BioLineRx Reports 2022 Financial Results and Recent Corporate and Portfolio Updates

March 22, 2023 11:00 AM 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 -

- Named Tami Rachmilewitz, M.D., as new Chief Medical Officer and Completed Formation of U.S. Commercial Leadership Team with Extensive Drug Launch and Sales Experience -

- Entered into Clinical Trial Collaboration with Washington University School of Medicine to Evaluate Motixafortide for Hematopoietic Stem Cell Mobilization for Gene Therapies in Sickle Cell Disease -

- Management to hold conference call today, March 22, at 10:00 am EDT -

TEL AVIV, Israel, March 22, 2023 /PRNewswire/ -- BioLineRx Ltd. (NASDAQ: BLRX) (TASE: BLRX), a pre-commercial-stage biopharmaceutical company focused on oncology, today reported its audited 2022 annual financial results for the year ended December 31, 2022, and provided recent corporate and portfolio updates.

"Over the last quarter and into this year, we continue to proceed with activities to advance the NDA review process of APHEXDA®, while in parallel progressing with pre-launch activities in anticipation of potential approval later this year," said Philip Serlin, Chief Executive Officer of BioLineRx. "Importantly, we recently announced the appointment of our new chief medical officer and completed the formation of our U.S. commercialization team that includes industry veterans with significant and very relevant drug launch and sales experience. Additionally, we announced a new collaboration to evaluate motixafortide for stem cell mobilization for gene therapies in sickle cell disease, which continues our goal of fully maximizing its clinical potential for patients. This is an extremely exciting year for the Company, with the potential commercial approval of our first product, anticipated pancreatic cancer clinical trial data, as well as the planned initiation of two new clinical trials that may further our growth."

Recent Corporate Updates

- Appointed Tami Rachmilewitz, M.D. as Chief Medical Officer
- Finalized formation of the U.S. commercial leadership team, which collectively has significant drug launch and sales experience, with particular expertise in stem cell mobilization and transplantation

Portfolio Execution

Motixafortide (selective inhibitor of CXCR4 chemokine receptor)

Multiple Myeloma

- Announced FDA acceptance of the APHEXDA® (motixafortide) NDA in stem cell mobilization for autologous transplantation in multiple myeloma patients. PDUFA target action date set for September 9, 2023
- Presented a cost-effectiveness analysis of APHEXDA® (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 was held December 10-13, 2022, in New Orleans, Louisiana. The analysis demonstrated significant net cost savings with APHEXADA® (motixafortide)

Pancreatic Ductal Adenocarcinoma (PDAC)

- 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 in first line mPDAC patients. 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. Clinical trial design was presented at the American Society of Hematology (ASH) 64th Annual Meeting, which was held December 10-13, 2022, in New Orleans, Louisiana

AGI-134 (synthetic alpha-Gal glycolipid)

Solid Tumor Immunotherapy

- Announced results from Phase 1/2a study of investigational anti-tumor vaccine AGI-134 in metastatic solid tumors. First-in-human, single-agent study met primary endpoint for safety and tolerability and demonstrated immune activity across multiple biomarkers. The Company is evaluating potential development program pathways in consultation with its scientific advisory board

Financial Results for Year Ended December 31, 2022

- Research and development expenses for the year ended December 31, 2022, were $17.6 million compared to $19.5 million for the year ended December 31, 2021. The decrease resulted primarily from lower expenses related to NDA supporting activities related to motixafortide, as well as lower expenses associated with the completed motixafortide GENESIS clinical trial, offset by an increase in expenses associated with the AGI-134 study and an increase in payroll and related expenses
- Sales and marketing expenses for the year ended December 31, 2022, were $6.5 million compared to $1.0 million the year ended December 31, 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 year ended December 31, 2022, were $5.1 million compared to $4.3 million for the year ended December 31, 2021. The increase resulted primarily from an increase in share-based compensation and small increases in a number of general and administrative expenses
- Net loss for the year ended December 31, 2022, was $25.0 million, compared to $27.1 million for the year ended December 31, 2021
- As of December 31, 2022, the Company had cash, cash equivalents, and short-term bank deposits of $51.1 million and anticipates this will be sufficient to fund operations, as currently planned, into the first half of 2024

A copy of the Company's annual report on Form 20-F for the year ended December 31, 2022 has been filed with the U.S. Securities and Exchange Commission at https://www.sec.gov/ and posted on the Company's investor relations website at https://ir.biolinerx.com.The Company will deliver a hard copy of its annual report, including its complete audited consolidated financial statements, free of charge, to its shareholders upon request at IR@BioLineRx.com.

