BioLineRx Reports Third Quarter 2022 Financial Results and Recent Corporate and Portfolio Updates

November 15, 2022 12:00 PM IST

- Announced FDA acceptance of APHEXDA® (motixafortide) New Drug Application (NDA) in stem cell mobilization with Prescription Drug User Fee Act (PDUFA) target action date of September 9, 2023 -

- Introduced plan to commercialize APHEXDA® independently in the U.S., if approved, and named Holly May, President, BioLineRx USA -

- Completed $40M debt financing agreement and $15M equity offering to support aggressive commercial U.S. launch of APHEXDA® -

- Management to hold conference call today, November 15, at 10:00 am EST -

TEL AVIV, Israel, Nov. 15, 2022 /PRNewswire/ -- BioLineRx Ltd. (NASDAQ: BLRX) (TASE: BLRX), a pre-commercial-stage biopharmaceutical company focused on oncology, today reported third quarter financial results and recent corporate and portfolio updates.

"The Company delivered outstanding performance during the third quarter and subsequent period. Last week's FDA acceptance of our new drug application for APHEXDA® (motixafortide) substantially advances our twin goals of delivering an important new therapy for the mobilization of stem cells in preparation for autologous transplantation in patients with multiple myeloma, and in parallel, transitioning to a commercial stage company," said Philip Serlin, Chief Executive Officer of BioLineRx. "Importantly, we took steps that allow us to rapidly commercialize APHEXDA®, if approved, including securing financing, building out our U.S. operations, and progressing our launch strategy. We believe that APHEXDA® has the potential to become the standard-of-care mobilizing agent for multiple myeloma patients."

"Additionally, working with our collaborators, we advanced motixafortide development programs for pancreatic cancer, reflecting motixafortide's potential broad clinical utility. Finally, we anticipate sharing data from the Phase 1/2a trial of our solid tumor investigational immunotherapy AGI-134 prior to year-end. We believe we are well-positioned to execute across all of our programs and continue to aggressively plan for the potential launch of APHEXDA® next year," Mr. Serlin concluded.

Recent Corporate Updates

- Completed $40 million non-dilutive debt financing agreement with Kreos Capital and $15 million registered direct offering to support commercial launch of APHEXDA® in the U.S.
- Announced APHEXDA® U.S. commercialization plan and named Holly May, President, BioLineRx USA

Portfolio Execution

Motixafortide (selective inhibitor of CXCR4 chemokine receptor)

Multiple Myeloma

- Announced FDA acceptance of APHEXDA® NDA in stem cell mobilization for autologous transplantation in multiple myeloma patients. PDUFA target action date set for September 9, 2023
- Announced presentation of cost-effectiveness analysis of motixafortide versus plerixafor in stem cell mobilization for autologous transplantation in patients with multiple myeloma at the American Society of Hematology (ASH) 64th Annual Meeting, which is being held December 10-13, 2022, in New Orleans, Louisiana

Pancreatic Ductal Adenocarcinoma (PDAC)

- Began Phase 2b PDAC randomized clinical trial preparation activities with collaboration partner GenFleet. Anticipate clinical trial initiation in 2023. The collaboration agreement allows BioLineRx to retain global rights to motixafortide in all indications
- Continued collaboration progress in Columbia University investigator-initiated Phase 2 study of motixafortide in combination with an anti-PD-1 and standard-of-care chemotherapy in first-line PDAC patients

Sickle Cell Disease & Gene Therapy

- Announced presentation of clinical trial study design of novel stem cell mobilization regimen with motixafortide to support gene therapy development for sickle cell patients at the ASH Annual Meeting, which is being held December 10-13, 2022, in New Orleans, Louisiana

AGI-134 (synthetic alpha-Gal glycolipid)

Solid Tumor Immunotherapy

- Advanced biomarker analysis from the Phase 1/2a trial of AGI-134 in solid tumors and anticipate announcing results from Part 2 of the trial by year-end

