



FOR IMMEDIATE RELEASE

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

- Steady growth in APHEXDA® adoption in first full quarter post-approval -

- Among top 80 transplant centers, secured APHEXDA formulary placement to date at institutions representing ~26% of stem cell transplant procedures performed - on track to reach stated goal of ~35% by end of Q2 -

- Announced new data in abstract accepted at the American Society of Clinical Oncology (ASCO) 2024 Annual Meeting on pilot phase of ongoing Phase 2b pancreatic cancer clinical trial collaboration with Columbia University -

- Collaboration partner Gloria Biosciences' motixafortide HSC mobilization bridging study IND was filed and approved by the Center for Drug Evaluation of the National Medical Products Administration in China. Anticipate clinical trial initiation 2H 2024 -

- Completed debt and equity financing totaling \$26 million to support U.S. commercialization of APHEXDA and advance lifecycle expansion activities -

- Management to host conference call today, May 28, at 8:30 am EDT -

TEL AVIV, Israel, May 28, 2024 – BioLineRx Ltd. (NASDAQ/TASE: BLRX), a commercial stage biopharmaceutical company pursuing life-changing therapies in oncology and rare diseases, today reported its unaudited financial results for the first quarter ended March 31, 2024, and provided recent corporate and portfolio updates.

“In this first full quarter post APHEXDA® approval, we were pleased by the steady growth in adoption and repeat purchases by transplant centers, which is consistent with our expectations during this foundational period,” said Philip Serlin, Chief Executive Officer of BioLineRx. “This growth comes as we see continued increases in the number of transplant centers that have completed Pharmacy & Therapeutics committee reviews and granted approval for APHEXDA usage. As a reminder, end users of APHEXDA are well defined, with 80 of the 212 U.S. transplant centers performing approximately 85% of all transplant procedures. Importantly, among these top 80 transplant centers, we’ve secured formulary placement to date at institutions representing ~26% of stem cell transplant procedures performed, keeping us on track to reach our stated goal of 35% by the end of Q2.

“In our major pipeline program in pancreatic cancer, we continue to see strong data emerge from the pilot phase of the Phase 2 PDAC trial sponsored by Columbia University. Last week we announced new data in an accepted ASCO abstract on paired pre- and on-treatment biopsy data that show a significant increase in CD8+ T-cell density in tumors from all 11 patients treated—further reinforcing our belief in the potential of the combination of motixafortide with a PD-1 inhibitor to treat this very challenging cancer with substantial unmet need.

“Finally, we are also making great progress pursuing motixafortide’s potential to support gene therapy for patients with sickle cell disease, which requires significant quantities of hematopoietic stem cells. This is an important growth program, and we are actively working with a number of leaders in the gene therapy field, while looking forward to the second half of this year when early data from our collaboration with Washington University in St. Louis is expected.”

Corporate Updates

- Accessed \$20 million in non-dilutive debt financing from previously announced agreement with BlackRock EMEA Venture and Growth Lending (previously Kreos Capital) and completed a \$6 million registered direct equity offering. Funds will be used to support ongoing commercialization of APHEXDA in the U.S. and to advance lifecycle expansion activities
- Strengthened motixafortide intellectual property estate with notice of allowance for U.S. patent covering method of manufacturing motixafortide suitable for large scale production; the patent supplements existing protections offered by Orphan Drug Designation in the U.S. and Europe for the treatment of pancreatic cancer, as well as Orphan Drug market exclusivity for autologous stem cell mobilization in multiple myeloma patients in the U.S. following last year’s FDA approval of APHEXDA

APHEXDA Launch Updates

- Among top 80 transplant centers, secured formulary placement to date at institutions representing ~26% of stem cell transplant procedures performed – on track to reach stated goal of ~35% by end of Q2 and ~60% by year-end 2024
- Granted “pass through” status from the Centers for Medicare and Medicaid Services (CMS), ensuring that reimbursement for APHEXDA for Medicare and certain commercial payers will be separate from payment bundling methodologies when administered in the hospital outpatient setting

Clinical Portfolio Updates

Motixafortide (selective inhibitor of CXCR4 chemokine receptor)

Multiple Myeloma

- Presented posters at both the American Society for Apheresis 2024 Annual Meeting on April 17, 2024, and the International Society for Pharmacoeconomics and Outcomes Research on April 6, 2024. The posters reviewed apheresis center efficiency between CXCR4 antagonists, including APHEXDA, in patients with multiple myeloma, as well as economic model data on APHEXDA for HSC mobilization in patients with multiple myeloma
- Collaboration partner Gloria Biosciences’ stem cell mobilization bridging study IND 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

Pancreatic Ductal Adenocarcinoma (mPDAC)

