# 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 February 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 February 16, 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: February 16, 2024

**Exhibit 1**

**BioLineRx Announces Acceptance of Two Poster Presentations on APHEXDA® (motixafortide) for CD34+ Hematopoietic Stem Cell (HSC) Mobilization in Patients with Multiple Myeloma at the 2024 Tandem Meetings of ASTCT® and CIBMTR®**

*- Results include pharmacokinetic and pharmacodynamic data, and post-hoc subgroup analyses of the Phase 3 GENESIS trial -*

*- Presentations on Thursday, February 22, 2024 in San Antonio, Texas -*

**TEL AVIV, Israel, February 16, 2024**– BioLineRx Ltd. (NASDAQ/TASE: BLRX), a commercial stage biopharmaceutical company pursuing life-changing therapies in oncology and rare diseases, today announced that new post-hoc subgroup analyses and pharmacodynamic data will be presented on APHEXDA® (motixafortide) for CD34+ hematopoietic stem cell (HSC) mobilization in patients with multiple myeloma at the 2024 Tandem Meetings: Transplantation & Cellular Therapy Meetings of the American Society for Transplantation and Cellular Therapy (ASTCT®) and the Center for International Blood and Marrow Transplant Research (CIBMTR®), taking place February 21-24, 2024, in San Antonio, Texas.

Results include pharmacokinetics (PK) and pharmacodynamics (PD) data as well as post-hoc subgroup analyses from the Phase 3 GENESIS trial, a randomized, double-blind, placebo-controlled study evaluating the safety and efficacy of APHEXDA (motixafortide) plus filgrastim, compared to placebo plus filgrastim (G-CSF), for the mobilization of hematopoietic stem cells for autologous transplantation in multiple myeloma patients. Phase 1 study results demonstrated an extended PD effect with complete receptor occupancy by motixafortide starting at a concentration of 3nM. In the GENESIS trial, post-hoc subgroup analyses based on baseline characteristics and risk factors for impaired HSC mobilization demonstrated a consistent benefit of motixafortide + G-CSF over placebo + G-CSF mobilization for all patients.

**Poster Presentations at the 2024 Tandem Meetings: Transplantation & Cellular Therapy Meetings of the ASTCT and the CIBMTR.**

**Henry B. González Convention Center, San Antonio, Texas**

**Poster Session Details**

- **Poster:** Number 537. See abstract.

  **Title:** Motixafortide Enables Consistent, Robust Hematopoietic Stem Cell Collection (HSC) across Populations with Increased Impaired HSC Mobilization: A Sub-Group Analysis of the Genesis Study

  **Presenter:** Zachary D. Crees, MD, Washington University School of Medicine in St. Louis

  **Poster Session:** Myeloma - Clinical

  **Date:** Thursday, February 22, 2024

  **Time:** 6:45 PM - 7:45 PM

- **Poster:** Number 535. See abstract.

  **Title:** Prolonged CXCR4 Receptor Occupancy By Motixafortide Following a Single Subcutaneous Injection Is Associated with Extended Mobilization of CD34+ Cells in Peripheral Blood for > 24 Hours

  **Presenter:** Ella Sorani, PhD, BioLineRx Ltd

  **Poster Session:** Myeloma - Clinical

  **Date:** Thursday, February 22, 2024

  **Time:** 6:45 PM - 7:45 PM

**About the GENESIS Trial**
GENESIS (NCT 03246529) is a 2-part, Phase-3, randomized, double-blind, placebo-controlled, multicenter study evaluating the safety and efficacy of APHEXDA (motixafortide) plus filgrastim (G-CSF), compared to placebo plus filgrastim, for the mobilization of hematopoietic stem cells for autologous transplantation in multiple myeloma patients. Part 1 was a single center, lead-in, open-label study involving 12 patients treated with motixafortide plus filgrastim designed to ascertain the dose. Part 2 involved 122 patients who were randomized 2:1 in a double-blind, placebo-controlled, multicenter study. The primary objective of the study was to evaluate if one dose of motixafortide plus filgrastim is superior to placebo plus filgrastim in the ability to mobilize ≥ 6 million CD34+ cells in up to two apheresis sessions. A key secondary objective of the study was to evaluate if one dose of motixafortide plus filgrastim is superior to placebo plus filgrastim in the ability to mobilize ≥ 6 million CD34+ cells in one apheresis session.

