BioLineRx Reports First Quarter 2025 Financial Results and Provides Corporate Update

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- Reports continued progress in the evaluation of assets for potential in-licensing and development in the areas of oncology and rare disease -

- New data from pilot phase of ongoing CheMo4METPANC Phase 2b combination trial of motixafortide in PDAC, sponsored by Columbia University, to be presented at upcoming 2025 ASCO Annual Meeting –

- APHEXDA performing well under Ayrmid stewardship -

- Management to host conference call today, May 27th, at 8:30 am EDT -

TEL AVIV, Israel, May 27, 2025 /PRNewswire/ -- BioLineRx Ltd. (NASDAQ: BLRX) (TASE: BLRX), a development stage biopharmaceutical company pursuing life-changing therapies in oncology and rare diseases, today reported its unaudited financial results for the quarter ended March 31, 2025, and provided a corporate update.

"Following our announcement last November that we out-licensed APHEXDA®, our FDA-approved stem cell mobilization agent, to Ayrmid Ltd., we have been actively evaluating new assets in the areas of oncology and rare disease where we can leverage our drug development and regulatory expertise to bring new medicines to market," said Philip Serlin, Chief Executive Officer of BioLineRx. "I remain optimistic that we will announce a meaningful transaction this year."

"At the same time, APHEXDA is performing well under the stewardship of Ayrmid, and I believe this license agreement will contribute significant long-term value to our company," Mr. Serlin concluded.

Financial Updates

- Completed financing in January 2025 raising gross proceeds of $10 million.
- Successfully reduced operating expense run rate by over 70% beginning January 1, 2025, through the APHEXDA program transfer to Ayrmid and the resulting shutdown of the Company's U.S. commercial operations in Q4 2024, as well as additional headcount and other operating expense reductions.
- Reaffirms cash runway through the second half of 2026.

APHEXDA Performance Update

- APHEXDA generated sales of $1.4 million in the first quarter of 2025, providing royalty revenues to the Company of $0.3 million.

Clinical Updates

Motixafortide

Pancreatic Ductal Adenocarcinoma (mPDAC)

- Additional trial sites were activated for the CheMo4METPANC Phase 2b clinical trial, which is expected to have a positive impact on patient recruitment. Full enrollment in the randomized trial, which is being led by Columbia University, and supported by both Regeneron and BioLineRx, is planned for completion in 2027, with a prespecified interim analysis planned when 40% of progression free survival (PFS) events are observed.
- An abstract featuring updated data from the pilot phase of the ongoing CheMo4METPANC clinical trial has been accepted for a poster presentation at the 2025 ASCO Annual Meeting on

Saturday, May 31st. Key highlights include:

- Two patients underwent definitive treatment for metastatic pancreatic cancer: one had complete resolution of all radiologically detected liver lesions and underwent definitive radiation to the primary pancreatic tumor, and one had a sustained partial response and underwent pancreaticoduodenectomy with pathology demonstrating a complete response.
- An analysis of pre- and on-treatment biopsies revealed that CD8+ T-cell tumor infiltration increased across all eleven patients treated with the motixafortide combination.

Sickle Cell Disease (SCD) & Gene Therapy

- Enrollment is continuing into the multi-center Phase 1 clinical trial evaluating motixafortide for the mobilization of CD34+ hematopoietic stem cells (HSCs) used in the development of gene therapies for patients with Sickle Cell Disease (SCD). The trial is sponsored by St. Jude Children's Research Hospital.
- Reported continued progress of 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 is sponsored by Washington University School of Medicine in St. Louis.

Financial Results for the Quarter Ended March 31, 2025

- Revenues for the three-month period ended March 31, 2025 were $0.3 million, a decrease of $6.6 million, compared to revenues of $6.9 million for the three-month period ended March 31, 2024. The significant decrease in revenues from 2024 to 2025 reflects the one-time revenues recorded in 2024 relating to the out-licensing transaction with Gloria during the fourth quarter of 2023, as well as the change in the Company's operations following the out-licensing of APHEXDA to Ayrmid during the fourth quarter of 2024. The revenues in 2025 reflect the royalties paid by Ayrmid from the commercialization of APHEXDA in stem cell mobilization in the U.S. The revenues in 2024 primarily reflect a portion of the up-front payment received by the Company and a milestone payment achieved under the license agreement with Gloria, which collectively amounted to $5.9 million, as well as $0.9 million of net revenues from product sales of APHEXDA in the U.S.
- Cost of revenues for the three-month period ended March 31, 2025 was immaterial, compared to cost of revenues of $1.5 million for the three-month period ended March 31, 2024. The cost of revenues in 2025 reflects sub-license fees on royalties paid by Ayrmid from the commercialization of APHEXDA in stem cell mobilization in the U.S. The cost of revenues in 2024 primarily reflects sub-license fees on a milestone payment received under the Gloria license agreement and royalties on net product sales of APHEXDA in the U.S., as well as amortization of intangible assets and cost of goods sold on product sales.
- Research and development expenses for the three months ended March 31, 2025 were $1.6 million, a decrease of $0.9 million, or 34.9%, compared to $2.5 million for the three months ended March 31, 2024. The decrease resulted primarily from lower expenses related to motixafortide due to the out-licensing of U.S. rights to Ayrmid, as well as a decrease in payroll and share-based compensation, primarily due to a decrease in headcount.
- There were no sales and marketing expenses for the three months ended March 31, 2025, compared to $6.3 million for the three months ended March 31, 2024. The decrease resulted primarily from the shutdown of U.S. commercial operations in the fourth quarter of 2024 following the Ayrmid out-licensing transaction.
- General and administrative expenses for the three months ended March 31, 2025 were $1.0 million, a decrease of $0.4 million, or 28.6%, compared to $1.4 million for the three months

