BioLineRx Reports 2024 Financial Results and Provides Corporate Update

March 31, 2025 11:00 AM IDT

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

- Executed license agreement with Ayrmid Pharma Ltd. for APHEXDA® (motixafortide) with $10 million upfront payment, up to $87 million in commercial milestones, and high double-digit royalties on net sales -

- Completed financings raising combined gross proceeds of $19 million and reduced operating expense run rate by 70%, extending the Company's cash runway through H2 2026 -

- Management to host conference call today, March 31st, at 8:30 am EDT -

TEL AVIV, Israel, March 31, 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 audited financial results for the year ended December 31, 2024, and provided a corporate update.

"It has been just over four months since we implemented a major strategy shift, highlighted by the transformational exclusive licensing agreement that we entered into with Ayrmid Ltd., granting it the rights to commercialize APHEXDA® (motixafortide) in all non-solid-tumor indications and all territories other than Asia," said Philip Serlin, Chief Executive Officer of BioLineRx. "Since then, we implemented cost efficiencies across the Company, including the shutdown of our U.S. commercial operations, that have resulted in an approximate 70% reduction in our operating expense base, which, together with recent financings, have put us on a firm footing with a cash runway through the second half of 2026."

"As we return to our roots as a lean drug development company, with a highly validated development platform focused on oncology and rare diseases, we believe these actions help ensure that we remain nimble and capable of seizing the opportunities in front of us. Our strategy moving forward is to in-license additional assets over the next year that we can advance through clinical proof-of-concept, funded in part by milestones and royalties from our out-licensing transactions. To that end, I am pleased to report that we are evaluating numerous promising candidates. This process is methodical and steady to ensure that our due diligence is thorough as we look for new chemical entities. Based on our deep and validated experience in drug development, I believe we are well positioned to create sustained value for our shareholders. I am excited about what the future holds for our Company this year and beyond," Mr. Serlin concluded.

Corporate Updates

- Executed license agreement with Ayrmid Pharma Ltd. to develop and commercialize APHEXDA® (motixafortide) in all indications except solid tumors, and across all territories except Asia
  - License agreement included a $10 million upfront payment, up to $87 million in potential commercial milestones, and royalties on net sales ranging from 18% to 23%
- Announced receipt of a Notice of Allowance from the U.S. Patent & Trademark Office (USPTO) for a patent, titled "Composition of BL-8040," which strengthens BioLineRx's robust intellectual property (IP) estate and extends its patent protection on motixafortide (BL-8040) in the U.S. through December 2041

Financial Updates

- Completed two financings in past few months which raised combined gross proceeds of $19 million
- Reduced operating expense run rate by approximately 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 Q424, as well as additional headcount and other operating expense reductions

- Significantly reduced outstanding debt and restructured the remainder on favorable terms to the Company

APHEXDA 2024 Performance Update

- Aphexda achieved 10 percent market share of total CXCR4 inhibitor usage in the U.S., which compares APHEXDA to branded MOZOBIL and generic plerixafor in all indications
- BioLineRx generated more than $6 million in net product sales year-to-date through the November 2024 completion of the Ayrmid out-licensing transaction

Clinical Updates
Motixafortide
Pancreatic Ductal Adenocarcinoma (mPDAC)

- Additional trial sites activated for the CheMo4METPANC Phase 2b clinical trial being led by Columbia University. Full enrollment in the randomized trial targeting 108 patients is anticipated in 2027, with a prespecified interim futility analysis planned when 40% of PFS events are observed

Sickle Cell Disease (SCD) & Gene Therapy

- First patient dosed in 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.
- Oral presentation delivered at the 66th American Society of Hematology (ASH) Annual Meeting & Exposition detailing initial results from a Phase 1 clinical trial evaluating motixafortide as monotherapy and in combination with natalizumab for CD34+ hematopoietic stem cell (HSC) mobilization for gene therapies in SCD. Sponsored by investigators at Washington University in St. Louis, the findings from this proof-of-concept study suggest motixafortide alone, and in combination with natalizumab, could support the collection of the large number of stem cells required by gene therapies for sickle cell disease within a single apheresis cycle.

