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

August 30, 2023 11:00 AM IDT

- On Track for September 9, 2023 PDUFA Target Action Date on NDA for Motixafortide in Stem Cell Mobilization (SCM) for Autologous Transplantation in Multiple Myeloma (MM) -

- Signed Exclusive License Agreement to Motixafortide in Asia Region with Concurrent Equity Investment -

- Announced Initiation of Investigator-Initiated Randomized Phase 2 Combination Trial with Motixafortide in First Line PDAC in Collaboration with Columbia University -

- Management to host conference call today, August 30, at 10:00 am EDT -

TEL AVIV, Israel, Aug. 30, 2023 /PRNewswire/ -- BioLineRx Ltd. (NASDAQ: BLRX) (TASE: BLRX), a pre-commercial stage biopharmaceutical company pursuing life-changing therapies for certain cancers and rare diseases, today reported its unaudited financial results for the second quarter ended June 30, 2023, and provided corporate and portfolio updates.

"We had a very productive second quarter across all areas of the company, including our focused pre-launch preparation activities tied to the potential U.S. approval of motixafortide in the next few weeks, as well as the formation of a new strategic partnership, announced today, to develop and commercialize motixafortide in Asia," said Philip Serlin, Chief Executive Officer of BioLineRx. "The partnership, which is subject to certain closing conditions, provides a pathway forward to pursue potential indications for motixafortide in stem cell mobilization and pancreatic cancer in Asia, as well as a source of substantial funding to the company.

Additionally, we advanced our second major development program for motixafortide in pancreatic cancer through the initiation of a randomized Phase 2 clinical trial with Columbia University in first line metastatic pancreatic cancer based on promising data from a single-arm pilot phase.

"Finally, our clinical trial collaboration with Washington University School of Medicine in St. Louis to evaluate motixafortide as monotherapy and in combination with natalizumab for stem cell mobilization for gene therapies in sickle cell disease continues to progress, and we anticipate clinical trial initiation this year. I am extremely pleased with our progress to date and look forward to a fruitful second half of the year, including our potential transition to a commercial stage company," Mr. Serlin concluded.

Corporate Updates

- On track for September 9, 2023 PDUFA target action date on NDA for motixafortide in stem cell mobilization for autologous transplantation in multiple myeloma
- Signed exclusive license agreement to develop and commercialize motixafortide in Asia with concurrent equity investment; license agreement includes $15 million upfront payment, plus potential development, regulatory and sales milestones, and tiered double-digit royalties, as well as various development obligations for the licensee, including the planned initiation in China of a registrational study in stem-cell mobilization and a randomized Phase 2/3 study in first-line pancreatic cancer; straight common equity investment of $14.6 million in BioLineRx at $2.136 per ADS with no warrants; effectiveness and closing of transactions is contingent upon approval by Israeli Innovation Authority of license agreement within four months of execution, and other closing conditions

Clinical Portfolio Updates

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

- Announced initiation of randomized, investigator-initiated Phase 2 clinical trial in collaboration with Columbia University, with joint funding of the study by Regeneron and BioLineRx,

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. A poster of the amended clinical trial design was presented at the 2023 American Society of Clinical Oncology (ASCO) Annual Meeting in June

Sickle Cell Disease & Gene Therapy

- Continued to advance plans for a clinical trial in 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 trial initiation later this year