ended March 31, 2024. The decrease resulted primarily from a decrease in payroll and share-based compensation, primarily due to a decrease in headcount, as well as small decreases in a number of general and administrative expenses.

- Net non-operating income for the three months ended March 31, 2025 was $7.6 million, compared to net non-operating income of $4.5 million for the three months ended March 31, 2024. Non-operating income for both periods primarily relates to fair-value adjustments of warrant liabilities on the balance sheet, as a result of changes in the Company's share price.
- Net financial expenses for the three months ended March 31, 2025 were $0.1 million, compared to net financial expenses of $0.4 million for the three months ended March 31, 2024. Net financial expenses for both periods primarily relate to loan interest paid, partially offset by investment income earned on bank deposits.
- Net income for the quarter ended March 31, 2025 was $5.1 million, compared to $0.7 million for the quarter ended March 31, 2024.
- As of March 31, 2025, the Company had cash, cash equivalents, and short-term bank deposits of $26.4 million

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 May 29, 2025; please dial +1-888-295-2634 from the US or +972-3-925-5904 internationally.

About BioLineRx

BioLineRx Ltd. (NASDAQ/TASE: BLRX) is a 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, which is being developed and commercialized by Ayrmid Ltd. (globally, excluding Asia) and Gloria Biosciences (in Asia). BioLineRx is utilizing its end-to-end expertise in development, regulatory affairs and manufacturing to advance its innovative pipeline and ensure 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 success of the license agreement with Ayrmid and the commercial potential of motixafortide, expectations with regard to clinical trials of motixafortide, the expected cash runway, and BioLineRx's business strategy. 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 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; 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; 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, manage, and maintain corporate collaborations, as well as the ability of BioLineRx's collaborators to execute on their development and commercialization plans; BioLineRx's ability to integrate new therapeutic candidates and new personnel as well as new collaborations; 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; BioLineRx's ability to maintain the listing of its ADSs on Nasdaq; and statements as to the impact of the political and security situation in Israel on BioLineRx's business, 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 31, 2025. 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.

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

	December 31,	March 31,

	2024	2025
	in USD thousands	
Assets		
CURRENT ASSETS		
Cash and cash equivalents	10,436	9,036
Short-term bank deposits	9,126	17,333
Trade receivables	2,476	1,469
Prepaid expenses	443	312
Other receivables	1,478	452
Inventory	3,145	3,315
Total current assets	27,104	31,917
NON-CURRENT ASSETS		
Property and equipment, net	386	299
Right-of-use assets, net	967	863
Intangible assets, net	10,449	10,431
Total non-current assets	11,802	11,593
Total assets	38,906	43,510
Liabilities and equity		
CURRENT LIABILITIES		
Current maturities of long-term loan	4,479	4,684
Accounts payable and accruals:		
Trade	5,583	4,693
Other	3,131	1,751
Current maturities of lease liabilities	522	440
Warrants	1,691	2,462
Total current liabilities	15,406	14,030
NON-CURRENT LIABILITIES		
Long-term loan, net of current maturities	8,958	7,633
Lease liabilities	1,081	985
Total non-current liabilities	10,039	8,618
COMMITMENTS AND CONTINGENT LIABILITIES		
Total liabilities	25,445	22,648
EQUITY		
Ordinary shares	38,097	62,570
Share premium	353,693	333,627
Warrants	5,367	3,686
Capital reserve	17,547	17,095
Other comprehensive loss	(1,416)	(1,416)
Accumulated deficit	(399,827)	(394,700)
Total equity	13,461	20,862
Total liabilities and equity	38,906	43,510

BioLineRx Ltd.