Conference Call and Webcast Information

BioLineRx will hold a conference call today, Wednesday, March 22 at 10:00 a.m. EDT.

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 March 24, 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. APHEXDA® (motixafortide) was successfully evaluated in a Phase 3 study in stem cell mobilization for autologous

transplantation for 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 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 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; 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.
CONSOLIDATED STATEMENTS OF FINANCIAL POSITION

	December 31,	
	2021	2022
	in USD thousands	
Assets		
CURRENT ASSETS		
Cash and cash equivalents	12,990	10,587
Short-term bank deposits	44,145	40,495
Prepaid expenses	127	198
Other receivables	142	721
Total current assets	57,404	52,001
NON-CURRENT ASSETS		
Property and equipment, net	952	726
Right-of-use assets, net	1,331	1,772
Intangible assets, net	21,704	21,885
Total non-current assets	23,987	24,383
Total assets	81,391	76,384
Liabilities and equity		
CURRENT LIABILITIES		
Current maturities of long-term loans	2,757	1,542
Accounts payable and accruals:		

Trade	5,567	6,966
Other	1,227	1,744
Current maturities of lease liabilities	168	427
Total current liabilities	9,719	10,679
NON-CURRENT LIABILITIES		
Warrants	1,859	4,509
Long-term loans, net of current maturities	-	8,626
Lease liabilities	1,726	1,729
Total non-current liabilities	3,585	14,864
COMMITMENTS AND CONTINGENT LIABILITIES		
Total liabilities	13,304	25,543
EQUITY		
Ordinary shares	21,066	27,100
Share premium	339,346	338,976
Warrants	975	1,408
Capital reserve	13,157	14,765
Other comprehensive loss	(1,416)	(1,416)
Accumulated deficit	(305,041)	(329,992)
Total equity	68,087	50,841
Total liabilities and equity	81,391	76,384

BioLineRx Ltd.
CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

	Year ended December 31,		
	2020	**2021**	**2022**
	in USD thousands		
RESEARCH AND DEVELOPMENT EXPENSES	(18,173)	(19,466)	(17,629)
SALES AND MARKETING EXPENSES	(840)	(1,003)	(6,462)
GENERAL AND ADMINISTRATIVE EXPENSES	(3,914)	(4,308)	(5,066)
OPERATING LOSS	(22,927)	(24,777)	(29,157)
NON-OPERATING INCOME (EXPENSES), NET	(5,701)	(1,830)	5,670
FINANCIAL INCOME	236	559	694
FINANCIAL EXPENSES	(1,629)	(1,006)	(2,158)
LOSS AND COMPREHENSIVE LOSS	(30,021)	(27,054)	(24,951)
	in USD		
LOSS PER ORDINARY SHARE – BASIC AND DILUTED	(0.12)	(0.04)	(0.03)
WEIGHTED AVERAGE NUMBER OF SHARES USED IN CALCULATION OF LOSS PER ORDINARY SHARE	252,844,394	662,933,695	773,956,973

BioLineRx Ltd.

STATEMENTS OF CHANGES IN EQUITY

	Ordinary shares	**Share premium**	**Warrants**	**Capital reserve**	**Other comprehensive loss**	**Accumulated deficit**	**Total**
	in USD thousands						
BALANCE AT JANUARY 1, 2020	4,692	265,938	-	12,132	(1,416)	(247,966)	33,380
CHANGES IN 2020:							
Issuance of share capital and warrants, net	4,777	9,395	-	-	-	-	14,172