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

Second Quarter 2023 Financial Results

- Research and development expenses for the three months ended June 30, 2023 were $3.0 million, a decrease of $2.4 million, or 44.3%, compared to $5.4 million for the three months ended June 30, 2022. The decrease resulted primarily from lower expenses related to NDA supporting activities related to motixafortide as well as lower expenses associated with the completed AGI-134 clinical trial
- Sales and marketing expenses for the three months ended June 30, 2023 were $5.6 million, an increase of $4.4 million, or 383.9% compared to $1.2 million for the three months ended June 30, 2022. The increase resulted primarily from the ramp-up of pre-launch activities related to motixafortide
- General and administrative expenses for the three months ended June 30, 2023 were $1.3 million, an increase of $0.3 million, or 24.4% compared to $1.0 million for the three months ended June 30, 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
- Net loss for the three months ended June 30, 2023 was $18.5 million, compared to $7.4 million for the three months ended June 30, 2022. The Company's net loss for the six months ended June 30, 2023 amounted to $30.7 million, compared to $12.4 million for the six months ended June 30, 2022. The increases in net loss for both the three and six months ended June 30, 2023 were due primarily to a non-operating expense of approximately $7.8 million and $10.8 million respectively, related to the revaluation of outstanding warrants resulting from an increase in the Company's share price over the preceding three and six months
- As of June 30, 2023, the Company held cash, cash equivalents, and short-term bank deposits of $32.8 million and anticipates this will be sufficient to fund operations, as currently planned, into the first half of 2024. This amount does not include $29.6 million in total funding from the exclusive license agreement and equity investment announced today, which the Company anticipates closing in Q3 subject to formal transaction approval by the Israeli Innovation Authority and other closing conditions

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 September 1, 2023; please dial +1-888-295-2634 from the US or +972-3-925-5904 internationally.

About BioLineRx

BioLineRx Ltd. is a pre-commercial stage biopharmaceutical company pursuing life-changing therapies for certain cancers and rare diseases. The company is advancing a pipeline of investigational medicines for patients with multiple myeloma, sickle cell disease, pancreatic cancer, and other solid tumors. Headquartered in Israel, and with operations in the U.S., BioLineRx is driving innovative therapeutics with end-to-end expertise in development and commercialization, ensuring life-changing discoveries move beyond the bench to the bedside.

Learn more about who we are, what we do, and how we do it at www.biolinerx.com, or on Twitter and LinkedIn.

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, our planned and ongoing clinical trials, the plans and objectives of management for future operations, regulatory filings submitted to the FDA (including potential timing of the FDA's review of the NDA for motixafortide), commercial potential of motixafortide, expectations regarding the announced license agreement, statements relating to the private placement, including, as to the consummation of the private placement and license agreement, and our financial condition and results of operations. 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 and academic collaborations and licensees, including the collaboration contemplated in the license; BioLineRx's ability to integrate new therapeutic candidates and new personnel; the interpretation or characterization 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, Asia, or elsewhere; competitive companies, technologies and BioLineRx's industry, including generic entrants; 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.

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CONDENSED CONSOLIDATED INTERIM STATEMENTS OF FINANCIAL POSITION
(UNAUDITED)

	December 31, 2022	June 30, 2023
	in USD thousands	
Assets		
CURRENT ASSETS		
Cash and cash equivalents	10,587	10,104
Short-term bank deposits	40,495	22,711
Prepaid expenses	198	1,749
Other receivables	721	128
Total current assets	52,001	34,692
NON-CURRENT ASSETS		
Property and equipment, net	726	648

Right-of-use assets, net	1,772	1,583
Intangible assets, net	21,885	22,013
Total non-current assets	24,383	24,244
Total assets	76,384	58,936
Liabilities and equity		
CURRENT LIABILITIES		
Current maturities of long-term loan	1,542	3,078
Accounts payable and accruals:		
Trade	6,966	6,733
Other	1,744	2,260
Current maturities of lease liabilities	427	375
Total current liabilities	10,679	12,446
NON-CURRENT LIABILITIES		
Warrants	4,509	15,352
Long-term loan, net of current maturities	8,626	8,495
Lease liabilities	1,729	1,589
Total non-current liabilities	14,864	25,436
Total liabilities	25,543	37,882
EQUITY		
Ordinary shares	27,100	27,100
Share premium	338,976	339,045
Warrants	1,408	1,408
Capital reserve	14,765	15,616
Other comprehensive loss	(1,416)	(1,416)
Accumulated deficit	(329,992)	(360,699)
Total equity	50,841	21,054
Total liabilities and equity	76,384	58,936

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CONDENSED CONSOLIDATED INTERIM STATEMENTS OF COMPREHENSIVE LOSS

(UNAUDITED)

