BioLineRx Reports First Quarter 2022 Financial Results and Provides Corporate Update

May 11, 2022

- On track to submit New Drug Application to FDA for Motixafortide in stem cell mobilization (SCM) for autologous stem cell transplantation in mid-2022, consistent with prior guidance -

- Progressing critical Motixafortide pre-launch activities while maintaining full optionality on commercialization strategies -

- Cash and cash equivalents at March 31, 2022 of $50.6 million, sufficient to fund operations, as currently planned, into first half of 2024 -

- Management to hold conference call today, May 11, at 10:00 am EDT -

TEL AVIV, Israel, May 11, 2022 /PRNewswire/ -- BioLineRx Ltd. (NASDAQ: BLRX) (TASE: BLRX), a late clinical-stage biopharmaceutical company focused on oncology, today reports its financial results for the first quarter ended March 31, 2022 and provides a corporate update.

Significant events and achievements during the first quarter 2022 and subsequent period:

- Progressed the New Drug Application (NDA) for Motixafortide in stem cell mobilization, remaining on track to submit mid-year;
- Advanced critical pre-launch activities while maintaining full optionality with respect to Motixafortide commercialization plans in the U.S., if approved;
- Commissioned a comprehensive third-party market assessment of the US stem cell mobilization market, which identified a commercial opportunity of ~$360 million annually in the U.S. alone;
- 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:

  - 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).

- Completed recruitment of part 2 of ongoing Phase 1/2a trial of AGI-134 in solid tumors;
- Ended the first quarter on solid financial footing, with cash and cash equivalents of $50.6 million, sufficient to fund operations, as currently planned, into the first half of 2024.

"During the first quarter and subsequent period, we continued to prepare our New Drug Application for Motixafortide in stem cell mobilization, and we remain on track for submission to the FDA mid-year, consistent with our prior guidance," stated Philip Serlin, Chief Executive Officer of BioLineRx. "In parallel, we are advancing a range of critical pre-launch activities, should Motixafortide be approved, while maintaining full optionality with respect to our commercialization plans, in light of the highly concentrated end market in the U.S., in which 80 transplant centers conduct the vast majority of stem cell transplant procedures.

"The third-party commercial market assessment that we recently commissioned estimates the size of the stem cell mobilization market to be $360 million annually in the U.S. alone and growing. In this respect, the overwhelmingly positive results from our GENESIS Phase 3 study, together with the very compelling cost savings identified through our pharmacoeconomic cost effectiveness studies, give us optimism that Motixafortide, if approved, can quickly become a core component of a new mobilization paradigm in multiple myeloma patients, and in potential other indications as well.

"With over $50 million in cash, we believe we are well financed to extract maximum value from Motixafortide in stem cell mobilization while at the same time advancing our other pipeline programs, allowing us to achieve notable corporate and clinical milestones into the first half of 2024," 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;
- Initial results from 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 Quarter Ended March 31, 2022:

Research and development expenses for the quarter ended March 31, 2022 were $4.4 million, an increase of $0.1 million, or 3.7%, compared to $4.3 million for the quarter ended March 31, 2021. The increase resulted primarily from an increase in expenses associated with the AGI-134 study, offset by lower expenses associated with the completed Motixafortide GENESIS and COMBAT clinical trials.

Sales and marketing expenses for the quarter ended March 31, 2022 were $0.7 million, an increase of $0.5 million, or 313% compared to $0.2 million for the quarter ended March 31, 2021. The increase resulted primarily from an increase in market research and consultancy services, as well as initiation of pre-launch activities related to Motixafortide.

General and administrative expenses for the quarter ended March 31, 2022 were $1.0 million, similar to the comparable period in 2021.

The Company's operating loss for the quarter ended March 31, 2022 amounted to $6.1 million, compared to an operating loss of $5.4 million for the quarter ended March 31, 2021.

Non-operating income amounted to $1.3 million for the quarter ended March 31, 2022, compared to non-operating expenses of $4.6 million for the quarter ended March 31, 2021. 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 $0.1 million for the quarter ended March 31, 2022, compared to net financial expenses of $0.2 million for the quarter ended March 31, 2021. 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, 2022 amounted to $4.9 million, compared with a net loss of $10.2 million for the quarter ended March 31, 2021.

The Company held $50.6 million in cash, cash equivalents and short-term bank deposits as of March 31, 2022, compared with $57.1 million as of December 31, 2021.

Net cash used in operating activities was $5.6 million for the quarter ended March 31, 2022, compared with net cash used in operating activities of $6.2 million for the quarter ended March 31, 2021. The $0.6 million decrease in net cash used in operating activities between the two periods was primarily the result of changes in operating asset and liability items in the two periods, i.e., a smaller increase in prepaid expenses and other receivables in 2022 versus 2021, as well as increase in accounts payable and accruals in 2022, versus a decrease in the 2021 period.

Net cash provided by investing activities was $5.0 million for the quarter ended March 31, 2022, compared to net cash used in investing activities of $36.3 million for the quarter ended March 31, 2021. The changes in cash flows from investing activities relate primarily to investments in, and maturities of, short-term bank deposits.

Net cash used in financing activities was $1.0 million for the quarter ended March 31, 2022, compared to net cash provided by financing activities of $41.9 million for the quarter ended March 31, 2021. The cash flows in 2022 primarily reflect repayments of the loan from Kreos Capital. The cash flows in 2021 primarily reflect the underwritten public offering of ADSs in January 2021, warrant exercises, and net proceeds from an ATM facility, offset by repayments of the loan from Kreos Capital.

