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 December 2023

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 December 21, 2023, the registrant issued the press release which is filed as Exhibit 1 to this Report on Form 6-K.

The first paragraph of the press release attached to this Form 6-K is hereby incorporated by reference into all effective registration statements filed by the registrant under the Securities Act of 1933.

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: December 21, 2023

Exhibit 1

BioLineRx Announces First Patient Dosed in Phase 1 Clinical Trial Evaluating Motixafortide for CD34+ Hematopoietic Stem Cell Mobilization for Gene Therapies in Sickle Cell Disease

- *Proof-of-concept* study is initial step toward goal of identifying more efficient CD34+ HSC mobilization regimen for patients with sickle cell disease choosing gene therapy -

TEL AVIV, Israel, December 21, 2023– BioLineRx Ltd. (NASDAQ/TASE: BLRX), a commercial stage biopharmaceutical company pursuing life-changing therapies in oncology and rare diseases, today announced that the first patient has been dosed in the 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). The proof-of-concept trial, which plans to enroll five patients diagnosed with SCD, is being conducted in collaboration with Washington University School of Medicine in St. Louis and will assess the safety and tolerability of the two regimens.

"Stem-cell based gene therapy has delivered significant progress in the treatment of sickle cell disease; however, identifying novel mobilization approaches that safely and reliably secure the necessary stem cell collection numbers is clinically relevant for patients," said Zachary Crees, MD, principal investigator for the trial, Division of Oncology, Washington University School of Medicine. "This is an exciting area of clinical research with the potential to meaningfully increase patients' access to stem-cell based gene therapies."

Approved gene therapies rely on the collection of significant quantities of CD34+ hematopoietic stem cells to enable therapeutic manufacturing and backup storage. However, available mobilization regimens may not reliably yield desired numbers of HSCs for gene therapy, and the common mobilization agent G-CSF is contraindicated in patients with SCD. Difficulties in obtaining target quantities of HSCs may extend patient treatment journeys and increase patient and caregiver burdens.

"The recent FDA approvals of two gene therapies for sickle cell disease in the U.S. is an exciting development for the sickle cell community, and we are eager to advance clinical research of motixafortide that may potentially lead to additional CD34+ hematopoietic stem cell mobilization options in the future for patients with this condition," said Ella Sorani, PhD, Chief Development Officer at BioLineRx. "We'd like to thank the patients participating in this important collaboration with Washington University who are helping to advance the field's understanding in this area where there is unmet need."

Initial data from this study is expected in the second half of 2024. Motixafortide, BioLineRx's lead therapeutic candidate, was approved by the U.S. Food & Drug Administration (FDA) in September 2023, in combination with filgrastim (G-CSF), to mobilize hematopoietic stem cells for collection and subsequent autologous transplantation in patients with multiple myeloma, under the brand name APHEXDA®.

About the Clinical Trial of Motixafortide in Sickle Cell Disease (SCD)
The trial (ClinicalTrials.gov Identifier: NCT05618301) is a safety and feasibility study to evaluate motixafortide (CXCR4 inhibitor) as monotherapy and in combination with natalizumab (VLA-4 inhibitor) as novel regimens to mobilize CD34+ hematopoietic stem cells for gene therapies in SCD. The study plans to enroll five adults with a diagnosis of SCD who are receiving automated red blood cell exchanges via apheresis. The trial's primary objective is to assess the safety and tolerability of motixafortide alone and the combination of motixafortide + natalizumab in SCD patients, defined by dose-limiting toxicities. Secondary objectives include determining the number of CD34+ hematopoietic stem and progenitor cells (HSPCs) mobilized via leukapheresis; and determining the kinetics of CD34+ HSPC mobilization to peripheral blood in response to motixafortide alone and motixafortide + natalizumab in SCD patients.

About Sickle Cell Disease
Sickle cell disease (SCD) is one of the most common genetic diseases globally, affecting millions of people throughout the world and disproportionately impacting persons of color. Sickle cell disease arises from mutations in the hemoglobin gene, ultimately leading to the production of abnormally shaped (sickle) red blood cells that tend to stick within blood vessels causing their occlusion. The clinical manifestations of SCD include anemia and blood vessel occlusion which can lead to both acute and chronic pain, as well as tissue ischemia across multiple organ systems (e.g., stroke, heart attack, respiratory failure), ultimately compromising end organ function. The cumulative impact of these complications significantly impacts morbidity and mortality for patients with SCD.

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 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.

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