	Three months ended June 30,		**Six months ended June 30,**	
	2022	**2023**	**2022**	**2023**
	in USD thousands		**in USD thousands**	
RESEARCH AND DEVELOPMENT EXPENSES	(5,395)	(3,006)	(9,830)	(6,690)
SALES AND MARKETING EXPENSES	(1,158)	(5,604)	(1,795)	(9,478)
GENERAL AND ADMINISTRATIVE EXPENSES	(1,049)	(1,305)	(2,056)	(2,603)
OPERATING LOSS	(7,602)	(9,915)	(13,681)	(18,771)
NON-OPERATING INCOME (EXPENSES), NET	458	(7,733)	1,726	(10,649)
FINANCIAL INCOME	80	440	147	977
FINANCIAL EXPENSES	(379)	(1,337)	(565)	(2,264)
NET LOSS AND COMPREHENSIVE LOSS	(7,443)	(18,545)	(12,373)	(30,707)
	in USD		**in USD**	
LOSS PER ORDINARY SHARE - BASIC AND DILUTED	(0.01)	(0.02)	(0.02)	(0.03)
WEIGHTED AVERAGE NUMBER OF SHARES USED IN CALCULATION OF LOSS PER ORDINARY SHARE	715,365,554	922,958,942	715,260,781	922,958,942

CONDENSED 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 SIX MONTHS ENDED JUNE 30, 2022:							
Issuance of share capital, net	89	177	-	-	-	-	266
Employee stock options exercised	2	12	-	(12)	-	-	2
Employee stock options expired	-	135	-	(135)	-	-	-
Share-based compensation	-	-	-	586	-	-	586
Comprehensive loss for the period	-	-	-	-	-	(12,373)	(12,373)
BALANCE AT JUNE 30, 2022	21,157	339,670	975	13,596	(1,416)	(317,414)	56,568

	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 SIX MONTHS ENDED JUNE 30, 2023:							
Employee stock options expired	-	69	-	(69)	-	-	-
Share-based compensation	-	-	-	920	-	-	920
Comprehensive loss for the period	-	-	-	-	-	(30,707)	(30,707)
BALANCE AT JUNE 30, 2023	27,100	339,045	1,408	15,616	(1,416)	(360,699)	21,054

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CONDENSED CONSOLIDATED INTERIM CASH FLOW STATEMENTS

(UNAUDITED)

	Six months ended June 30,	
	2022	2023
	in USD thousands	
CASH FLOWS - OPERATING ACTIVITIES		
Net loss for the period	(12,373)	(30,707)
Adjustments required to reflect net cash used in operating activities (see appendix below)	498	13,009
Net cash used in operating activities	(11,875)	(17,698)
CASH FLOWS – INVESTING ACTIVITIES		
Investments in short-term deposits	(9,000)	(6,006)
Maturities of short-term deposits	24,141	24,000
Purchase of property and equipment	(62)	(99)
Purchase of intangible assets	-	(153)
Net cash provided by investing activities	15,079	17,742
CASH FLOWS – FINANCING ACTIVITIES		
Issuance of share capital and warrants, net of issuance costs	266	-
Employee stock options exercised	2	-
Repayments of loan	(1,812)	-
Repayments of lease liabilities	(88)	(183)
Net cash used in financing activities	(1,632)	(183)
INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	1,572	(139)
CASH AND CASH EQUIVALENTS - BEGINNING OF PERIOD	12,990	10,587
EXCHANGE DIFFERENCES ON CASH AND CASH EQUIVALENTS	(562)	(344)
CASH AND CASH EQUIVALENTS - END OF PERIOD	14,000	10,104

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APPENDIX TO CONDENSED CONSOLIDATED INTERIM CASH FLOW STATEMENTS

(UNAUDITED)

	Six months ended June 30,	
	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	314	457
Exchange differences on cash and cash equivalents	562	344
Fair value adjustments of warrants	(1,673)	10,843
Share-based compensation	586	920
Interest and exchange differences on short-term deposits	(142)	(210)
Interest on loan	68	1,405
Exchange differences on lease liability	(205)	(75)
	(490)	13,684
Changes in operating asset and liability items:		
Increase in prepaid expenses and other receivables	(688)	(958)
Increase in accounts payable and accruals	1,676	283
	988	(675)
	498	13,009
Supplemental information on interest received in cash	146	761
Supplemental information on interest paid in cash	217	640
Supplemental information on non-cash transactions:		
Acquisition of right-of-use asset	-	66

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