
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 6-K

**REPORT OF FOREIGN PRIVATE ISSUER
PURSUANT TO RULE 13a-16 OR 15d-16 OF
THE SECURITIES EXCHANGE ACT OF 1934**

For the month of March 2024

Commission file number: 001-35223

BioLineRx Ltd.

(Translation of registrant's name into English)

2 HaMa'ayan Street

Modi'in 7177871, Israel

(Address of Principal Executive Offices)

Indicate by check mark whether the registrant files or will file annual reports under cover of Form 20-F or Form 40-F:

Form 20-F

Form 40-F

On March 26, 2024, the registrant issued the press release which is filed as [Exhibit 1](#) to this Report on Form 6-K.

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

BioLineRx Ltd.

By: /s/ Philip A. Serlin

Philip A. Serlin
Chief Executive Officer

Dated: March 26, 2024



FOR IMMEDIATE RELEASE

BioLineRx Reports 2023 Financial Results and Recent Corporate and Portfolio Updates

- *Reported significant commercial progress for APHEXDA® -- secured payer coverage representing ~95% of covered lives in the U.S.; continued progress on formulary approvals at targeted major transplant centers; received Healthcare Common Procedure Coding System (HCPCS) J-Code to facilitate Medicare reimbursement -*
- *Announced first patient dosed in randomized Phase 2b clinical trial evaluating motixafortide in first-line pancreatic cancer -*
- *Continued to support partner Gloria Biosciences in plans to execute pivotal bridging study of motixafortide in stem cell mobilization and Phase 2b randomized study in first-line pancreatic cancer in China -*
- *Management to host conference call today, March 26, at 8:30 am EDT -*

TEL AVIV, Israel, March 26, 2024 – BioLineRx Ltd. (NASDAQ/TASE: BLRX), a commercial stage biopharmaceutical company pursuing life-changing therapies in oncology and rare diseases, today reported its financial results for the year ended December 31, 2023, and provided recent corporate and portfolio updates.

“Following FDA approval of APHEXDA® in September, physicians and transplant centers have been very receptive to the value of our strong clinical data, and our commercial team has made substantial progress establishing relationships with transplant centers across the country,” said Philip Serlin, Chief Executive Officer of BioLineRx. “This year will continue to be primarily a foundational period for the commercialization of APHEXDA. We are seeing substantial progress on Pharmacy & Therapeutics committee approvals—the first step toward center adoption—and are actively supporting centers as they build usage protocols and treat their first patients. Initial feedback on patient experiences has been positive, and we are already seeing repeat purchases. Notably, we have achieved payer coverage representing approximately 95% of covered lives in the U.S. to date, which we believe reflects the value that APHEXDA offers to payers and patients alike, particularly its ability to mobilize the targeted number of stem cells in fewer apheresis sessions.

“Additionally, through a clinical collaboration with Washington University, we are actively evaluating the potential of motixafortide to support gene therapy for patients with sickle cell disease, a treatment process that requires significant quantities of hematopoietic stem cells. We anticipate data from this proof-of-concept Phase 1 study in patients with sickle cell disease in the second half of this year.

“At the same time, we are making significant progress advancing clinical programs evaluating motixafortide in pancreatic cancer, which if ultimately approved in combination with PD-1 inhibitors, would serve a much larger patient population and provide confidence for expanding into additional solid tumors. In pancreatic cancer, our enthusiasm is bolstered by the compelling data presented last fall from the single-arm pilot phase of the Phase 2b trial sponsored by Columbia University. The first patient has now been dosed in the randomized Phase 2b portion of that study, and we are also working with Gloria Biosciences on the design and execution of a similar randomized Phase 2b combination trial of motixafortide and zimberelimab in pancreatic cancer in China.

“Our vision of bringing a best-in-class stem cell mobilization agent to market, as well as advancing development in pancreatic cancer and other solid tumor areas with major unmet needs, is being actively realized. We look forward to the exciting, continued execution progress that our commercial and development teams will make this year,” Mr. Serlin concluded.

