BioLineRx Reports Second Quarter 2024 Financial Results and Recent Corporate and Portfolio Updates

August 15, 2024 11:00 AM IDT

- Secured APHEXDA® formulary placement among top 80 transplant centers representing ~37% of stem cell transplant procedures performed, surpassing stated goal for quarter; on-track to reach goal of ~60% by end of Q4 -

- Doubled the number of centers ordering APHEXDA during the second quarter -

- Entered into clinical trial agreement with St. Jude Children's Research Hospital to evaluate motixafortide for hematopoietic stem cell mobilization for gene therapies in sickle cell disease -

- Management to host conference call today, August 15, at 8:30 am EDT -

TEL AVIV, Israel, Aug. 15, 2024 /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 second quarter ended June 30, 2024, and provided recent corporate and portfolio updates.

"We continue to demonstrate positive commercial launch momentum with APHEXDA, our best-in-class stem cell mobilization agent," said Philip Serlin, Chief Executive Officer of BioLineRx. "Importantly, among our targeted top 80 transplant centers, we've secured formulary placement to date at institutions representing ~37% of stem cell transplant procedures performed, surpassing our stated goal. Additionally, we doubled the number of transplant centers ordering APHEXDA during the second quarter, which is a strong leading indicator and, we believe, reflects centers' growing recognition of the value that APHEXDA offers relative to other mobilization agents. Our goal is to achieve formulary placement at institutions representing approximately 60% of procedures by the end of year, which will support continued revenue growth and ease burdens on patients, caregivers, and transplant centers.

"Our vision is to maximize the potential of APHEXDA by expanding into key areas with high unmet need. To that end, we announced our second clinical trial collaboration, with St. Jude Children's Research Hospital, evaluating APHEXDA for stem cell mobilization in patients with sickle cell disease (SCD) seeking gene therapy. This new collaboration complements the ongoing SCD stem cell mobilization Phase 1 trial at Washington University in St. Louis (Wash U.). APHEXDA has the potential to support the collection of the immense amount of stem cells needed for these complex gene therapies in a more predictable and condensed timeline for patients. The companies launching these new gene therapies for SCD report continued expansion of authorized treatment centers and increased numbers of patients initiating cell collection. We look forward to seeing early data from the Wash U. Phase 1 trial later this year."

APHEXDA Launch Updates

- Among top 80 transplant centers, secured formulary placement to date at institutions representing ~37% of stem cell transplant procedures performed, exceeding the company's stated goal for the quarter; on track to achieve ~60% by year-end 2024
- Saw double the number of centers ordering APHEXDA during the second quarter as compared to the first quarter, which contributed to quarter-over-quarter net revenue growth of 100%

Clinical Portfolio Updates

Motixafortide

Multiple Myeloma

- Presented a poster at the American Society for Apheresis (ASFA) 2024 Annual Meeting on April 17, 2024, demonstrating that transplant centers (averaging, for example, 20 transplants

per month), when switching to G-CSF plus APHEXDA, could increase capacity by 52.0 patient days per month versus G-CSF alone, or by 12.3 patient days per month versus G-CSF in combination with plerixafor
- Presented a poster at the International Society for Pharmacoeconomics and Outcomes Research (ISPOR) on April 6, 2024, showing that even with APHEXDA's higher drug acquisition cost compared to other mobilization regimens, specifically G-CSF alone or G-CSF plus generic plerixafor, the combination of G-CSF plus APHEXDA may confer a similar or better overall financial impact while providing centers and patients with an improved mobilization experience
- Collaboration partner Gloria Biosciences' stem cell mobilization bridging study IND was filed and approved by the Center for Drug Evaluation of the National Medical Products Administration in China. Anticipate initiation of pivotal clinical trial in 2H 2024

Sickle Cell Disease (SCD) & Gene Therapy

- Entered into clinical trial agreement with St. Jude Children's Research Hospital to evaluate motixafortide for hematopoietic stem cell mobilization for gene therapies in sickle cell disease. The Phase 1 clinical trial is an open-label, multi-center study evaluating the safety, tolerability, and feasibility of single-agent motixafortide for the mobilization and collection of CD34+ HSCs in 12 patients (aged 18 and older) with SCD. Anticipate first patient dosed in September 2024 and initial data in 2025
- Reported continuing enrollment of patients into a Phase 1 clinical trial evaluating motixafortide as monotherapy and in combination with natalizumab for stem cell mobilization for gene therapies in sickle cell disease. The trial, in collaboration with Washington University School of Medicine in St. Louis, has been expanded from five to 10 patients. Anticipate initial data in 2H 2024

Pancreatic Ductal Adenocarcinoma (mPDAC)