Third Quarter 2022 Financial Results

- Research and development expenses for the quarter ended September 30, 2022, were $4.4 million compared to $4.9 million for the same period in 2021; the decrease resulted primarily from lower expenses related to motixafortide NDA supporting activities, as well as lower expenses associated with the completed motixafortide GENESIS clinical trial, offset by an increase in payroll and related expenses
- Sales and marketing expenses for the quarter ended September 30, 2022, were $1.3 million compared to $0.2 million for the same period in 2021; the increase resulted primarily from initiation of pre-commercialization activities related to motixafortide, as well as an increase in market research
- General and administrative expenses for the quarter ended September 30, 2022, were $1.4 million compared to $1.0 million for the same period in 2021; the increase resulted primarily from an increase in share-based compensation and small increases across several G&A expenses
- Net loss for the quarter ended September 30, 2022, was $6.8 million, compared to $5.7 million for the same period in 2021
- As of September 30, 2022, the Company had cash, cash equivalents, and short-term bank deposits of $57.3 million and anticipates this will be sufficient to fund operations, as currently planned, into the first half of 2024

Conference Call and Webcast Information

BioLineRx will hold a conference call today, Tuesday, November 15 at 10:00 a.m. EST. To access the conference call, please dial +1-888-281-1167 from the U.S. or +972-3-918-0685 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 November 17, 2022; please dial +1-888-295-2634 from the US or +972-3-925-5903 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. APHEXDA® (motixafortide) was successfully evaluated in a Phase 3 study in stem cell mobilization for autologous transplantation in multiple myeloma patients, has reported positive results from a pre-planned pharmacoeconomic study in the U.S., and has had its NDA submission accepted by the FDA with a PDUFA date of September 9, 2023. Motixafortide was also successfully evaluated in a Phase 2a study for the treatment of pancreatic cancer (PDAC) in combination with KEYTRUDA® and chemotherapy and is currently being studied in combination with LIBTAYO® and chemotherapy as a first-line PDAC therapy. A randomized phase 2b study with 200 patients in combination with PD1 and chemotherapy as a first-line PDAC therapy will initiate in 2023. 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.

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 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 COMPREHENSIVE LOSS
(UNAUDITED)

	Three months ended September 30,		Nine months ended September 30,	
	2021	2022	2021	2022
	in USD thousands		in USD thousands	
RESEARCH AND DEVELOPMENT EXPENSES	(4,923)	(4,369)	(14,340)	(14,199)
SALES AND MARKETING EXPENSES	(247)	(1,317)	(731)	(3,112)
GENERAL AND ADMINISTRATIVE EXPENSES	(1,047)	(1,392)	(3,108)	(3,448)
OPERATING LOSS	(6,217)	(7,078)	(18,179)	(20,759)
NON-OPERATING INCOME (EXPENSES), NET	710	389	(4,068)	2,115
FINANCIAL INCOME	52	109	299	256
FINANCIAL EXPENSES	(261)	(267)	(802)	(832)
NET LOSS AND COMPREHENSIVE LOSS	(5,716)	(6,847)	(22,750)	(19,220)
	in USD		in USD	
LOSS PER ORDINARY SHARE - BASIC AND DILUTED	(0.01)	(0.01)	(0.04)	(0.03)
WEIGHTED AVERAGE NUMBER OF SHARES USED IN CALCULATION OF LOSS PER ORDINARY SHARE	708,473,164	740,767,492	646,427,790	723,805,390

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

	December 31, 2021	September 30, 2022
	in USD thousands	
Assets		
CURRENT ASSETS		
Cash and cash equivalents	12,990	13,105
Short-term bank deposits	44,145	44,157
Prepaid expenses	127	537
Other receivables	142	143

Total current assets	57,404	57,942
NON-CURRENT ASSETS		
Property and equipment, net	952	726
Right-of-use assets, net	1,331	1,289
Intangible assets, net	21,704	21,716
Total non-current assets	23,987	23,731
Total assets	81,391	81,673
Liabilities and equity		
CURRENT LIABILITIES		
Current maturities of long-term loan	2,757	802
Accounts payable and accruals:		
Trade	5,567	5,829
Other	1,227	1,351
Current maturities of lease liabilities	168	151
Total current liabilities	9,719	8,133
NON-CURRENT LIABILITIES		
Warrants	1,859	8,156
Long-term loan, net of current maturities	-	8,353
Lease liabilities	1,726	1,507
Total non-current liabilities	3,585	18,016
COMMITMENTS AND CONTINGENT LIABILITIES		
Total liabilities	13,304	26,149
EQUITY		
Ordinary shares	21,066	27,098
Share premium	339,346	338,841
Warrants	975	1,408
Capital reserve	13,157	13,854
Other comprehensive loss	(1,416)	(1,416)
Accumulated deficit	(305,041)	(324,261)
Total equity	68,087	55,524
Total liabilities and equity	81,391	81,673

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