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

November 20, 2023 12:00 PM IST

- Received FDA Approval of APHEXDA® (motixafortide) in Combination with Filgrastim (G-CSF) to Mobilize Hematopoietic Stem Cells for Collection and Subsequent Autologous Transplantation in Patients with Multiple Myeloma -

- Closed Exclusive License Agreement for Motixafortide in Asia Region with Concurrent Strategic Equity Investment -

- Presented Encouraging Data at AACR from Pilot Phase of Randomized Phase 2 Combination Trial with Motixafortide in Patients with First Line PDAC -

- Began Enrollment of Phase 1 Trial Evaluating Motixafortide for CD34+ Hematopoietic Stem Cell Mobilization for Gene Therapies in Sickle Cell Disease -

- Management to host conference call today, November 20, at 10:00 a.m. EST -

TEL AVIV, Israel, Nov. 20, 2023 /PRNewswire/ -- BioLineRx Ltd. (NASDAQ: BLRX) (TASE: BLRX), a commercial stage biopharmaceutical company pursuing life-changing therapies in oncology and rare diseases, today reported its unaudited financial results for the third quarter ended September 30, 2023, and provided corporate and portfolio updates.

"FDA approval of APHEXDA® in September was a transformative event for the company, and our U.S. commercial team is now working with payers and providers to make this important innovation available to patients," said Philip Serlin, Chief Executive Officer of BioLineRx. "We were pleased that APHEXDA® was recently added to the NCCN guidelines, and we believe that as centers adjust their protocols to include and gain experience with APHEXDA®, transplant teams will gain a deep appreciation for the efficiencies that it can provide, and more importantly, the improved treatment journey patients experience as they navigate their essential transplant process.

"In addition, the company also closed its motixafortide licensing agreement covering the important Asia market. The agreement, which provided significant upfront funding, will first advance potential indications in the region for stem cell mobilization and pancreatic cancer, areas of high unmet need. We continue to evaluate additional commercial partnership opportunities in other markets.

"Lastly, exciting data were presented at AACR from the single-arm pilot phase of the randomized Phase 2 combination clinical trial with motixafortide in first-line pancreatic cancer by the study's lead investigator at Columbia University. The highly encouraging data triggered a change in the protocol, from a small, single-arm study to a much larger randomized study. This study, as well as the enrolling Phase 1 study evaluating motixafortide for stem cell mobilization in patients with sickle cell disease seeking gene therapy, highlight the potential versatility of motixafortide and the tremendous progress we are making to realize the full promise of this novel molecule for patients around the world," Mr. Serlin concluded.

Corporate Updates

- Received U.S. Food and Drug Administration approval of APHEXDA® (motixafortide) in combination with filgrastim (G-CSF) to mobilize hematopoietic stem cells to the peripheral blood for collection and subsequent autologous transplantation in patients with multiple myeloma
- Closed exclusive license agreement to develop and commercialize motixafortide in Asia, alongside strategic equity investment:
  - License agreement included $15 million upfront payment, up to $50 million in potential development and regulatory milestones, up to $200 million in potential commercial milestones, and tiered double-digit royalties on sales
  - Straight common equity investment of $14.6 million in BioLineRx American Depository Shares (ADSs)
  - Gloria Biosciences expected to begin pivotal bridging study to support potential approval and commercialization of motixafortide in stem cell mobilization in China
  - Gloria Biosciences planning randomized Phase 2/3 first-line pancreatic cancer clinical trial evaluating motixafortide in combination with PD-1 inhibitor zimberelimab and standard of care combination chemotherapy

Clinical Portfolio Updates

Motixafortide (selective inhibitor of CXCR4 chemokine receptor)

Multiple Myeloma

- Received inclusion of APHEXDA® in the National Comprehensive Cancer Network (NCCN) guidelines for Hematopoietic Cell Transplantation
- Received acceptance of an abstract on combination premedication benefits in the Phase 3 GENESIS trial, further educating on the use of APHEXDA at transplant centers. The poster will be presented at the American Society of Hematology (ASH) 65th Annual Meeting on December 10, 2023, in San Diego, California
- Initiated pivotal bridging study preparation activities with Gloria Biosciences to support potential approval and commercialization of motixafortide in stem cell mobilization in China

