BioLineRx Reports First Quarter 2023 Financial Results and Recent Corporate and Portfolio Updates

May 24, 2023 11:00 AM IDT

- ***On Track for September PDUFA Target Action Date on NDA for Motixafortide in Stem Cell Mobilization (SCM) for Autologous Transplantation in Multiple Myeloma (MM)***
- ***Rapidly Advancing U.S. Commercial Activities in Support of Potential September Launch***
- ***Announced Publication in Nature Medicine of GENESIS Phase 3 Clinical Trial Data Evaluating Motixafortide and G-CSF in SCM for Autologous Transplantation in MM***
- ***Management to hold conference call today, May 24, at 10:00 am EDT***

TEL AVIV, Israel, May 24, 2023 /PRNewswire/ -- BioLineRx Ltd. (NASDAQ/TASE: BLRX), a pre-commercial-stage biopharmaceutical company focused on oncology, today reported its unaudited financial results for the first quarter ended March 31, 2023, and provided corporate and portfolio updates.

"This has been an exciting quarter for the Company as we prepare for the potential approval and U.S. commercial launch of motixafortide in September of this year," said Philip Serlin, Chief Executive Officer of BioLineRx. "Last month's publication in Nature Medicine of our GENESIS Phase 3 clinical trial data suggest motixafortide's potential to address critical challenges and evolving needs in the autologous stem cell transplant setting in appropriate multiple myeloma patients, and in preparation for an aggressive launch, our U.S. operation continues its commercialization-readiness activities. We recently completed hiring an experienced sales force, and have substantially advanced supply chain, market access and medical affairs activities. Additionally, the Company, along with our collaboration partners, continues to make clinical development progress evaluating motixafortide in pancreatic cancer (PDAC) and in SCM for gene therapies. We anticipate PDAC clinical data later this year, as well as the initiation of new clinical trials for both PDAC and SCM in gene therapy. We believe each of these areas can support long-term growth."

Corporate Updates

- *On track for September 9, 2023 PDUFA target action date*
- *Hired targeted sales force with expertise in high opportunity transplant centers, in preparation for potential September launch*

Portfolio Execution

Motixafortide (selective inhibitor of CXCR4 chemokine receptor)

Multiple Myeloma

- *Announced publication in Nature Medicine* of GENESIS Phase 3 clinical trial data evaluating motixafortide and G-CSF in stem cell mobilization for autologous transplantation in multiple myeloma

Pancreatic Ductal Adenocarcinoma

- Continued to advance preparation activities for a Phase 2b randomized clinical trial with 200 patients assessing motixafortide in combination with a PD-1 inhibitor and standard-of-care chemotherapy as a first-line metastatic PDAC (mPDAC) therapy with collaboration partner GenFleet. Anticipate clinical trial initiation in 2023
- Continued collaboration progress with Columbia University investigator-initiated Phase 2 study assessing motixafortide in combination with the PD-1 inhibitor cemiplimab and standard-of-care chemotherapy as first-line treatment in patients with mPDAC. Anticipate initial patient data in 2023

Sickle Cell Disease & Gene Therapy

- Announced clinical trial collaboration with Washington University School of Medicine in St. Louis to evaluate motixafortide as monotherapy and in combination with natalizumab for CD34+ hematopoietic stem cell mobilization for gene therapies in sickle cell disease. Anticipate clinical trial initiation in 2023

AGI-134 (synthetic alpha-Gal glycolipid)

Solid Tumor Immunotherapy

- Evaluating next development pathways for AGI-134 program in consultation with scientific advisory board. Results from Phase 1/2a first-in-human, single-agent study announced in Q4 2022. Study met primary endpoint for safety and tolerability and demonstrated immune activity across multiple biomarkers

First Quarter 2023 Financial Results

- Research and development expenses for the three months ended March 31, 2023 were $3.7 million, a decrease of $0.7 million, or 16.9%, compared to $4.4 million for the three months ended March 31, 2022. The decrease resulted primarily from lower expenses related to NDA supporting activities for motixafortide, as well as lower expenses associated with the completed AGI-134 clinical trial.
- Sales and marketing expenses for the three months ended March 31, 2023 were $3.9 million, an increase of $3.2 million, or 508%, compared to $0.6 million for the three months ended March 31, 2022. The increase resulted primarily from the ramp-up of pre-commercialization activities related to motixafortide.
- General and administrative expenses for the three months ended March 31, 2023 were $1.3 million, an increase of $0.3 million, or 28.9%, compared to $1.0 million for the three months ended March 31, 2022. The increase resulted primarily from an increase in payroll and related expenses due to a small increase in headcount and share-based compensation, as well as small increases in a number of G&A expenses.
- As of March 31, 2023, the Company held cash, cash equivalents, and short-term bank deposits of $43.3 million and anticipates this will be sufficient to fund operations, as currently planned, into the first half of 2024.