- Announced new data in an abstract accepted at the American Society of Clinical Oncology (ASCO) 2024 Annual Meeting on the pilot phase of the ongoing CheMo4METPANC Phase 2 clinical trial collaboration with Columbia University, including new analysis of paired pre- and on-treatment biopsy samples. The presentation will be held on June 1, 2024 in Chicago, IL
- Announced first patient dosed in the randomized CheMo4METPANC Phase 2 clinical trial, an expansion of the pilot phase single-arm study, evaluating motixafortide in combination with the PD-1 inhibitor cemiplimab and standard-of-care chemotherapy as first-line treatment in 108 patients with metastatic pancreatic cancer
- Advanced plans with collaboration partner Gloria Biosciences on a Phase 2b randomized clinical trial in China assessing 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

Sickle Cell Disease (SCD) & Gene Therapy

- Continued to enroll patients into a clinical trial in collaboration with Washington University School of Medicine in St. Louis to evaluate motixafortide as monotherapy and in combination with natalizumab for stem cell mobilization for gene therapies in sickle cell disease. Anticipate initial data in 2H 2024

First Quarter 2024 Financial Results

- Total revenue for the first three months ended March 31, 2024 was \$6.9 million. The Company did not record any revenue during the first quarter of 2023. Revenue for the quarter reflect a portion of the upfront payment from the Gloria Biosciences license agreement and a milestone payment achieved under the same license agreement, which collectively amounted to \$5.9 million, as well as \$0.9 million of net revenue from product sales of APHEXDA in the U.S.
- Cost of revenue for the first three months ended March 31, 2024 was \$1.5 million. The Company did not record any cost of revenue during the first quarter of 2023. The cost of revenue for the quarter primarily reflects sub-license fees on a milestone payment received under the Gloria Biosciences 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 first three months ended March 31, 2024 were \$2.5 million, compared to \$3.7 million for the same period in 2023. The decrease resulted primarily from lower expenses related to motixafortide New Drug Application (NDA) supporting activities, as well as termination of the development of AGI-134
- Sales and marketing expenses for the first three months ended March 31, 2024 were \$6.3 million, compared to \$3.9 million for the same period in 2023. The increase resulted

primarily from the ramp-up of commercialization activities related to motixafortide, including headcount costs associated with fully hired field team

- General and administrative expenses for the first three months ended March 31, 2024 were \$1.4 million, compared to \$1.3 million for the same period in 2023. The increase resulted primarily from a small increase in share-based compensation
- Non-operating income for the first three months ended March 31, 2024 was \$4.5 million, compared to non-operating expenses of \$2.9 million for the same period in 2023. Non-operating expenses and income primarily relate to the non-cash revaluation of outstanding warrants resulting from changes in the Company's share price during the respective periods
- Net loss for the first three months ended March 31, 2024 was \$0.7 million, compared to \$12.2 million for the same period in 2023. The net loss for the 2024 period included \$4.5 million in non-cash income, compared to non-operating expenses of \$2.9 million for the same period in 2023, both specifically related to the revaluation of warrants
- As of March 31, 2024, the Company had cash, cash equivalents, and short-term bank deposits of \$28.2 million. This amount does not include \$6.0 million in gross proceeds received from a registered direct offering and a \$20.0 million drawdown of the second tranche from the existing loan agreement with BlackRock, which were both completed in April 2024. 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 May 30, 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.

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BioLineRx Ltd.

CONDENSED CONSOLIDATED INTERIM STATEMENTS OF FINANCIAL POSITION

(UNAUDITED)

	December 31,	March 31,
	2023	2024
	in USD thousands	
Assets		
CURRENT ASSETS		
Cash and cash equivalents	4,255	5,990
Short-term bank deposits	38,739	22,183
Trade receivables	358	2,832
Prepaid expenses	1,048	1,290
Other receivables	830	507
Inventory	1,953	2,889
Total current assets	47,183	35,691
NON-CURRENT ASSETS		
Property and equipment, net	473	411
Right-of-use assets, net	1,415	1,308
Intangible assets, net	14,854	14,190
Total non-current assets	16,742	15,909
Total assets	63,925	51,600
Liabilities and equity		
CURRENT LIABILITIES		
Current maturities of long-term loan	3,145	3,680
Contract liabilities	12,957	9,027
Accounts payable and accruals:		
Trade	10,869	8,256
Other	3,353	2,455
Current maturities of lease liabilities	528	467
Warrants	11,932	7,488
Total current liabilities	42,784	31,373
NON-CURRENT LIABILITIES		
Long-term loan, net of current maturities	6,628	5,938
Lease liabilities	1,290	1,229
Total non-current liabilities	7,918	7,167
COMMITMENTS AND CONTINGENT LIABILITIES		
Total liabilities	50,702	38,540
EQUITY		
Ordinary shares	31,355	31,355
Share premium	355,482	355,482
Warrants	1,408	1,408
Capital reserve	17,000	17,533
Other comprehensive loss	(1,416)	(1,416)
Accumulated deficit	(390,606)	(391,302)
Total equity	13,223	13,060
Total liabilities and equity	63,925	51,600

BioLineRx Ltd.