Financial Results for the Year Ended December 31, 2024

- Revenues for the year ended December 31, 2024 were $28.9 million, an increase of $24.1 million, or 502.1%, compared to $4.8 million for the year ended December 31, 2023. The revenues in 2024 primarily reflect a portion of the up-front payment received, and a milestone payment achieved, under the Gloria license, which collectively amounted to $15.0 million, as well as the up-front payment received under the Ayrmid license and $6.0 million of net revenues from product sales of APHEXDA in the U.S. The revenues in 2023 (all of which were recorded in the fourth quarter of 2023) primarily reflect a portion of the up-front payment received under the Gloria license of $4.6 million, as well as $0.2 million of revenues from product sales of APHEXDA in the U.S.
- Cost of revenues for the year ended December 31, 2024 were $9.3 million, an increase of $5.6, or 151.4%, compared to $3.7 million for the year ended December 31, 2023. The cost of revenues in 2024 primarily reflects amortization of intangible assets, Biokine's share of the up-front payment received under the Ayrmid license, sub-license fees accrued on a milestone payment recorded under the Gloria license, as well as royalties on net product sales of APHEXDA in the U.S. and cost of goods sold on product sales. The cost of revenues in 2023 primarily reflects Biokine's share of the up-front payment received under the Gloria license and of the net sales.

- Research and development expenses for the year ended December 31, 2024 were $9.2 million, a decrease of $3.3 million, or 26.4%, compared to $12.5 million for the year ended December 31, 2023. The decrease resulted primarily from lower expenses related to motixafortide NDA supporting activities, termination of the development of AGI-134 and a decrease in payroll and share-based compensation.
- Sales and marketing expenses for the year ended December 31, 2024 were $23.6 million, a decrease of $1.7 million, or 6.7%, compared to $25.3 million for the year ended December 31, 2023. The decrease resulted primarily from the shutdown of U.S. commercial operations in the fourth quarter of 2024 following the Ayrmid license.
- General and administrative expenses for the year ended December 31, 2024 were $6.3 million, similar to the year ended December 31, 2023.
- Net non-operating income amounted to $18.4 million for the year ended December 31, 2024, compared to net non-operating expenses of $10.8 million for the year ended December 31, 2023. Non-operating income for the year ended December 31, 2024 primarily relates to non-cash, fair-value adjustments of warrant liabilities on the Company's balance sheet, as a result of changes in the Company's share price, offset by warrant offering expenses. Non-operating expenses for the year ended December 31, 2023 primarily relate to non-cash, fair-value adjustments of warrant liabilities on the Company's balance sheet.
- Net financial expenses amounted to $7.3 million for the year ended December 31, 2024, compared to net financial expenses of $0.1 million for the year ended December 31, 2023. Net financial expenses for both periods primarily relate to interest paid on loans, which increased in 2024 due to a one-time $4.0 million charge to interest expense in connection with the November 2024 amendment to the loan agreement with BlackRock, partially offset by investment income earned on bank deposits.
- Net loss for the year ended December 31, 2024 was $9.2 million, compared to $60.6 million for the year ended December 31, 2023.
- As of December 31, 2024, the Company had cash, cash equivalents, and short-term bank deposits of $19.6 million (approximately $29.0 million on a pro-forma basis, following the financing completed at the beginning of January 2025).

A copy of the Company's annual report on Form 20-F for the year ended December 31, 2024 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

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 April 2, 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, manufacturing and commercialization 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.

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BioLineRx Ltd.