Conference Call and Webcast Information

To access the conference call, please dial +1-888-281-1167 from the U.S. or +972-3-918-0685 internationally. A live webcast and a replay of the call can be accessed through the event page on the Company'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. The call replay will be available approximately two hours after completion of the live conference call. A dial-in replay of the call will be available until May 26, 2023; please dial +1-888-295-2634 from the US or +972-3-925-5904 internationally.

About BioLineRx

BioLineRx Ltd. (NASDAQ/TASE: BLRX) is a pre-commercial-stage biopharmaceutical company focused on oncology. The Company's lead development program, motixafortide, a novel selective inhibitor of the CXCR4 chemokine receptor, may support diverse therapeutic approaches in oncology and other diseases. Motixafortide was successfully evaluated in a Phase 3 study in stem cell mobilization for autologous transplantation for multiple myeloma patients and has had its NDA submission accepted by the FDA with an assigned PDUFA date of September 9, 2023. Motixafortide was also successfully evaluated in a Phase 2a study for the treatment of metastatic pancreatic cancer (mPDAC) in combination with the PD-1 inhibitor pembrolizumab and chemotherapy and is currently being studied in combination with the PD-1 inhibitor cemiplimab and chemotherapy as a first-line mPDAC therapy. In addition, a randomized phase 2b study with 200 patients assessing motixafortide in combination with a PD-1 inhibitor and chemotherapy as a first-line mPDAC therapy is expected to initiate in 2023. BioLineRx is also developing a second oncology program, AGI-134, an immunotherapy treatment for multiple solid tumors. A first-in-human Phase 1/2a study of AGI-134 met its primary endpoint for safety and tolerability and demonstrated immune activity across multiple biomarkers. 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.

Forward Looking Statement

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 include statements regarding management's expectations, beliefs and intentions regarding, among other things, the GENESIS trial, including the plans and objectives of management for future operations and expectations and commercial potential of motixafortide. 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, including BioLineRx's ability to secure adequate and viable pricing and reimbursement coverage of any marketed product; 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; BioLineRx's ability to successfully hire, train, and retain necessary personnel for its business; 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; risks related to unfavorable economic and market conditions and adverse developments with respect to financial institutions and associated liquidity risk; 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 22, 2023. 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.

Contacts:

United States
John Lacey
BioLineRx
IR@biolinerx.com

Israel
Moran Meir
LifeSci Advisors, LLC
moran@lifesciadvisors.com

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

	December 31, 2022	March 31, 2023
	in USD thousands	
Assets		
CURRENT ASSETS		
Cash and cash equivalents	10,587	9,066
Short-term bank deposits	40,495	34,221
Prepaid expenses	198	738
Other receivables	721	302
Total current assets	52,001	44,327
NON-CURRENT ASSETS		
Property and equipment, net	726	666
Right-of-use assets, net	1,772	1,692
Intangible assets, net	21,885	21,961
Total non-current assets	24,383	24,319
Total assets	76,384	68,646
Liabilities and equity		
CURRENT LIABILITIES		
Current maturities of long-term loan	1,542	2,558
Accounts payable and accruals:		
Trade	6,966	7,136
Other	1,744	1,968
Current maturities of lease liabilities	427	379
Total current liabilities	10,679	12,041
NON-CURRENT LIABILITIES		
Warrants	4,509	7,549
Long-term loan, net of current maturities	8,626	8,240
Lease liabilities	1,729	1,702
Total non-current liabilities	14,864	17,491
COMMITMENTS AND CONTINGENT LIABILITIES		