- Presented positive biopsy data from the completed pilot phase of the ongoing CheMo4METPANC Phase 2b clinical trial collaboration with Columbia University at the American Society of Clinical Oncology (ASCO) 2024 Annual Meeting held on June 1, 2024 in Chicago, IL. New analyses of paired pre- and on-treatment biopsy samples demonstrated a statistically significant increase in CD8+ T-cell density in tumors from all 11 patients treated with the combination therapy approach (P=0.007). Enrollment in the randomized trial targeting 108 patients continues with full enrollment anticipated in 2027
- Completed design of Phase 2b randomized clinical trial in China with collaboration partner Gloria Biosciences intended to assess motixafortide in combination with the PD-1 inhibitor zimberelimab and standard-of-care chemotherapy as first-line treatment in patients with metastatic pancreatic cancer. Anticipate clinical trial initiation in 2025

Second Quarter 2024 Financial Results

- Total revenue for the three months ended June 30, 2024 was $5.4 million. The Company did not record any revenue during the second quarter of 2023. Revenue for the quarter reflects a portion of the upfront payment from the Gloria Biosciences license, which amounted to $3.6 million, as well as $1.8 million of net revenue from product sales of APHEXDA in the U.S.
- Cost of revenue for the three months ended June 30, 2024 was $0.9 million. The Company did not record any cost of revenue during the second quarter of 2023. Cost of revenue for the quarter primarily reflects the amortization of intangible assets, royalties on net product sales of APHEXDA in the U.S., and cost of goods sold on product sales
- Research and development expenses for the three months ended June 30, 2024 were $2.2

million, compared to $3.0 million for the same period in 2023. The decrease resulted primarily from lower expenses related to motixafortide New Drug Application (NDA) supporting activities, termination of the development of AGI-134 and a decrease in share-based compensation

- Sales and marketing expenses for the three months ended June 30, 2024 were $6.4 million, compared to $5.6 million for the same period in 2023. The increase resulted primarily from the ramp-up in headcount costs associated with a fully hired field team
- General and administrative expenses for the three months ended June 30, 2024 were $1.6 million, compared to $1.3 million for the same period in 2023. The increase resulted primarily from an increase in legal and certain other expenses
- Net income for the three months ended June 30, 2024 was $0.5 million, compared to net loss of $18.5 million for the same period in 2023. The net income for the 2024 period included $7.8 million in non-operating income, compared to non-operating expenses of $7.7 million for the same period in 2023, both primarily related to the non-cash revaluation of warrants
- As of June 30, 2024, the Company had cash, cash equivalents, and short-term bank deposits of $40.1 million. The Company anticipates that this amount 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 August 19, 2024; please dial +1-888-295-2634 from the US or +972-3-925-5904 internationally.

About BioLineRx

BioLineRx Ltd. (NASDAQ/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 BioLineRx's collaboration partners will be able to execute on collaboration goals in a timely manner; 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 26, 2024. 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.

Logo: https://mma.prnewswire.com/media/2154863/4858892/BioLineRx_Ltd_Logo.jpg

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, 2023	June 30, 2024
	in USD thousands	
Assets		
CURRENT ASSETS		
Cash and cash equivalents	4,255	9,623
Short-term bank deposits	38,739	30,437
Trade receivables	358	3,179
Prepaid expenses	1,048	1,581
Other receivables	830	656
Inventory	1,953	3,634
Total current assets	47,183	49,110
NON-CURRENT ASSETS		
Property and equipment, net	473	344
Right-of-use assets, net	1,415	1,452
Intangible assets, net	14,854	13,690
Total non-current assets	16,742	15,486
Total assets	63,925	64,596
Liabilities and equity		
CURRENT LIABILITIES		
Current maturities of long-term loan	3,145	10,656
Contract liabilities	12,957	5,477
Accounts payable and accruals:		
Trade	10,869	6,266
Other	3,353	2,530
Current maturities of lease liabilities	528	500
Warrants	11,932	5,087
Total current liabilities	42,784	30,516
NON-CURRENT LIABILITIES		
Long-term loan, net of current maturities	6,628	18,790
Lease liabilities	1,290	1,309
Total non-current liabilities	7,918	20,099
CONTINGENT LIABILITIES		
Total liabilities	50,702	50,615
EQUITY		
Ordinary shares	31,355	34,411
Share premium	355,482	352,428
Warrants	1,408	1,408
Capital reserve	17,000	17,968
Other comprehensive loss	(1,416)	(1,416)
Accumulated deficit	(390,606)	(390,818)
Total equity	13,223	13,981
Total liabilities and equity	63,925	64,596

BioLineRx Ltd.

