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 April 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 April 17, 2023, 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: April 17, 2023

Exhibit 1

BioLineRx Announces Publication in *Nature Medicine* of its GENESIS Phase 3 Clinical Trial Data Evaluating Motixafortide and G-CSF in Stem Cell Mobilization for Autologous Transplantation in Multiple Myeloma

- GENESIS trial achieved statistical significance (p<0.0001) across all primary and secondary endpoints -

- Nature Medicine publication describes how GENESIS trial included patients representative of current multiple myeloma population undergoing autologous HSCT, including older patients and those who received lenalidomide-containing induction therapies – factors associated with impaired HSPC mobilization -

- Motixafortide plus G-CSF preferentially mobilized primitive stem and early progenitor cells with unique transcriptional profiles associated with enhanced self-renewal and regeneration -

TEL AVIV, Israel, April 17, 2023 – BioLineRx Ltd. (NASDAQ/TASE: BLRX), a pre-commercial-stage biopharmaceutical company focused on oncology, today announced the publication of data from the Company's GENESIS Phase 3 clinical trial in the peer-reviewed journal *Nature Medicine*. The international GENESIS trial evaluated the safety and efficacy of the Company's lead investigational candidate motixafortide plus granulocyte colony-stimulating factor (G-CSF) versus placebo plus G-CSF for the mobilization of hematopoietic stem cells in patients with multiple myeloma prior to autologous stem cell transplantation (ASCT).

Multiple myeloma is the second most common hematologic malignancy and ASCT has been shown to improve survival and plays a central role in the treatment of these patients. A meaningful number of patients, however, are unable to collect a desired number of peripheral blood CD34+ hematopoietic stem and progenitor cells (HSPC) with current treatment modalities.

The primary objective of the study was to demonstrate that one dose of motixafortide with G-CSF, compared to placebo with G-CSF, allowed more patients to mobilize ≥ 6 million CD34+ cells per kilogram of bodyweight, in up to two apheresis sessions. A secondary objective of the study was to demonstrate that one dose of motixafortide with G-CSF was superior to placebo with G-CSF in its ability to mobilize ≥ 6 million CD34+ cells per kilogram of bodyweight in just one apheresis session. The clinical trial found that all primary and secondary endpoints were achieved with a statistical significance of p<0.0001.

"Despite improvements in survival that ASCT offers patients with multiple myeloma, there has not been significant innovation in stem cell mobilization treatments in over a decade," said John DiPersio, MD, PhD, Professor of Medicine and Director of the Center for Gene and Cellular Immunotherapy at Washington University School of Medicine in St. Louis, and principal investigator of the GENESIS study. "With today's increased use of multiple drug induction therapies and transplants in increasingly older patients, there is a corresponding increased need for new treatment options. These data highlight the potential of motixafortide plus G-CSF, if approved, to enhance the treatment options for clinicians and patients with multiple myeloma undergoing ASCT."

“This first peer-reviewed publication of results from the Phase 3 GENESIS trial is an important validation of the potential of motixafortide to address critical clinical challenges and the evolving needs of today’s ASCT treatment landscape in appropriate multiple myeloma patients,” said Tami Rachmilewitz, MD, Chief Medical Officer at BioLineRx. “We look forward to continuing the development of motixafortide with the aim of advancing care for patients with multiple myeloma.”

Additional GENESIS clinical trial objectives included time to engraftment of neutrophils and platelets and durability of engraftment. The motixafortide-plus-G-CSF regimen resulted in rapid and durable engraftment[1] of HSPCs following transplantation, and the regimen was also shown to have a favorable safety-profile and that it was generally well-tolerated, with the most common treatment-emergent adverse events observed being transient, grade 1/2 injection site reactions.[2]

The study included patients that are representative of the typical multiple myeloma population undergoing ASCT, with a median age of 63 years and with ~70% of patients in both arms of the trial receiving lenalidomide-containing induction therapy. Increased age, as well as increased exposure to lenalidomide-containing induction regimens, including four-drug combination regimens, have been associated with impaired HSPC mobilization.[3]

The study authors also performed parallel comparative FACS and single-cell transcriptional profile analyses, using GENESIS data and data from trial cohorts with other mobilization regimens, to better understand the types of cells mobilized.

The FACS analysis, as described by the study authors in Nature, found that motixafortide plus G-CSF resulted in a 10.5-fold increase in primitive HSPCs collected versus placebo plus G-CSF ($p<0.0001$); and significantly greater numbers of early stem and progenitor cells versus both placebo plus G-CSF ($p<0.0001$) and plerixafor plus G-CSF ($p=0.0327$). Primitive HSPCs and early stem and progenitor cells may be associated with enhanced self-renewal and regeneration.[4] “The cohort analyses were not designed to understand potential clinical outcomes; nevertheless, we believe the findings are of interest and a compelling area for further research,” said Dr. DiPersio.