**About Multiple Myeloma**
Multiple myeloma is an incurable blood cancer that affects some white blood cells called plasma cells, which are found in the bone marrow. When damaged, these plasma cells rapidly spread and replace normal cells in the bone marrow. According to the American Cancer Society, in 2024, it is estimated that more than 35,000 people will be diagnosed with multiple myeloma, and nearly 13,000 people will die from the disease in the U.S.[1] While some people diagnosed with multiple myeloma initially have no symptoms, most patients are diagnosed due to symptoms that can include bone fracture or pain, low red blood cell counts, tiredness, high calcium levels, kidney problems, or infections.

**About APHEXDA®**
APHEXDA (motixafortide) is a CXCR4 antagonist with long receptor occupancy (greater than 72 hours) that, in combination with filgrastim (G-CSF), enables mobilization of hematopoietic stem cells to the peripheral blood for collection and subsequent autologous stem cell transplantation in patients with multiple myeloma.[2]

**INDICATION AND IMPORTANT SAFETY INFORMATION**

**INDICATION**

APHEXDA is indicated in combination with filgrastim (G-CSF) to mobilize hematopoietic stem cells to the peripheral blood for collection and subsequent autologous transplantation in patients with multiple myeloma.

**IMPORTANT SAFETY INFORMATION**

**CONTRAINDICATIONS**

APHEXDA is contraindicated in patients with a history of serious hypersensitivity reactions to motixafortide.

**WARNINGS AND PRECAUTIONS**

- **Anaphylactic Shock and Hypersensitivity Reactions**: Anaphylactic shock and hypersensitivity reactions have occurred. Premedicate all patients with a triple drug premedication regimen that includes an H1-antihistamine, an H2 blocker, and a leukotriene inhibitor approximately 30-60 minutes prior to each dose of APHEXDA. Administer APHEXDA in a setting where personnel and therapies are immediately available for treatment of anaphylaxis and other systemic reactions. Monitor patients for 1 hour following APHEXDA administration and manage reactions promptly. Patients receiving negative chronotropic drugs (e.g., beta-blockers) may be more at risk for hypotension in the event of a hypersensitivity reaction and these drugs, when appropriate, should be replaced with non-chronotropic drugs.

- **Injection Site Reactions:** Injection site reactions (73%) including pain (53%), erythema (27%), and pruritus (24%) have occurred. Severe reactions occurred in 9% of patients. Premedicate with an analgesic premedication (e.g., acetaminophen) prior to each APHEXDA dose. Use analgesic medication and local treatments post-dose, as needed.

- **Tumor Cell Mobilization in Patients with Leukemia:** For the purpose of hematopoietic stem cell (HSC) mobilization, APHEXDA may cause mobilization of leukemic cells and subsequent contamination of the apheresis product. Therefore, APHEXDA is not intended for HSC mobilization and harvest in patients with leukemia.

- **Leukocytosis:** Administering APHEXDA in conjunction with filgrastim increases circulating leukocytes as well as HSC populations. Monitor white blood cell counts during APHEXDA use.

- **Potential for Tumor Cell Mobilization:** When APHEXDA is used in combination with filgrastim for HSC mobilization, tumor cells may be released from the marrow and subsequently collected in the leukapheresis product. The effect of potential reinfusion of tumor cells has not been well-studied.

- **Embryo-fetal Toxicity**: Based on its mechanism of action, APHEXDA can cause fetal harm. Advise pregnant women of the potential risk to the fetus. Verify pregnancy status in females of reproductive potential prior to initiating treatment with APHEXDA and advise use of effective contraception during treatment and for 8 days after the final dose.

**ADVERSE REACTIONS**
The most common adverse reactions (incidence >20%) in patients treated with APHEXDA were injection site reactions [73%, including pain (53%), erythema (27%), pruritus (24%)]; pruritus (38%); flushing (33%); back pain (21%).

**USE IN SPECIFIC POPULATIONS**

**Pregnancy:** Please see the important information in Warnings and Precautions under Embryo-fetal Toxicity.

**Lactation**: There are no data on the presence of motixafortide in human milk, the effects on the breastfed child, or the effects on milk production. Advise females that breastfeeding is not recommended during treatment with APHEXDA and for 8 days after the final dose.

**Pediatric Use:** The safety and effectiveness of APHEXDA have not been established in pediatric patients.

Please see the accompanying full **Prescribing Information**.

**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; whether early stage clinical trial results, or pre-clinical results, will be predictive of, or repeatable in, later clinical trials; 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; 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 22, 2023. 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.*


1. American Cancer Society. *Key Statistics About Multiple Myeloma*. Atlanta, Ga: American Cancer Society; 2024.

2. APHEXDA. Prescribing Information. BioLineRx Ltd; 2023.


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