use assets, net	1,355	1,297
Intangible assets, net	21,714	21,707
Total non-current assets	24,410	24,247
Total assets	47,290	83,599
Liabilities and equity		
CURRENT LIABILITIES		
Current maturities of long-term loans	3,092	3,220
Accounts payable and accruals:		
Trade	5,918	5,756
Other	1,440	1,100
Lease liabilities	191	140
Total current liabilities	10,641	10,216
NON-CURRENT LIABILITIES		
Warrants	10,218	5,247
Long-term loans, net of current maturities	2,740	1,891
Lease liabilities	1,661	1,598
Total non-current liabilities	14,619	8,736
COMMITMENTS AND CONTINGENT LIABILITIES		
Total liabilities	25,260	18,952
EQUITY		
Ordinary shares	9,870	18,731
Share premium	279,241	321,920
Warrants	-	975

Capital reserve	12,322	12,616
Other comprehensive loss	(1,416)	(1,416)
Accumulated deficit	(277,987)	(288,179)
Total equity	22,030	64,647
Total liabilities and equity	47,290	83,599

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

	Three months ended March 31,	
	2020	2021
	in USD thousands	
RESEARCH AND DEVELOPMENT EXPENSES	(5,422)	(4,278)
SALES AND MARKETING EXPENSES	(175)	(154)
GENERAL AND ADMINISTRATIVE EXPENSES	(1,243)	(1,017)
OPERATING LOSS	(6,840)	(5,449)
NON-OPERATING INCOME (EXPENSES), NET	469	(4,561)
FINANCIAL INCOME	140	117
FINANCIAL EXPENSES	(414)	(299)
NET LOSS AND COMPREHENSIVE LOSS	(6,645)	(10,192)
LOSS PER ORDINARY SHARE - BASIC AND DILUTED	(0.04)	(0.02)
WEIGHTED AVERAGE NUMBER OF SHARES USED IN CALCULATION OF LOSS PER ORDINARY SHARE	176,454,423	559,537,952

BioLineRx Ltd.
CONDENSED CONSOLIDATED 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 THREE MONTHS ENDED MARCH 31, 2020:							
Issuance of share capital, net	208	895	-	-	-	-	1,103
Employee stock options exercised	7	204	-	(204)	-	-	7
Employee stock options forfeited and expired	-	103	-	(103)	-	-	-
Share-based compensation	-	-	-	663	-	-	663
Comprehensive loss for the period	-	-	-	-	-	(6,645)	(6,645)
BALANCE AT MARCH 31, 2020	4,907	267,140	-	12,488	(1,416)	(254,611)	28,508

	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 THREE MONTHS ENDED MARCH 31, 2021:							
Issuance of share capital and warrants, net	6,805	24,979	975	-	-	-	32,759
Warrants exercised	2,051	17,523	-	-	-	-	19,574
Employee stock options exercised	5	38	-	(38)	-	-	5
Employee stock options forfeited and expired	-	139	-	(139)	-	-	-

Share-based compensation	-	-	-	471	-	-	471
Comprehensive loss for the period	-	-	-	-	-	(10,192)	(10,192)
BALANCE AT MARCH 31, 2021	18,731	321,920	975	12,616	(1,416)	(288,179)	64,647

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

	Three months ended March 31,	
	2020	2021
	in USD thousands	
CASH FLOWS - OPERATING ACTIVITIES		
Comprehensive loss for the period	(6,645)	(10,192)
Adjustments required to reflect net cash used in operating activities (see appendix below)	(93)	3,963
Net cash used in operating activities	(6,738)	(6,229)
CASH FLOWS - INVESTING ACTIVITIES		
Investments in short-term deposits	(6,000)	(42,000)
Maturities of short-term deposits	12,191	5,758
Purchase of property and equipment	-	(19)
Net cash provided by (used in) investing activities	6,191	(36,261)
CASH FLOWS - FINANCING ACTIVITIES		
Issuance of share capital and warrants, net of issuance costs	1,103	42,765
Employee stock options exercised	7	5
Repayments of loans	(682)	(814)
Repayments of lease liabilities	(41)	(49)
Net cash provided by financing activities	387	41,907
DECREASE IN CASH AND CASH EQUIVALENTS	(160)	(583)
CASH AND CASH EQUIVALENTS – BEGINNING OF PERIOD	5,297	16,831
EXCHANGE DIFFERENCES ON CASH AND CASH EQUIVALENTS	(65)	(201)
CASH AND CASH EQUIVALENTS - END OF PERIOD	5,072	16,047

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

	Three months ended March 31,	
	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	321	182
Exchange differences on cash and cash equivalents	65	201
Fair value adjustments of warrants	(476)	4,597
Share-based compensation	663	471
Interest and exchange differences on short-term deposits	(108)	(38)
Interest on loans	44	93
Exchange differences on lease liability	(82)	(65)
	427	5,441
Changes in operating asset and liability items:		

Increase in prepaid expenses and other receivables	(238)	(976)
Decrease in accounts payable and accruals	(282)	(502)
	(520)	(1,478)
	(93)	3,963

Supplemental information on interest received in cash	184	22
Supplemental information on interest paid in cash	275	200
Supplemental information on non-cash portion oftransaction related to exercised warrants	-	9,568

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