Corporate Updates

- Launched APHEXDA (motixafortide) in the U.S.
- Announced closing of exclusive license agreement that includes development and commercialization rights to motixafortide across all indications in the Asia region, as well as a strategic equity investment
- 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 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

- Reported positive coverage decisions by payers representing ~95% of all covered lives in the U.S.
- Received inclusion of APHEXDA in the National Comprehensive Cancer Network (NCCN) guidelines for Hematopoietic Cell Transplantation
- Achieved "on formulary" status for APHEXDA within targeted top 80 transplantation centers (which perform 85% of all U.S. transplants) managing ~20% of stem cell transplant procedures at these institutions; anticipate similar on formulary status of ~35% at end of Q2 2024 and ~60% at year-end 2024
- Received Healthcare Common Procedure Coding System (HCPCS) *J-Code* to facilitate Medicare reimbursement for APHEXDA to transplant centers treating Medicare beneficiaries

Clinical Portfolio Updates

Motixafortide (selective inhibitor of CXCR4 chemokine receptor)

Multiple Myeloma

- Presented posters at both the *American Society of Hematology (ASH) 65th Annual Meeting* on December 10, 2023, and the *2024 Tandem Meetings* on February 21-24, 2024. The posters reviewed combination premedication benefits in the Phase 3 GENESIS trial, extended PD effect of elevated CD34⁺ cells in peripheral blood, and a post-hoc subgroup analysis of impaired HSC mobilization patients that demonstrated a consistent benefit of motixafortide + G-CSF over placebo + G-CSF mobilization for all patients
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- Supported collaboration partner Gloria Biosciences with stem cell mobilization bridging study IND filing in February with the Center for Drug Evaluation of the National Medical Products Administration in China. Anticipate regulatory action in May 2024 and initiation of pivotal clinical trial in 2H 2024

Pancreatic Ductal Adenocarcinoma (mPDAC)

- Announced first patient dosed in a randomized, investigator-initiated Phase 2b clinical trial in collaboration with Columbia University assessing motixafortide in combination with the PD-1 inhibitor cemiplimab and standard-of-care chemotherapy as first-line treatment in 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 data in 2H 2024

Financial Results for Year Ended December 31, 2023

- Total revenues for the year ended December 31, 2023, were \$4.8 million, compared to no revenues for the year ended December 31, 2022. Revenues in 2023 (all of which were recorded in the fourth quarter) primarily reflect a portion of the upfront payment from the Gloria Biosciences license agreement, of which \$4.6 million was recognized in 2023, 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, 2023, amounted to \$3.7 million, compared to no cost of revenues for the year ended December 31, 2022. The cost of revenues in 2023 (all of which was recorded in the fourth quarter) primarily reflects a \$3.0 million sub-license fee to the upstream licensor of motixafortide payable on closing of the exclusive license agreement in Asia, as well as amortization of an intangible asset in respect of these license revenues in the amount of \$0.5 million. Cost of product sales were insignificant, representing approximately 6% of related sales.
 - Research and development expenses for the year ended December 31, 2023, were \$12.5 million, compared to \$17.6 million for the year ended December 31, 2022. The decrease resulted primarily from lower expenses related to motixafortide NDA supporting activities, as well as lower expenses associated with completion of the AGI-134 study
 - Sales and marketing expenses for the year ended December 31, 2023, were \$25.3 million, compared to \$6.5 million for the year ended December 31, 2022. The increase resulted primarily from the ramp-up of pre-commercialization and commercialization activities related to motixafortide
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- General and administrative expenses for the year ended December 31, 2023, were \$6.3 million, compared to \$5.1 million for the year ended December 31, 2022. The increase resulted primarily from an increase in payroll and related expenses associated with a small headcount increase during the 2022 period, as well as an increase in professional services and legal expenses
- Non-operating expenses for the year ended December 31, 2023, were \$10.8 million, compared to non-operating income of \$5.7 million for the year ended December 31, 2022. 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 year ended December 31, 2023 was \$60.6 million, compared to \$25.0 million for the year ended December 31, 2022. The net loss for 2023 included \$17.8 million in non-cash expenses, specifically an expense of \$11.1 million for the revaluation of warrants and a one-time \$6.7 million impairment of intangible assets associated with discontinuation of the AGI-134 development program. The net loss for 2022 included \$6.4 million in non-cash income specifically related to the revaluation of warrants.
- As of December 31, 2023, the Company had cash, cash equivalents, and short-term bank deposits of \$43.0 million. The Company anticipates that this amount and other available resources, including amounts available under a debt facility with Kreos Capital, will be sufficient to fund operations, as currently planned, into 2025