Conference Call and Webcast Information

BioLineRx will hold a conference call today, Wednesday, May 11 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 May 13, 2022; 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 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, 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.

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BioLineRx Ltd.
CONDENSED CONSOLIDATED INTERIM STATEMENTS OF FINANCIAL POSITION
(UNAUDITED)

	December 31, 2021	March 31, 2022
	in USD thousands	
Assets		
CURRENT ASSETS		
Cash and cash equivalents	12,990	11,446
Short-term bank deposits	44,145	39,144
Prepaid expenses	127	161
Other receivables	142	190
Total current assets	57,404	50,941
NON-CURRENT ASSETS		
Property and equipment, net	952	855
Right-of-use assets, net	1,331	1,273
Intangible assets, net	21,704	21,704
Total non-current assets	23,987	23,832
Total assets	81,391	74,773
Liabilities and equity		
CURRENT LIABILITIES		
Current maturities of long-term loan	2,757	1,903
Accounts payable and accruals:		
Trade	5,567	5,784
Other	1,227	1,264
Lease liabilities	168	147
Total current liabilities	9,719	9,098
NON-CURRENT LIABILITIES		
Warrants	1,859	604
Lease liabilities	1,726	1,658
Total non-current liabilities	3,585	2,262
COMMITMENTS AND CONTINGENT LIABILITIES		
Total liabilities	13,304	11,360
EQUITY		
Ordinary shares	21,066	21,066
Share premium	339,346	339,444
Warrants	975	975
Capital reserve	13,157	13,315
Other comprehensive loss	(1,416)	(1,416)

Accumulated deficit	(305,041)	(309,971)
Total equity	68,087	63,413
Total liabilities and equity	81,391	74,773

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

	Three months ended March 31,	
	2021	2022
	in USD thousands	
RESEARCH AND DEVELOPMENT EXPENSES	(4,278)	(4,435)
SALES AND MARKETING EXPENSES	(154)	(637)
GENERAL AND ADMINISTRATIVE EXPENSES	(1,017)	(1,007)
OPERATING LOSS	(5,449)	(6,079)
NON-OPERATING INCOME (EXPENSES), NET	(4,561)	1,268
FINANCIAL INCOME	117	67
FINANCIAL EXPENSES	(299)	(186)
NET LOSS AND COMPREHENSIVE LOSS	(10,192)	(4,930)
LOSS PER ORDINARY SHARE - BASIC AND DILUTED	(0.02)	(0.01)
WEIGHTED AVERAGE NUMBER OF SHARES USED IN CALCULATION OF LOSS PER ORDINARY SHARE	559,537,952	715,156,008

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, 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

	Ordinary shares	Share premium	Warrants	Capital Reserve	Other comprehensive loss	Accumulated deficit	Total
	in USD thousands						
BALANCE AT JANUARY 1, 2022	21,066	339,346	975	13,157	(1,416)	(305,041)	68,087
CHANGES FOR THREE MONTHS ENDED MARCH 31, 2022:							
Employee stock options forfeited and expired	-	98	-	(98)	-	-	-
Share-based compensation	-	-	-	256	-	-	256
Comprehensive loss for the period	-	-	-	-	-	(4,930)	(4,930)
BALANCE AT MARCH 31, 2022	21,066	399,444	975	13,315	(1,416)	(309,971)	63,413

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

	Three months ended March 31,	
	2021	2022
	in USD thousands	
CASH FLOWS - OPERATING ACTIVITIES		
Comprehensive loss for the period	(10,192)	(4,930)
Adjustments required to reflect net cash used in operating activities (see appendix below)	3,963	(656)
Net cash used in operating activities	(6,229)	(5,586)
CASH FLOWS - INVESTING ACTIVITIES		
Investments in short-term deposits	(42,000)	(7,000)
Maturities of short-term deposits	5,758	12,066
Purchase of property and equipment	(19)	(18)
Net cash provided by (used in) investing activities	(36,261)	5,048
CASH FLOWS - FINANCING ACTIVITIES		
Issuance of share capital and warrants, net of issuance costs	42,765	-
Employee stock options exercised	5	-
Repayments of loan	(814)	(895)
Repayments of lease liabilities	(49)	(48)
Net cash provided by (used in) financing activities	41,907	(943)
DECREASE IN CASH AND CASH EQUIVALENTS	(583)	(1,481)
CASH AND CASH EQUIVALENTS – BEGINNING OF PERIOD	16,831	12,990
EXCHANGE DIFFERENCES ON CASH AND CASH EQUIVALENTS	(201)	(63)
CASH AND CASH EQUIVALENTS - END OF PERIOD	16,047	11,446

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

	Three months ended March 31,	
	2021	2022
	in USD thousands	
Adjustments required to reflect net cash used in operating activities:		
Income and expenses not involving cash flows:		
Depreciation and amortization	182	173
Exchange differences on cash and cash equivalents	201	63
Fair value adjustments of warrants	4,597	(1,255)
Share-based compensation	471	256
Interest on short-term deposits	(38)	(65)
Interest on loan	93	41
Exchange differences on lease liabilities	(65)	(41)
	5,441	(828)
Changes in operating asset and liability items:		
Increase in prepaid expenses and other receivables	(976)	(82)
Increase (decrease) in accounts payable and accruals	(502)	254
	(1,478)	172
	3,963	(656)
Supplemental information on interest received in cash	22	68
Supplemental information on interest paid in cash	200	112

Supplemental information on non-cash portion of transaction related to exercised warrants	9,568	-

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