CONDENSED CONSOLIDATED INTERIM STATEMENTS OF COMPREHENSIVE LOSS

(UNAUDITED)

	Three months ended March 31,	
	2023	2024
	in USD thousands	
REVENUES	-	6,855
COST OF REVENUES	-	(1,455)
GROSS PROFIT	-	5,400
RESEARCH AND DEVELOPMENT EXPENSES	(3,684)	(2,494)
SALES AND MARKETING EXPENSES	(3,874)	(6,342)
GENERAL AND ADMINISTRATIVE EXPENSES	(1,298)	(1,386)
OPERATING LOSS	(8,856)	(4,822)
NON-OPERATING INCOME (EXPENSES), NET	(2,916)	4,490
FINANCIAL INCOME	537	565
FINANCIAL EXPENSES	(927)	(929)
NET LOSS AND COMPREHENSIVE LOSS	<u>(12,162)</u>	<u>(696)</u>
	in USD	
LOSS PER ORDINARY SHARE - BASIC AND DILUTED	<u>(0.01)</u>	<u>(0.00)</u>
WEIGHTED AVERAGE NUMBER OF SHARES USED IN CALCULATION OF LOSS PER ORDINARY SHARE	<u>922,958,942</u>	<u>1,086,589,165</u>

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CONDENSED CONSOLIDATED 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 THREE MONTHS ENDED MARCH 31, 2023:							
Employee stock options expired	-	66	-	(66)	-	-	-
Share-based compensation	-	-	-	435	-	-	435
Comprehensive loss for the period	-	-	-	-	-	(12,162)	(12,162)
BALANCE AT MARCH 31, 2023	<u>27,100</u>	<u>339,042</u>	<u>1,408</u>	<u>15,134</u>	<u>(1,416)</u>	<u>(342,154)</u>	<u>39,114</u>
	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 THREE MONTHS ENDED MARCH 31, 2024:							
Share-based compensation	-	-	-	533	-	-	533
Comprehensive loss for the period	-	-	-	-	-	(696)	(696)
BALANCE AT MARCH 31, 2024	<u>31,355</u>	<u>355,482</u>	<u>1,408</u>	<u>17,533</u>	<u>(1,416)</u>	<u>(391,302)</u>	<u>13,060</u>

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CONDENSED CONSOLIDATED INTERIM CASH FLOW STATEMENTS

(UNAUDITED)

	Three months ended March 31,	
	2023	2024
	in USD thousands	
CASH FLOWS - OPERATING ACTIVITIES		
Comprehensive loss for the period	(12,162)	(696)
Adjustments required to reflect net cash used in operating activities (see appendix below)	4,146	(13,413)
Net cash used in operating activities	<u>(8,016)</u>	<u>(14,109)</u>
CASH FLOWS - INVESTING ACTIVITIES		
Investments in short-term deposits	(5,500)	-
Maturities of short-term deposits	12,271	16,719
Purchase of property and equipment	(32)	(32)
Purchase of intangible assets	(97)	-
Net cash provided by investing activities	<u>6,642</u>	<u>16,687</u>
CASH FLOWS - FINANCING ACTIVITIES		
Repayments of loan	-	(765)
Repayments of lease liabilities	(49)	(129)
Net cash used in financing activities	<u>(49)</u>	<u>(894)</u>
INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	(1,423)	1,684
CASH AND CASH EQUIVALENTS – BEGINNING OF PERIOD	10,587	4,255
EXCHANGE DIFFERENCES ON CASH AND CASH EQUIVALENTS	(98)	51
CASH AND CASH EQUIVALENTS - END OF PERIOD	<u>9,066</u>	<u>5,990</u>

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APPENDIX TO CONDENSED CONSOLIDATED INTERIM CASH FLOW STATEMENTS (UNAUDITED)

	Three months ended	
	March 31,	
	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	259	897
Exchange differences on cash and cash equivalents	98	(51)
Fair value adjustments of warrants	3,040	(4,444)
Share-based compensation	435	533
Interest on short-term deposits	(497)	(163)
Interest on loan	630	610
Exchange differences on lease liabilities	(92)	(25)
	<u>3,873</u>	<u>(2,643)</u>
Changes in operating asset and liability items:		
Increase in trade receivables	-	(2,474)
Increase in inventory	-	(936)
Decrease (increase) in prepaid expenses and other receivables	(121)	81
Increase (decrease) in accounts payable and accruals	394	(3,511)
Decrease in contract liabilities	-	(3,930)
	<u>273</u>	<u>(10,770)</u>
	<u>4,146</u>	<u>(13,413)</u>
 Supplemental information on interest received in cash	 <u>276</u>	 <u>357</u>
Supplemental information on interest paid in cash	<u>311</u>	<u>255</u>
Changes in right-of-use asset and lease liabilities	<u>66</u>	<u>32</u>