Total liabilities	25,543	29,532
EQUITY		
Ordinary shares	27,100	27,100
Share premium	338,976	339,042
Warrants	1,408	1,408
Capital reserve	14,765	15,134
Other comprehensive loss	(1,416)	(1,416)
Accumulated deficit	(329,992)	(342,154)
Total equity	50,841	39,114
Total liabilities and equity	76,384	68,646

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

	Three months ended March 31,	
	2022	2023
	in USD thousands	
RESEARCH AND DEVELOPMENT EXPENSES	(4,435)	(3,684)
SALES AND MARKETING EXPENSES	(637)	(3,874)
GENERAL AND ADMINISTRATIVE EXPENSES	(1,007)	(1,298)
OPERATING LOSS	(6,079)	(8,856)
NON-OPERATING INCOME (EXPENSES), NET	1,268	(2,916)
FINANCIAL INCOME	67	537
FINANCIAL EXPENSES	(186)	(927)
NET LOSS AND COMPREHENSIVE LOSS	(4,930)	(12,162)
	in USD	
LOSS PER ORDINARY SHARE - BASIC AND DILUTED	(0.01)	(0.01)
WEIGHTED AVERAGE NUMBER OF SHARES USED IN CALCULATION OF LOSS PER ORDINARY SHARE	715,156,008	922,958,942

BioLineRx Ltd.

CONDENSED CONSOLIDATED INTERIM STATEMENTS OF CHANGES IN EQUITY

(UNAUDITED)

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, 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 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

	Ordinary shares	Share premium	Warrants	Capital reserve	Other comprehensive loss	Accumulated deficit	Total
	in USD thousands						
BALANCE AT JANUARY 1, 2023	27,100	338,976	1,408	14,765	(1,416)	(329,992)	50,841
CHANGES FOR THREE MONTHS ENDED MARCH 31, 2023:							
Employee stock options expired		66		(66)			-
Share-based compensation				435			435
Comprehensive loss for the period						(12,162)	(12,162)
BALANCE AT MARCH 31, 2023	27,100	339,042	1,408	15,134	(1,416)	(342,154)	39,114

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

	Three months ended March 31,	
	2022	2023
	in USD thousands	
CASH FLOWS - OPERATING ACTIVITIES		
Comprehensive loss for the period	(4,930)	(12,162)
Adjustments required to reflect net cash used in operating activities (see appendix below)	(656)	4,146
Net cash used in operating activities	(5,586)	(8,016)
CASH FLOWS - INVESTING ACTIVITIES		
Investments in short-term deposits	(7,000)	(5,500)
Maturities of short-term deposits	12,066	12,271
Purchase of property and equipment	(18)	(32)
Purchase of intangible assets	-	(97)
Net cash provided by investing activities	5,048	6,642
CASH FLOWS - FINANCING ACTIVITIES		
Repayments of loan	(895)	-
Repayments of lease liabilities	(48)	(49)
Net cash used in financing activities	(943)	(49)
DECREASE IN CASH AND CASH EQUIVALENTS	(1,481)	(1,423)
CASH AND CASH EQUIVALENTS – BEGINNING OF PERIOD	12,990	10,587
EXCHANGE DIFFERENCES ON CASH AND CASH EQUIVALENTS	(63)	(98)
CASH AND CASH EQUIVALENTS - END OF PERIOD	11,446	9,066

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

	Three months ended March 31,	
	2022	2023
	in USD thousands	
Adjustments required to reflect net cash used in operating activities:		
Income and expenses not involving cash flows:		
Depreciation and amortization	173	259
Exchange differences on cash and cash equivalents	63	98
Fair value adjustments of warrants	(1,255)	3,040
Share-based compensation	256	435

Interest on short-term deposits	(65)	(497)
Interest on loan	41	630
Exchange differences on lease liabilities	(41)	(92)
	(828)	3,873
Changes in operating asset and liability items:		
Increase in prepaid expenses and other receivables	(82)	(121)
Increase in accounts payable and accruals	254	394
	172	273
	(656)	4,146
Supplemental information on interest received in cash	68	276
Supplemental information on interest paid in cash	112	311
Changes in right-of-use asset and lease liabilities	-	66

View original content:https://www.prnewswire.com/news-releases/biolinerx-reports-first-quarter-2023-financial-results-and-recent-corporate-and-portfolio-updates-301832671.html

SOURCE BioLineRx Ltd