Warrants exercised	393	2,826	-	-	-	-	3,219
Employee stock options exercised	8	228	-	(228)	-	-	8
Employee stock options expired	-	854	-	(854)	-	-	-
Share-based compensation	-	-	-	1,272	-	-	1,272
Comprehensive loss for the year	-	-	-	-	-	(30,021)	(30,021)
BALANCE AT DECEMBER 31, 2020	9,870	279,241	-	12,322	(1,416)	(277,987)	22,030
CHANGES IN 2021:							
Issuance of share capital and warrants, net	8,956	40,476	975	-	-	-	50,407
Warrants exercised	2,235	18,967	-	-	-	-	21,202
Employee stock options exercised	5	41	-	(39)	-	-	7
Employee stock options expired	-	621	-	(621)	-	-	-
Share-based compensation	-	-	-	1,495	-	-	1,495
Comprehensive loss for the year	-	-	-		-	(27,054)	(27,054)
BALANCE AT DECEMBER 31, 2021	21,066	339,346	975	13,157	(1,416)	(305,041)	68,087
CHANGES IN 2022:							
Issuance of share capital and warrants, net	6,029	(1,007)	433	-	-	-	5,455
Employee stock options exercised	5	14	-	(14)	-	-	5
Employee stock options expired	-	623	-	(623)	-	-	-
Share-based compensation	-	-	-	2,245	-	-	2,245
Comprehensive loss for the year	-	-	-		-	(24,951)	(24,951)
BALANCE AT DECEMBER 31, 2022	27,100	338,976	1,408	14,765	(1,416)	(329,992)	50,841

BioLineRx Ltd.
CONSOLIDATED STATEMENTS OF CASH FLOWS

	Year ended December 31,		
	2020	**2021**	**2022**
	in USD thousands		
CASH FLOWS - OPERATING ACTIVITIES			
Loss	(30,021)	(27,054)	(24,951)
Adjustments required to reflect net cash used in operating activities (see appendix below)	6,815	3,481	(1,289)
Net cash used in operating activities	(23,206)	(23,573)	(26,240)
CASH FLOWS - INVESTING ACTIVITIES			
Investments in short-term deposits	(33,500)	(78,000)	(44,000)
Maturities of short-term deposits	50,168	39,873	48,322
Purchase of property and equipment	-	(97)	(131)
Purchase of intangible assets	-	-	(185)
Net cash provided by (used in) investing activities	16,668	(38,224)	4,006
CASH FLOWS - FINANCING ACTIVITIES			
Issuance of share capital and warrants, net of issuance costs	19,246	50,407	14,359
Exercise of warrants	1,969	10,907	-
Employee stock options exercised	8	7	5
Proceeds from long-term loan, net of issuance costs	-	-	9,126
Repayments of loans	(3,133)	(3,376)	(2,832)
Repayments of lease liabilities	(224)	(196)	(220)
Net cash provided by financing activities	17,866	57,749	20,438
INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	11,328	(4,048)	(1,796)
CASH AND CASH EQUIVALENTS - BEGINNING OF YEAR	5,297	16,831	12,990
EXCHANGE DIFFERENCES ON CASH AND CASH EQUIVALENTS	206	207	(607)
CASH AND CASH EQUIVALENTS - END OF YEAR	16,831	12,990	10,587

BioLineRx Ltd.
CONSOLIDATED STATEMENTS OF CASH FLOWS

Year ended December 31,

	2020	2021	2022
	in USD thousands		
APPENDIX			
Adjustments required to reflect net cash used in operating activities:			
Income and expenses not involving cash flows:			
Depreciation and amortization	934	703	654
Exchange differences on cash and cash equivalents	(206)	(207)	607
Fair value adjustments of warrants	5,142	1,936	(6,425)
Share-based compensation	1,272	1,495	2,245
Interest and exchange differences on short-term deposits	(232)	(262)	(672)
Interest accrued	474	301	1,117
Warrant issuance costs	594	-	171
Exchange differences on lease liabilities	125	55	(224)
	8,103	4,021	(2,527)
Changes in operating asset and liability items:			
Decrease (increase) in prepaid expenses and other receivables	428	24	(650)
Increase (decrease) in accounts payable and accruals	(1,716)	(564)	1,888
	(1,288)	(540)	1,238
	6,815	3,481	(1,289)
Supplemental information on interest received in cash	381	138	342
Supplemental information on interest paid in cash	994	682	593
Supplemental information on non-cash transactions:			
Changes in right-of-use asset and lease liabilities	13	183	706
Warrant issuance costs	-	-	262
Purchase of property and equipment	-	-	28
Fair value of exercised warrants (portion related to accumulated fair value adjustments)	1,251	10,295	-

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