Pancreatic Ductal Adenocarcinoma

- Presented data from the single-arm pilot phase of the investigator-initiated CheMo4METPANC Phase 2 combination clinical trial in first-line pancreatic cancer (PDAC) at the American Association of Cancer Research (AACR) Special Conference on Pancreatic Cancer. Of 11 patients with metastatic pancreatic cancer enrolled, 7 patients (64%) experienced a partial response (PR), of which 5 (45%) were confirmed PRs with one patient experiencing resolution of the hepatic (liver) metastatic lesion. Three patients (27%) experienced stable disease, resulting in a disease control rate of 91%. Based on these encouraging results, the study was substantially revised to a multi-institution, randomized trial of 108 patients
- Initiated preparation activities with Gloria Biosciences to support the development of a randomized Phase 2/3 clinical trial evaluating motixafortide in combination with the PD-1 inhibitor zimberelimab and standard of care combination chemotherapy in first-line pancreatic cancer

Sickle Cell Disease & Gene Therapy

- Began enrollment in investigator-initiated Phase 1 pilot study led by Washington University School of Medicine in St. Louis evaluating motixafortide as monotherapy and in combination with natalizumab for CD34+ hematopoietic stem cell mobilization for gene therapies in sickle cell disease. Anticipate data in 2H of 2024

AGI-134 (synthetic alpha-Gal glycolipid)

Solid Tumor Immunotherapy

- Evaluating next development pathways for AGI-134 program. The Phase 1/2a first-in-human, single-agent study, results of which were announced in Q4 2022, met the primary endpoint for safety and tolerability and demonstrated immune activity across multiple biomarkers

Third Quarter 2023 Financial Results

- Research and development expenses for the three months ended September 30, 2023 were $2.7 million, a decrease of $1.6 million, or 37.6%, compared to $4.3 million for the three months ended September 30, 2022. The decrease resulted primarily from lower expenses associated with 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 September 30, 2023 were $8.1 million, an increase of $6.8 million, or 517.4% compared to $1.3 million for the three months ended September 30, 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 September 30, 2023 were $1.5 million, an increase of $0.1 million, or 7.7% compared to $1.4 million for the three months ended September 30, 2022. The increase resulted from small increases in a number of

individual G&A expenses

- Non-operating expenses for the three months ended September 30, 2023 were $3.1 million, an increase of $3.5 million, compared to non-operating income of $0.4 million for the three months ended September 30, 2022. The increase relates primarily to the revaluation of outstanding warrants resulting from an increase in the company's share price during the 2023 period
- Net loss for the three months ended September 30, 2023 was $16.0 million, compared to $6.8 million for the three months ended September 30, 2022. Net loss for the nine months ended September 30, 2023 amounted to $46.7 million, compared to $19.2 million for the nine months ended September 30, 2022. The increases in net loss for both the three- and nine-month periods in 2023 were primarily due to the significant non-operating expenses (which were also non-cash) related to revaluation of outstanding warrants, as well as the significant increases in sales and marketing expenses related to pre-commercialization and commercialization activities, which were partially offset by a decrease in research and development expenses
- As of September 30, 2023, we held $26.0 million of cash, cash equivalents and short-term bank deposits. We anticipate that this amount, as well as the consideration from the exclusive license agreement and the securities purchase agreement of $29.6 million that was received in October 2023, will be sufficient to fund operations, as currently planned, into 2025

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 November 22, 2023; please dial +1-888-295-2634 from the US or +972-3-925-5904 internationally.

