BioLineRx Reports Third Quarter 2024 Financial Results and Provides Update on Transformation to Drive Shareholder Value

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- Executed license agreement with Ayrmid Ltd. for APHEXDA® (motixafortide) for $10 million upfront, up to $87 million in commercial milestones, and 18-23% tiered royalties on sales -

- Received $9 million equity investment from certain funds managed by Highbridge Capital Management, LLC -

- Entered into agreement to reduce and restructure long-term debt by ~$16.5 million -

- Annual operational expenses expected to decline by over 70% following out-license of APHEXDA® (motixafortide) commercial program to Ayrmid -

- Company to continue to support motixafortide PDAC program while evaluating additional assets for development in rare diseases and oncology -

- Management to host conference call today, November 25, at 8:30 am EDT -

TEL AVIV, Israel, Nov. 25, 2024 /PRNewswire/ -- BioLineRx Ltd. (NASDAQ/TASE: BLRX), a development 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, 2024, and provided updates on strategic actions designed to drive shareholder value.

"The license agreement for APHEXDA that we announced last week was made possible by the tremendous work of our commercial team, who through their hard work proved the significant value that APHEXDA can bring to transplant centers and patients," said Philip Serlin, Chief Executive Officer of BioLineRx. "Our launch progress attracted Ayrmid, who will now, through Gamida Cell, continue to build on the strong commercial foundation that has been laid. We would like to thank our employees for their outstanding contributions to APHEXDA growth and expect this innovative product to reach even more patients with the additional resources from Ayrmid.

"Looking forward, our streamlined and nimble company has a new financial foundation supported by sales royalties and potential milestone payments, which will allow our experienced team to develop important new therapies in rare disease and oncology that address areas with high unmet need. We will also focus on advancing our motixafortide PDAC program through existing collaborations that require de-minimis investment. Through this strategy, we anticipate delivering near- and long-term value for our shareholders," Mr. Serlin concluded.

Corporate Updates

- Executed license agreement with Ayrmid 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%
  - BioLineRx will supply motixafortide on a cost-plus basis, for both commercial and development supply
  - Certain members of the BioLineRx U.S.-based commercial organization will be transitioned to Ayrmid Pharma Ltd.
- Received $9 million equity investment from certain funds managed by Highbridge Capital Management, LLC, to support BioLineRx's pipeline expansion
- Operating expense run-rate expected to decrease by more than 70% beginning January 1, 2025 through APHEXDA commercial program transfer and additional headcount reductions
- Company intends to evaluate additional asset opportunities in 2025, with a focus on early-stage clinical programs in oncology or rare diseases that address major areas of unmet need

Financial Updates

- Executed repayment and restructuring agreement with BlackRock EMEA Venture and Growth Lending to repay $16.5 million of approximately $29 million in total debt due; remaining balance will be paid over the next three years at the existing fixed annual interest rate of 9.5 percent
- As of September 30, 2024, the Company had cash, cash equivalents, and short-term bank deposits of $29.2 million
- Following the out-license to Ayrmid, the equity investment from Highbridge and the debt repayment to Blackrock, the Company's cash, cash equivalents and short-term bank deposits are expected to be approximately $20 million, which management believes will be sufficient to fund operations into 2026, as currently planned

APHEXDA Launch Updates

- Aphexda achieved 10 percent market share milestone of total CXCR4 inhibitor usage in the U.S., which compares APHEXDA to branded MOZOBIL and generic plerixafor in all indications
- Institutions ordering APHEXDA increased by 40 percent in the third quarter

Clinical Portfolio Updates
Motixafortide

Pancreatic Ductal Adenocarcinoma (mPDAC)

- Continued enrollment in the CheMo4METPANC Phase 2b clinical trial collaboration with Columbia University. In addition to Columbia, patient enrollment has begun at Brown University, and three additional sites are anticipated to begin enrollment over the next two quarters. 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

Multiple Myeloma

- 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 1H 2025
- Gloria Biosciences has received regulatory approval to commercialize APHEXDA in the Boao Region of China and Macao, areas in Asia that do not require a bridging study

Sickle Cell Disease (SCD) & Gene Therapy

- Announced oral presentation at ASH 2024 on 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 sickle cell disease (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. The presentation will occur at the 66th American Society of Hematology (ASH) Annual Meeting & Exposition taking place December 7-10, 2024, in San Diego, California

Third Quarter 2024 Financial Results

- Total revenue for the three months ended September 30, 2024 was $4.9 million. The Company did not record any revenue during the third quarter of 2023. Revenue for the quarter reflects a portion of the upfront payment from the Gloria Biosciences license, which amounted to $3.2

million, as well as $1.7 million of net revenue from product sales of APHEXDA in the U.S.