A copy of the Company's annual report on Form 20-F for the year ended December 31, 2023 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.bioglinerx.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 March 28, 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.bioglinerx.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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CONSOLIDATED STATEMENTS OF FINANCIAL POSITION

	December 31,	
	2022	2023
	in USD thousands	
Assets		
CURRENT ASSETS		
Cash and cash equivalents	10,587	4,255
Short-term bank deposits	40,495	38,739
Trade receivables	-	358
Prepaid expenses	198	1,048
Other receivables	721	830
Inventory	-	1,953
Total current assets	<u>52,001</u>	<u>47,183</u>
NON-CURRENT ASSETS		
Property and equipment, net	726	473
Right-of-use assets, net	1,772	1,415
Intangible assets, net	21,885	14,854
Total non-current assets	<u>24,383</u>	<u>16,742</u>
Total assets	<u><u>76,384</u></u>	<u><u>63,925</u></u>
Liabilities and equity		
CURRENT LIABILITIES		
Current maturities of long-term loans	1,542	3,145
Contract liabilities	-	12,957
Accounts payable and accruals:		
Trade	6,966	10,869
Other	1,744	3,353
Current maturities of lease liabilities	427	528
Total current liabilities	<u>10,679</u>	<u>30,852</u>
NON-CURRENT LIABILITIES		
Warrants	4,509	11,932
Long-term loans, net of current maturities	8,626	6,628
Lease liabilities	1,729	1,290
Total non-current liabilities	<u>14,864</u>	<u>19,850</u>
COMMITMENTS AND CONTINGENT LIABILITIES		
Total liabilities	<u>25,543</u>	<u>50,702</u>
EQUITY		
Ordinary shares	27,100	31,355
Share premium	338,976	355,482
Warrants	1,408	1,408
Capital reserve	14,765	17,000
Other comprehensive loss	(1,416)	(1,416)
Accumulated deficit	(329,992)	(390,606)
Total equity	<u>50,841</u>	<u>13,223</u>
Total liabilities and equity	<u><u>76,384</u></u>	<u><u>63,925</u></u>

BioLineRx Ltd.

CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

	Year ended December 31,		
	2021	2022	2023
	in USD thousands		
REVENUES	-	-	4,800
COST OF REVENUES	-	-	(3,692)
GROSS PROFIT	-	-	1,108
RESEARCH AND DEVELOPMENT EXPENSES	(19,466)	(17,629)	(12,519)
SALES AND MARKETING EXPENSES	(1,003)	(6,462)	(25,270)
GENERAL AND ADMINISTRATIVE EXPENSES	(4,308)	(5,066)	(6,310)
IMPAIRMENT OF INTANGIBLE ASSETS	-	-	(6,703)
OPERATING LOSS	(24,777)	(29,157)	(49,694)
NON-OPERATING INCOME (EXPENSES), NET	(1,830)	5,670	(10,819)
FINANCIAL INCOME	559	694	2,068
FINANCIAL EXPENSES	(1,006)	(2,158)	(2,169)
LOSS AND COMPREHENSIVE LOSS	(27,054)	(24,951)	(60,614)
	in USD		
LOSS PER ORDINARY SHARE – BASIC AND DILUTED	(0.04)	(0.03)	(0.06)
WEIGHTED AVERAGE NUMBER OF SHARES USED IN CALCULATION OF LOSS PER ORDINARY SHARE	662,933,695	773,956,973	963,365,525

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, 2021	9,870	279,241	-	12,322	(1,416)	(277,987)	22,030
CHANGES IN 2021:							
Issuance of share capital and warrants, net	8,956	40,476	975	-	-	-	50,407
Warrants exercised	2,235	18,967	-	-	-	-	21,202
Employee stock options exercised	5	41	-	(39)	-	-	7
Employee stock options expired	-	621	-	(621)	-	-	-
Share-based compensation	-	-	-	1,495	-	-	1,495
Comprehensive loss for the year	-	-	-	-	-	(27,054)	(27,054)
BALANCE AT DECEMBER 31, 2021	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

BioLineRx Ltd.