About BioLineRx
BioLineRx Ltd. (NASDAQ: BLRX) (TASE: BLRX) is a commercial stage biopharmaceutical company pursuing life-changing therapies in oncology and rare diseases. The company's first approved product is APHEXDA® (motixafortide) with an indication in the U.S. for stem cell mobilization for autologous transplantation in multiple myeloma. BioLineRx is advancing a pipeline of investigational medicines for patients with sickle cell disease, pancreatic cancer, and other solid tumors. Headquartered in Israel, and with operations in the U.S., the company 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, the potential benefits of APHEXDA, the execution of the launch of APHEXDA and the plans and objectives of management for future operations and expectations and commercial potential of motixafortide, as well as its potential investigational uses. 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; whether the clinical trial results for APHEXDA will be predictive of real-world results; 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, including the degree and pace of market uptake of APHEXDA for the mobilization of hematopoietic stem cells for autologous transplantation in multiple myeloma patients; whether access to APHEXDA is achieved in a commercially viable manner and whether APHEXDA receives adequate reimbursement from third-party payors; BioLineRx's ability to establish, operationalize 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, including any unexpected costs or delays in the commercial launch of APHEXDA; 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, the Russian invasion of Ukraine, the declared war by Israel against Hamas and the military campaigns against Hamas and other terrorist organizations, 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 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	September 30, 2023
	in USD thousands	
Assets		
CURRENT ASSETS		
Cash and cash equivalents	10,587	7,727
Short-term bank deposits	40,495	18,241
Inventory	-	1,352
Prepaid expenses	198	1,170
Other receivables	721	315
Total current assets	52,001	28,805
NON-CURRENT ASSETS		
Property and equipment, net	726	561
Right-of-use assets, net	1,772	1,462
Intangible assets, net	21,885	22,027
Total non-current assets	24,383	24,050
Total assets	76,384	52,855
Liabilities and equity		
CURRENT LIABILITIES		
Current maturities of long-term loan	1,542	3,078
Accounts payable and accruals:		
Trade	6,966	8,438
Other	1,744	2,683
Current maturities of lease liabilities	427	526
Total current liabilities	10,679	14,725
NON-CURRENT LIABILITIES		
Warrants	4,509	15,287
Long-term loan, net of current maturities	8,626	8,458
Lease liabilities	1,729	1,251
Total non-current liabilities	14,864	24,996
Total liabilities	25,543	39,721
EQUITY		
Ordinary shares	27,100	28,332
Share premium	338,976	345,462
Warrants	1,408	1,408
Capital reserve	14,765	16,070
Other comprehensive loss	(1,416)	(1,416)
Accumulated deficit	(329,992)	(376,722)
Total equity	50,841	13,134
Total liabilities and equity	76,384	52,855

BioLineRx Ltd.

CONDENSED CONSOLIDATED INTERIM STATEMENTS OF COMPREHENSIVE LOSS

(UNAUDITED)

	Three months ended September 30,		Nine months ended September 30,	
	2022	2023	2022	2023
	in USD thousands		in USD thousands	
RESEARCH AND DEVELOPMENT EXPENSES	(4,369)	(2,727)	(14,199)	(9,417)
SALES AND MARKETING EXPENSES	(1,317)	(8,131)	(3,112)	(17,609)
GENERAL AND ADMINISTRATIVE EXPENSES	(1,392)	(1,499)	(3,448)	(4,102)
OPERATING LOSS	(7,078)	(12,357)	(20,759)	(31,128)
NON-OPERATING INCOME (EXPENSES), NET	389	(3,141)	2,115	(13,790)
FINANCIAL INCOME	109	312	256	1,289
FINANCIAL EXPENSES	(267)	(837)	(832)	(3,101)
NET LOSS AND COMPREHENSIVE LOSS	(6,847)	(16,023)	(19,220)	(46,730)
	in USD		in USD	
LOSS PER ORDINARY SHARE - BASIC AND DILUTED	(0.01)	(0.02)	(0.03)	(0.05)
WEIGHTED AVERAGE NUMBER OF SHARES USED IN CALCULATION OF LOSS PER ORDINARY SHARE	740,767,492	929,058,619	723,805,390	925,014,511

BioLineRx Ltd.