- Cost of revenue for the three months ended September 30, 2024 was $0.8 million. The Company did not record any cost of revenue during the third 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 September 30, 2024 were $2.6 million, compared to $2.7 million for the same period in 2023. The decrease resulted primarily from lower expenses related to the termination of the development of AGI-134 and a decrease in payroll and share-based compensation
- Sales and marketing expenses for the three months ended September 30, 2024 were $5.5 million, compared to $8.1 million for the same period in 2023. The decrease resulted primarily from lower expenses of commercialization activities related to motixafortide. The higher expenses in the corresponding period of 2023 reflect the ramp-up of pre-commercialization activities related to motixafortide
- General and administrative expenses for the three months ended September 30, 2024 were $1.4 million, compared to $1.5 million for the same period in 2023. The decrease resulted primarily from small decreases in a number of G&A expenses
- Net loss for the three months ended September 30, 2024 was $5.8 million, compared to net loss of $16.0 million for the same period in 2023. The net loss for the 2024 period included $0.8 million in non-operating income, compared to non-operating expenses of $3.1 million for the same period in 2023, both primarily related to non-cash revaluation of warrants
- As of September 30, 2024, the Company had cash, cash equivalents, and short-term bank deposits of $29.2 million.

Third Quarter Results Conference Call and Webcast
BioLineRx will report its third quarter 2024 results on November 25, 2024. 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 27, 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 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.

Cautionary Note Regarding Forward-Looking Statements (BioLineRx)
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, expectations with regard to clinical trials of motixafortide, statements relating to the equity investment offering, including as to the consummation of the offering described above, the expected gross proceeds therefrom and the timing of the closings of the offering and the license agreement. 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.

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

	December 31, 2023	September 30, 2024
	in USD thousands	
Assets		
CURRENT ASSETS		
Cash and cash equivalents	4,255	8,836
Short-term bank deposits	38,739	20,337
Trade receivables	358	3,611
Prepaid expenses	1,048	1,171
Other receivables	830	350
Inventory	1,953	3,544
Total current assets	47,183	37,849
NON-CURRENT ASSETS		
Property and equipment, net	473	249
Right-of-use assets, net	1,415	1,398
Intangible assets, net	14,854	13,246
Total non-current assets	16,742	14,893
Total assets	63,925	52,742
Liabilities and equity		
CURRENT LIABILITIES		
Current maturities of long-term loan	3,145	9,822
Contract liabilities	12,957	2,255
Accounts payable and accruals:		
Trade	10,869	4,633
Other	3,353	3,370
Current maturities of lease liabilities	528	517
Warrants	11,932	4,365
Total current liabilities	42,784	24,962
NON-CURRENT LIABILITIES		
Long-term loan, net of current maturities	6,628	17,982
Lease liabilities	1,290	1,293
Total non-current liabilities	7,918	19,275
CONTINGENT LIABILITIES		
Total liabilities	50,702	44,237
EQUITY		
Ordinary shares	31,355	34,430
Share premium	355,482	353,005
Warrants	1,408	1,408
Capital reserve	17,000	17,718
Other comprehensive loss	(1,416)	(1,416)
Accumulated deficit	(390,606)	(396,640)
Total equity	13,223	8,505

Total liabilities and equity	63,925	52,742

BioLineRx Ltd.
CONDENSED CONSOLIDATED INTERIM STATEMENTS OF COMPREHENSIVE LOSS
(UNAUDITED)