CONSOLIDATED STATEMENTS OF FINANCIAL POSITION

	December 31,	
	2023	2024
	in USD thousands	
Assets		
CURRENT ASSETS		
Cash and cash equivalents	4,255	10,436
Short-term bank deposits	38,739	9,126
Trade receivables	358	2,476
Prepaid expenses	1,048	443
Other receivables	830	1,478
Inventory	1,953	3,145
Total current assets	47,183	27,104
NON-CURRENT ASSETS		
Property and equipment, net	473	386
Right-of-use assets, net	1,415	967
Intangible assets, net	14,854	10,449
Total non-current assets	16,742	11,802
Total assets	63,925	38,906
Liabilities and equity		
CURRENT LIABILITIES		
Current maturities of long-term loan	3,145	4,479
Contract liabilities	12,957	-
Accounts payable and accruals:		
Trade	10,869	5,583
Other	3,353	3,131
Current maturities of lease liabilities	528	522
Warrants	11,932	1,691
Total current liabilities	42,784	15,406
NON-CURRENT LIABILITIES		

Long-term loan, net of current maturities	6,628	8,958
Lease liabilities	1,290	1,081
Total non-current liabilities	7,918	10,039
COMMITMENTS AND CONTINGENT LIABILITIES		
Total liabilities	50,702	25,445
EQUITY		
Ordinary shares	31,355	38,097
Share premium	355,482	353,693
Warrants	1,408	5,367
Capital reserve	17,000	17,547
Other comprehensive loss	(1,416)	(1,416)
Accumulated deficit	(390,606)	(399,827)
Total equity	13,223	13,461
Total liabilities and equity	63,925	38,906

BioLineRx Ltd.

CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

	Year ended December 31,		
	2022	**2023**	**2024**
	in USD thousands		
REVENUES:			
License revenues	-	4,610	22,917
Product sales, net	-	190	6,023
Total revenues	-	4,800	28,940
COST OF REVENUES	-	(3,692)	(9,263)
GROSS PROFIT	-	1,108	19,677
RESEARCH AND DEVELOPMENT EXPENSES	(17,629)	(12,519)	(9,149)
SALES AND MARKETING EXPENSES	(6,462)	(25,270)	(23,605)
GENERAL AND ADMINISTRATIVE EXPENSES	(5,066)	(6,310)	(6,321)
IMPAIRMENT OF INTANGIBLE ASSETS	-	(6,703)	(1,010)
OPERATING LOSS	(29,157)	(49,694)	(20,408)
NON-OPERATING INCOME (EXPENSES), NET	5,670	(10,819)	18,435
FINANCIAL INCOME	694	2,068	1,871
FINANCIAL EXPENSES	(2,158)	(2,169)	(9,119)
LOSS AND COMPREHENSIVE LOSS	(24,951)	(60,614)	(9,221)
	in USD		
LOSS PER ORDINARY SHARE – BASIC AND DILUTED	(0.03)	(0.06)	(0.01)
WEIGHTED AVERAGE NUMBER OF SHARES USED IN CALCULATION OF LOSS PER ORDINARY SHARE	773,956,973	963,365,525	1,198,107,761

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, 2022	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
CHANGES IN 2023:							
Issuance of share capital, net	3,242	10,847	-	-	-	-	14,089
Warrants exercised	1,000	5,559	-	-	-	-	6,559
Employee stock options exercised	13	45	-	(31)	-	-	27
Employee stock options expired	-	55	-	(55)	-	-	-
Share-based compensation	-	-	-	2,321	-	-	2,321
Comprehensive loss for the year	-	-	-	-	-	(60,614)	(60,614)
BALANCE AT DECEMBER 31, 2023	31,355	355,482	1,408	17,000	(1,416)	(390,606)	13,223
CHANGES IN 2024:							
Issuance of share capital and warrants, net	4,712	(3,060)	6,650	-	-	-	8,302
Pre-funded warrants exercised	2,009	682	(2,691)	-	-	-	-
Employee stock options exercised	21	50	-	(49)	-	-	22
Employee stock options expired	-	539	-	(539)	-	-	-
Share-based compensation	-	-	-	1,135	-	-	1,135
Comprehensive loss for the year	-	-	-	-	-	(9,221)	(9,221)
BALANCE AT DECEMBER 31, 2024	38,097	353,693	5,367	17,547	(1,416)	(399,827)	13,461

BioLineRx Ltd.