CONSOLIDATED STATEMENTS OF CASH FLOWS

	Year ended December 31,		
	2021	2022	2023
	in USD thousands		
CASH FLOWS - OPERATING ACTIVITIES			
Loss	(27,054)	(24,951)	(60,614)
Adjustments required to reflect net cash used in operating activities (see appendix below)	3,481	(1,289)	38,006
Net cash used in operating activities	(23,573)	(26,240)	(22,608)
CASH FLOWS - INVESTING ACTIVITIES			
Investments in short-term deposits	(78,000)	(44,000)	(47,588)
Maturities of short-term deposits	39,873	48,322	49,329
Purchase of property and equipment	(97)	(131)	(116)
Purchase of intangible assets	-	(185)	(181)
Net cash provided by (used in) investing activities	(38,224)	4,006	1,444
CASH FLOWS - FINANCING ACTIVITIES			
Issuance of share capital and warrants, net of issuance costs	50,407	14,359	14,089
Exercise of warrants	10,907	-	2,928
Employee stock options exercised	7	5	27
Proceeds from long-term loan, net of issuance costs	-	9,126	-
Repayments of loans	(3,376)	(2,832)	(1,543)
Repayments of lease liabilities	(196)	(220)	(445)
Net cash provided by financing activities	57,749	20,438	15,056
DECREASE IN CASH AND CASH EQUIVALENTS	(4,048)	(1,796)	(6,108)
CASH AND CASH EQUIVALENTS - BEGINNING OF YEAR	16,831	12,990	10,587
EXCHANGE DIFFERENCES ON CASH AND CASH EQUIVALENTS	207	(607)	(224)
CASH AND CASH EQUIVALENTS - END OF YEAR	12,990	10,587	4,255

BioLineRx Ltd.

CONSOLIDATED STATEMENTS OF CASH FLOWS

	Year ended December 31,		
	2021	2022	2023
	in USD thousands		
APPENDIX			
Adjustments required to reflect net cash used in operating activities:			
Income and expenses not involving cash flows:			
Depreciation and amortization	703	654	1,384
Exchange differences on cash and cash equivalents	(207)	607	224
Fair value adjustments of warrants	1,936	(6,425)	11,054
Share-based compensation	1,495	2,245	2,321
Interest and exchange differences on short-term deposits	(262)	(672)	15
Interest on loans	301	1,117	1,148
Warrant issuance costs	-	171	-
Exchange differences on lease liabilities	55	(224)	(42)
Intangible assets impairment	-	-	6,703
	<u>4,021</u>	<u>(2,527)</u>	<u>22,807</u>
Changes in operating asset and liability items:			
Increase in trade receivables	-	-	(358)
Increase in inventory	-	-	(1,953)
Decrease (increase) in prepaid expenses and other receivables	24	(650)	(959)
Increase (decrease) in accounts payable and accruals	(564)	1,888	5,512
Increase in contract liabilities	-	-	12,957
	<u>(540)</u>	<u>1,238</u>	<u>15,199</u>
	<u>3,481</u>	<u>(1,289)</u>	<u>38,006</u>
Supplemental information on interest received in cash	<u>138</u>	<u>342</u>	<u>2,020</u>
Supplemental information on interest paid in cash	<u>682</u>	<u>593</u>	<u>1,111</u>
Supplemental information on non-cash transactions:			
Changes in right-of-use asset and lease liabilities	<u>183</u>	<u>706</u>	<u>149</u>
Warrant issuance costs	<u>-</u>	<u>262</u>	<u>-</u>
Purchase of property and equipment	<u>-</u>	<u>28</u>	<u>-</u>
Fair value of exercised warrants (portion related to accumulated fair value adjustments)	<u>10,295</u>	<u>-</u>	<u>3,631</u>