CONDENSED CONSOLIDATED INTERIM STATEMENTS OF COMPREHENSIVE INCOME (LOSS)
(UNAUDITED)

	Three months ended June 30,		Six months ended June 30,	
	2023	2024	2023	2024
	in USD thousands		in USD thousands	
REVENUES	-	5,393	-	12,248
COST OF REVENUES	-	(897)	-	(2,352)
GROSS PROFIT	-	4,496	-	9,896
RESEARCH AND DEVELOPMENT EXPENSES	(3,006)	(2,225)	(6,690)	(4,719)
SALES AND MARKETING EXPENSES	(5,604)	(6,415)	(9,478)	(12,757)
GENERAL AND ADMINISTRATIVE EXPENSES	(1,305)	(1,629)	(2,603)	(3,015)
OPERATING LOSS	(9,915)	(5,773)	(18,771)	(10,595)
NON-OPERATING INCOME (EXPENSES), NET	(7,733)	7,807	(10,649)	12,297
FINANCIAL INCOME	440	535	977	1,100
FINANCIAL EXPENSES	(1,337)	(2,085)	(2,264)	(3,014)
NET INCOME (LOSS) AND COMPREHENSIVE INCOME (LOSS)	(18,545)	484	(30,707)	(212)
	in USD		in USD	
EARNINGS (LOSS) PER SHARE ATTRIBUTABLE TO ORDINARY SHAREHOLDERS				
BASIC	(0.02)	0.00	(0.03)	(0.00)
DILUTED	(0.02)	0.00	(0.03)	(0.00)
WEIGHTED AVERAGE NUMBER OF SHARES USED IN CALCULATION OF EARNINGS (LOSS) PER SHARE				
BASIC	922,958,942	1,197,582,901	922,958,942	1,142,221,033
DILUTED	922,958,942	1,197,582,901	922,958,942	1,142,221,033

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, 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

	Ordinary shares	Share premium	Warrants	Capital reserve	Other comprehensive loss	Accumulated deficit	Total
	in USD thousands						
BALANCE AT JANUARY 1, 2024	31,355	355,482	1,408	17,000	(1,416)	(390,606)	13,223
CHANGES FOR SIX MONTHS ENDED JUNE 30, 2024:							
Issuance of share capital and warrants, net	3,056	(3,056)	-	-	-	-	-
Employee stock options forfeiture				(66)			(66)

Share-based compensation expenses	-	-	-	1,036	-	-	1,036
Comprehensive loss for the period	-	-	-	-	-	(212)	(212)
BALANCE AT JUNE 30, 2024	34,411	352,426	1,408	17,970	(1,416)	(390,818)	13,981

BioLineRx Ltd.

CONDENSED CONSOLIDATED INTERIM CASH FLOW STATEMENTS

(UNAUDITED)

	Six months ended June 30,	
	2023	2024
	in USD thousands	
CASH FLOWS - OPERATING ACTIVITIES		
Comprehensive loss for the period	(30,707)	(212)
Adjustments required to reflect net cash used in operating activities (see appendix below)	13,009	(25,226)
Net cash used in operating activities	(17,698)	(25,438)
CASH FLOWS – INVESTING ACTIVITIES		
Investments in short-term deposits	(6,006)	(20,559)
Maturities of short-term deposits	24,000	28,660
Purchase of property and equipment	(99)	(59)
Purchase of intangible assets	(153)	-
Net cash provided by investing activities	17,742	8,042
CASH FLOWS – FINANCING ACTIVITIES		
Issuance of share capital and warrants, net of issuance cost	-	5,565
Net proceeds from loan	-	19,223
Repayments of loan		(1,547)
Repayments of lease liabilities	(183)	(256)
Net cash provided by (used in) financing activities	(183)	22,985
INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	(139)	5,589
CASH AND CASH EQUIVALENTS - BEGINNING OF PERIOD	10,587	4,255
EXCHANGE DIFFERENCES ON CASH AND CASH EQUIVALENTS	(344)	(221)
CASH AND CASH EQUIVALENTS - END OF PERIOD	10,104	9,623

BioLineRx Ltd.

APPENDIX TO CONDENSED CONSOLIDATED INTERIM CASH FLOW STATEMENTS

(UNAUDITED)

	Six months ended June 30,	
	2023	2024
	in USD thousands	
Adjustments required to reflect net cash used in operating activities:		
Income and expenses not involving cash flows:		
Depreciation and amortization	457	1,373
Exchange differences on cash and cash equivalents	344	221
Fair value adjustments of warrants	10,843	(12,845)
Share-based compensation	920	970

Interest on short-term deposits	(210)	201
Interest on loan	1,405	1,997
Exchange differences on lease liabilities	(75)	189
Issuance cost of warrants	-	642
	13,684	(7,252)
Changes in operating asset and liability items:		
Increase in trade receivables	-	(2,821)
Increase in prepaid expenses and other receivables	(958)	(359)
Increase in inventory	-	(1,681)
Increase (decrease) in accounts payable and accruals	283	(5,633)
Decrease in contract liabilities	-	(7,480)
	(675)	(17,974)
	13,009	(25,226)
Supplemental information on interest received in cash	761	931
Supplemental information on interest paid in cash	640	971
Supplemental information on non-cash transactions:		
Changes in right-of-use asset and lease liabilities	66	58
Warrant issuance costs	-	207

View original content to download multimedia:https://www.prnewswire.com/news-releases/biolinerx-reports-second-quarter-2024-financial-results-and-recent-corporate-and-portfolio-updates-302222449.html

SOURCE BioLineRx Ltd.