	Three months ended September 30,		Nine months ended September 30,	
	2023	**2024**	**2023**	**2024**
	in USD thousands		**in USD thousands**	
REVENUES	-	4,943	-	17,191
COST OF REVENUES	-	(822)	-	(3,174)
GROSS PROFIT	-	4,121	-	14,017
RESEARCH AND DEVELOPMENT EXPENSES	(2,727)	(2,565)	(9,417)	(7,284)
SALES AND MARKETING EXPENSES	(8,131)	(5,553)	(17,609)	(18,310)
GENERAL AND ADMINISTRATIVE EXPENSES	(1,499)	(1,390)	(4,102)	(4,405)
OPERATING LOSS	(12,357)	(5,387)	(31,128)	(15,982)
NON-OPERATING INCOME (EXPENSES), NET	(3,141)	756	(13,790)	13,053
FINANCIAL INCOME	312	434	1,289	1,534
FINANCIAL EXPENSES	(837)	(1,625)	(3,101)	(4,639)
NET LOSS AND COMPREHENSIVE LOSS	(16,023)	(5,822)	(46,730)	(6,034)
	in USD		**in USD**	
LOSS PER ORDINARY SHARE - BASIC AND DILUTED	(0.02)	(0.00)	(0.05)	(0.01)
WEIGHTED AVERAGE NUMBER OF SHARES USED IN CALCULATION OF LOSS PER ORDINARY SHARE	929,058,619	1,199,485,845	925,014,511	1,161,448,634

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 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

	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 NINE MONTHS ENDED SEPTEMBER 30, 2024:							
Issuance of share capital and warrants, net	3,056	(3,056)	-	-	-	-	-
Employee stock options exercised	19	56	-	(48)	-	-	27
Employee stock options expired	-	523	-	(523)	-	-	-
Employee stock options forfeiture	-	-	-	(88)	-	-	(88)
Share-based compensation	-	-	-	1,377	-	-	1,377
Comprehensive loss for the period	-	-	-	-	-	(6,034)	(6,034)
BALANCE AT SEPTEMBER 30, 2024	34,430	353,005	1,408	17,718	(1,416)	(396,640)	8,505

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

	Nine months ended September 30,	
	2023	2024
	in USD thousands	
CASH FLOWS - OPERATING ACTIVITIES		
Net loss for the period	(46,730)	(6,034)
Adjustments required to reflect net cash used in operating activities (see appendix below)	19,131	(29,229)
Net cash used in operating activities	(27,599)	(35,263)
CASH FLOWS – INVESTING ACTIVITIES		
Investments in short-term deposits	(13,882)	(26,350)
Maturities of short-term deposits	36,000	44,626
Purchase of property and equipment	(100)	(59)
Purchase of intangible assets	(179)	-
Net cash provided by investing activities	21,839	18,217
CASH FLOWS – FINANCING ACTIVITIES		
Issuance of share capital and warrants, net of issuance costs	1,896	5,358
Exercise of warrants	2,530	-
Employee stock options exercised	15	27
Net proceeds from loan	-	19,223
Repayments of loan	(802)	(2,461)
Repayments of lease liabilities	(323)	(380)
Net cash provided by financing activities	3,316	21,767
INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	(2,444)	4,721
CASH AND CASH EQUIVALENTS - BEGINNING OF PERIOD	10,587	4,255
EXCHANGE DIFFERENCES ON CASH AND CASH EQUIVALENTS	(416)	(140)
CASH AND CASH EQUIVALENTS - END OF PERIOD	7,727	8,836

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

	Nine months ended September 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	678	2,213
Exchange differences on cash and cash equivalents	416	140
Fair value adjustments of warrants	13,968	(13,567)
Share-based compensation	1,392	1,289
Interest on short-term deposits	136	126
Interest on loan	2,170	1,269
Exchange differences on lease liability	(122)	67
Issuance cost of warrants	-	642
	18,638	(7,821)
Changes in operating asset and liability items:		
Increase in trade receivables	-	(3,253)
Decrease (increase) in prepaid expenses and other receivables	(566)	357

Increase in inventory	(1,352)	(1,591)
Increase (decrease) in accounts payable and accruals	2,411	(6,219)
Decrease in contract liabilities	-	(10,702)
	493	(21,408)
	19,131	(29,229)
Supplemental information on interest received in cash	1,268	1,644
Supplemental information on interest paid in cash	833	1,586
Supplemental information on non-cash transactions:		
Changes in right-of-use asset and lease liabilities	66	305

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