CONSOLIDATED STATEMENTS OF CASH FLOWS

	Year ended December 31,		
	2022	**2023**	**2024**
	in USD thousands		
CASH FLOWS - OPERATING ACTIVITIES			
Loss	(24,951)	(60,614)	(9,221)
Adjustments required to reflect net cash used in operating activities (see appendix below)	(1,289)	38,006	(34,652)
Net cash used in operating activities	(26,240)	(22,608)	(43,873)
CASH FLOWS - INVESTING ACTIVITIES			
Investments in short-term deposits	(44,000)	(47,588)	(26,350)
Maturities of short-term deposits	48,322	49,329	55,778
Purchase of property and equipment	(131)	(116)	(53)
Purchase of intangible assets	(185)	(181)	(1)
Net cash provided by investing activities	4,006	1,444	29,374
CASH FLOWS - FINANCING ACTIVITIES			
Issuance of share capital and warrants, net of issuance costs	14,359	14,089	16,357
Exercise of warrants	-	2,928	-
Employee stock options exercised	5	27	22
Proceeds from long-term loan, net of issuance costs	9,126	-	19,223
Repayments of loan	(2,832)	(1,543)	(14,433)
Repayments of lease liabilities	(220)	(445)	(511)
Net cash provided by financing activities	20,438	15,056	20,658
INCREASE)DECREASE(IN CASH AND CASH EQUIVALENTS	(1,796)	(6,108)	6,159
CASH AND CASH EQUIVALENTS - BEGINNING OF YEAR	12,990	10,587	4,255
EXCHANGE DIFFERENCES ON CASH AND CASH EQUIVALENTS	(607)	(224)	22
CASH AND CASH EQUIVALENTS - END OF YEAR	10,587	4,255	10,436

CONSOLIDATED STATEMENTS OF CASH FLOWS

	Year ended December 31,		
	2022	2023	2024
	in USD thousands		
APPENDIX			
Adjustments required to reflect net cash used in operating activities:			
Income and expenses not involving cash flows:			
Depreciation and amortization	654	1,384	4,065
Exchange differences on cash and cash equivalents	607	224	(22)
Fair value adjustments of warrants	(6,425)	11,054	(18,965)
Share-based compensation	2,245	2,321	1,135
Interest and exchange differences on short-term deposits	(672)	15	185
Interest on loan	1,117	1,148	(1,126)
Warrant issuance costs	171	-	669
Exchange differences on lease liabilities	(224)	(42)	(31)
Intangible assets impairment	-	6,703	1,010
Loss on abandonment of right-of-use asset	-	-	246
	(2,527)	22,807	(12,834)
Changes in operating asset and liability items:			
Increase in trade receivables	-	(358)	(2,118)
Increase in inventory	-	(1,953)	(1,192)
Increase in prepaid expenses and other receivables	(650)	(959)	(43)
Increase (decrease) in accounts payable and accruals	1,888	5,512	(5,508)
Increase (decrease) in contract liabilities	-	12,957	(12,957)
	1,238	15,199	(21,818)
	(1,289)	38,006	(34,652)
Supplemental information on interest received in cash	342	2,020	1,992
Supplemental information on interest paid in cash	593	1,111	10,387
Supplemental information on non-cash transactions:			
Changes in right-of-use asset and lease liabilities	706	149	327
Warrant issuance costs	262	-	-
Purchase of property and equipment	28	-	-
Fair value of exercised warrants (portion related to accumulated fair value adjustments)	-	3,631	-

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