CONDENSED CONSOLIDATED INTERIM STATEMENTS OF COMPREHENSIVE INCOME (LOSS)

(UNAUDITED)

	Three months ended March 31,	
	2024	2025
	in USD thousands	
REVENUES:		
License revenues	5,931	255
Product sales, net	924	-
Total revenues	6,855	255
COST OF REVENUES	(1,455)	(34)
GROSS PROFIT	5,400	221
RESEARCH AND DEVELOPMENT EXPENSES	(2,494)	(1,623)
SALES AND MARKETING EXPENSES	(6,342)	-
GENERAL AND ADMINISTRATIVE EXPENSES	(1,386)	(989)

OPERATING LOSS	(4,822)	(2,391)
NON-OPERATING INCOME (EXPENSES), NET	4,490	7,644
FINANCIAL INCOME	565	294
FINANCIAL EXPENSES	(929)	(420)
NET INCOME (LOSS) AND COMPREHENSIVE INCOME (LOSS)	(696)	5,127
	in USD	
EARNINGS)LOSS(PER ORDINARY SHARE - BASIC AND DILUTED	(0.00)	0.00
WEIGHTED AVERAGE NUMBER OF SHARES USED IN CALCULATION OF EARNINGS)LOSS(PER ORDINARY SHARE	1,086,589,165	2,217,728,234

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CONDENSED CONSOLIDATED INTERIM STATEMENTS OF CHANGES IN EQUITY
(UNAUDITED)

	Ordinary shares	Share pre-mium	Warrants	Capital re-serve	Other compre-hensive 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 THREE MONTHS ENDED MARCH 31, 2024:							
Share-based compensation	-	-	-	533	-	-	533
Comprehensive loss for the period	-	-	-	-	-	(696)	(696)
BALANCE AT MARCH 31, 2024	31,355	355,482	1,408	17,533	(1,416)	(391,302)	13,060

	Ordinary shares	Share pre-mium	Warrants	Capital re-serve	Other compre-hensive loss	Accumulated deficit	Total
	in USD thousands						
BALANCE AT JANUARY 1, 2025	38,097	353,693	5,367	17,547	(1,416)	(399,827)	13,461
CHANGES FOR THREE MONTHS ENDED MARCH 31, 2025:							
Issuance of share capital, pre-funded warrants and warrants, net	16,415	(14,836)	501	-	-	-	2,080
Pre-funded warrants exercised	8,058	(5,876)	(2,182)	-	-	-	-
Employee stock options expired	-	646	-	(646)	-	-	-
Share-based compensation	-	-	-	194	-	-	194
Comprehensive income for the period	-	-	-	-	-	5,127	5,127
BALANCE AT MARCH 31, 2025	62,570	333,627	3,686	17,095	(1,416)	(394,700)	20,862

BioLineRx Ltd.
CONDENSED CONSOLIDATED INTERIM CASH FLOW STATEMENTS
(UNAUDITED)

	Three months ended March 31,	
	2024	**2025**
	in USD thousands	
CASH FLOWS - OPERATING ACTIVITIES		
Comprehensive income (loss) for the period	(696)	5,127
Adjustments required to reflect net cash used in operating activities (see appendix below)	(13,413)	(7,718)
Net cash used in operating activities	(14,109)	(2,591)
CASH FLOWS - INVESTING ACTIVITIES		
Investments in short-term deposits	-	(12,307)

Maturities of short-term deposits	16,719	4,130
Purchase of property and equipment	(32)	-
Net cash provided by (used in) investing activities	16,687	(8,177)
CASH FLOWS - FINANCING ACTIVITIES		
Issuance of share capital, pre-funded warrants and warrants, net of issuance costs	-	10,697
Repayments of loan	(765)	(1,120)
Repayments of lease liabilities	(129)	(127)
Net cash provided by (used in) financing activities	(894)	9,450
INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	1,684	(1,318)
CASH AND CASH EQUIVALENTS – BEGINNING OF PERIOD	4,255	10,436
EXCHANGE DIFFERENCES ON CASH AND CASH EQUIVALENTS	51	(82)
CASH AND CASH EQUIVALENTS - END OF PERIOD	5,990	9,036

BioLineRx Ltd.

APPENDIX TO CONDENSED CONSOLIDATED INTERIM CASH FLOW STATEMENTS

(UNAUDITED)

	Three months ended March 31,	
	2024	**2025**
	in USD thousands	
Adjustments required to reflect net cash used in operating activities:		
Income and expenses not involving cash flows:		
Depreciation and amortization	897	165
Exchange differences on cash and cash equivalents	(51)	82
Fair value adjustments of warrants	(4,444)	(8,311)
Warrant issuance costs	-	702
Share-based compensation	533	194
Interest on short-term deposits	(163)	(30)
Interest on loan	610	-
Exchange differences on lease liabilities	(25)	(7)
	(2,643)	(7,205)
Changes in operating asset and liability items:		
Decrease (increase) in trade receivables	(2,474)	1,007
Increase in inventory	(936)	(170)
Decrease in prepaid expenses and other receivables	81	1,157
Decrease in accounts payable and accruals	(3,511)	(2,507)
Decrease in contract liabilities	(3,930)	-
	(10,770)	(513)
	(13,413)	(7,718)
Supplemental information on interest received in cash	357	236
Supplemental information on interest paid in cash	255	361
Supplemental information on non-cash transactions:		
Changes in right-of-use asset and lease liabilities	32	44
Warrant issuance costs	-	237

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