A New Drug Application (NDA) for motixafortide in stem cell mobilization for autologous transplantation in multiple myeloma patients is currently under review with the U.S. Food and Drug Administration (FDA), with an assigned PDUFA date of September 9, 2023.

About the GENESIS Trial

The GENESIS trial (NCT03246529) was initiated in December 2017. GENESIS was an international, randomized, double-blind, placebo-controlled, multicenter study, evaluating the safety and efficacy of motixafortide and G-CSF, compared to placebo and G-CSF, for the mobilization of hematopoietic stem-cells for autologous transplantation in multiple myeloma patients. The primary objective of the study was to demonstrate that one dose of motixafortide with G-CSF, compared to placebo with G-CSF, allowed more patients to mobilize ≥ 6 million CD34+ cells per kilogram of bodyweight, in up to two apheresis sessions. A secondary objective of the study was to demonstrate that one dose of motixafortide with G-CSF was superior to placebo with G-CSF in its ability to mobilize ≥ 6 million CD34+ cells per kilogram of bodyweight in just one apheresis session. Additional objectives included time to engraftment of neutrophils and platelets and durability of engraftment, as well as other efficacy and safety parameters.

CD34+ cells in the GENESIS trial were assessed using both central lab and local lab data, both of which achieved statistical significance ($p<0.0001$) across all primary and secondary endpoints. The *Nature Medicine* publication focused on the study's local lab data, as it was used for all clinical decisions in the study.

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 with tumors. According to the American Cancer Society, in 2023, 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. 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 Autologous Stem Cell Transplantation

Autologous stem cell transplantation (ASCT) is part of the standard treatment paradigm for a number of blood cancers, including multiple myeloma. In the U.S., nearly 15,000 ASCTs are performed each year with the majority in patients with multiple myeloma. The current standard of care includes the administration of 5-8 daily doses of granulocyte colony stimulating factor (G-CSF), with or without 1-4 doses of plerixafor, and the performance of 1-4 apheresis sessions. For patients unable to mobilize sufficient numbers of cells for harvesting during this primary mobilization phase, rescue therapy is carried out, consisting of 1-4 additional doses of plerixafor on top of G-CSF, and the performance of an additional number of apheresis sessions as necessary.

About BioLineRx

BioLineRx Ltd. (NASDAQ/TASE: BLRX) is a pre-commercial-stage biopharmaceutical company focused on oncology. The Company's lead development program, motixafortide, a novel selective inhibitor of the CXCR4 chemokine receptor, may support diverse therapeutic approaches in oncology and other diseases. Motixafortide was successfully evaluated in a Phase 3 study in stem cell mobilization for autologous transplantation for multiple myeloma patients and has had its NDA submission accepted by the FDA with an assigned PDUFA date of September 9, 2023. Motixafortide was also successfully evaluated in a Phase 2a study for the treatment of metastatic pancreatic cancer (mPDAC) in combination with the PD-1 inhibitor pembrolizumab and chemotherapy and is currently being studied in combination with the PD-1 inhibitor cemiplimab and chemotherapy as a first line mPDAC therapy. In addition, a randomized phase 2b study with 200 patients assessing motixafortide in combination with a PD-1 inhibitor and chemotherapy as a first line mPDAC therapy is expected to initiate in 2023. BioLineRx is also developing a second oncology program, AGI-134, an immunotherapy treatment for multiple solid tumors. A first-in-human Phase 1/2a study of AGI-134 met its primary endpoint for safety and tolerability and demonstrated immune activity across multiple biomarkers. For additional information on BioLineRx, please visit the Company's website at www.biolinerx.com, where you can review the Company's SEC filings, press releases, announcements and events.

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 GENESIS trial, including the plans and objectives of management for future operations and expectations and commercial potential of motixafortide. 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; BioLineRx's receipt of regulatory approvals for its therapeutic candidates, and the timing of other regulatory filings and approvals, including BioLineRx's ability to secure adequate and viable pricing and reimbursement coverage of any marketed product; the clinical development, commercialization and market acceptance of BioLineRx's therapeutic candidates; BioLineRx's ability to establish 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; risks related to changes in healthcare laws, rules and regulations in the United States or elsewhere; competitive companies, technologies and BioLineRx's industry; risks related to unfavorable economic and market conditions and adverse developments with respect to financial institutions and associated liquidity risk; and statements as to the impact of the political and security situation in Israel on BioLineRx's business. 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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[1] Z.D. Crees, J.F. DiPersio, A randomized, placebo-controlled, Phase III trial evaluating motixafortide and G-CSF to mobilize hematopoietic stem cells for autologous transplantation in multiple myeloma – the Genesis Trial. Nature Medicine, Volume 29, Issue 4 (2023)
[2] Ibid. p18
[3] Ibid. p35-36
[4] Ibid. p2