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 NINE MONTHS ENDED SEPTEMBER 30, 2022:							
Issuance of share capital and warrants, net	6,030	(1,008)	433	-	-	-	5,455
Employee stock options exercised	2	12	-	(12)	-	-	2
Employee stock options expired	-	491	-	(491)	-	-	-
Share-based compensation	-	-	-	1,200	-	-	1,200
Comprehensive loss for the period	-	-	-	-	-	(19,220)	(19,220)
BALANCE AT SEPTEMBER 30, 2022	27,098	338,841	1,408	13,854	(1,416)	(324,261)	55,524

	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 NINE MONTHS ENDED SEPTEMBER 30, 2023:							
Issuance of share capital, net	361	1,535	-	-	-	-	1,896
Warrants exercised	865	4,855	-	-	-	-	5,720
Employee stock options exercised	6	18	-	(9)	-	-	15
Employee stock options expired	-	78	-	(78)	-	-	-
Share-based compensation	-	-	-	1,392	-	-	1,392
Comprehensive loss for the period	-	-	-	-	-	(46,730)	(46,730)
BALANCE AT SEPTEMBER 30, 2023	28,332	345,462	1,408	16,070	(1,416)	(376,722)	13,134

BioLineRx Ltd.

CONDENSED CONSOLIDATED INTERIM CASH FLOW STATEMENTS

(UNAUDITED)

	Nine months ended September 30,	
	2022	2023
	in USD thousands	
CASH FLOWS - OPERATING ACTIVITIES		
Net loss for the period	(19,220)	(46,730)
Adjustments required to reflect net cash used in operating activities (see appendix below)	(1,337)	19,131
Net cash used in operating activities	(20,557)	(27,599)
CASH FLOWS – INVESTING ACTIVITIES		
Investments in short-term deposits	(36,000)	(13,882)
Maturities of short-term deposits	36,232	36,000
Purchase of property and equipment	(74)	(100)
Purchase of intangible assets	(14)	(179)
Net cash provided by investing activities	144	21,839
CASH FLOWS – FINANCING ACTIVITIES		
Issuance of share capital and warrants, net of issuance costs	14,359	1,896
Exercise of warrants	-	2,530
Employee stock options exercised	2	15
Proceeds of long-term loan, net of issuance costs	9,682	-
Repayments of loan	(2,832)	(802)
Repayments of lease liabilities	(126)	(323)
Net cash provided by financing activities	21,085	3,316
INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	672	(2,444)
CASH AND CASH EQUIVALENTS - BEGINNING OF PERIOD	12,990	10,587
EXCHANGE DIFFERENCES ON CASH AND CASH EQUIVALENTS	(557)	(416)
CASH AND CASH EQUIVALENTS - END OF PERIOD	13,105	7,727

BioLineRx Ltd.

APPENDIX TO CONDENSED CONSOLIDATED INTERIM CASH FLOW STATEMENTS

(UNAUDITED)

	Nine months ended September 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	467	678
Exchange differences on cash and cash equivalents	557	416
Fair value adjustments of warrants	(2,778)	13,968
Share-based compensation	1,200	1,392

Warrant issuance costs	171	-
Interest and exchange differences on short-term deposits	(244)	136
Interest on loan	104	2,170
Exchange differences on lease liability	(233)	(122)
Long-term loan issuance cost	(566)	-
	(1,312)	18,638
Changes in operating asset and liability items:		
Increase in inventory	-	(1,352)
Increase in prepaid expenses and other receivables	(411)	(566)
Increase in accounts payable and accruals	386	2,411
	(25)	493
	(1,337)	19,131
Supplemental information on interest received in cash	244	1,268
Supplemental information on interest paid in cash	307	833
Supplemental information on warrant issuance costs paid in cash	591	-
Supplemental information on non-cash transactions:		
Changes in right-of-use asset	123	66
Warrant issuance costs	262	-
Exercise of warrants (portion related to accumulated fair value adjustments)	-	3,190

View original content:https://www.prnewswire.com/news-releases/biolinerx-reports-third-quarter-2023-financial-results-and-recent-corporate-and-portfolio-updates-301992881.html

SOURCE BioLineRx Ltd.