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 November 2022

Commission file number: 001-35223

BioLineRx Ltd.

(Translation of registrant's name into English)

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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 ☐

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulations S-T Rule 101(b)(1):_____

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulations S-T Rule 101(b)(7):_____

On November 3, 2022, 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: November 3, 2022

Exhibit 1

For Immediate Release

BioLineRx Announces Presentations on Cost-Effectiveness of Motixafortide in Multiple Myeloma and Program for Potential Motixafortide Indication Expansion in Gene Therapy at the 64th American Society of Hematology (ASH) Annual Meeting

- Full data from pharmacoeconomic study will be presented demonstrating significant cost benefits from using motixafortide in combination with G-CSF, versus plerixafor with G-CSF, for stem cell mobilization in multiple myeloma patients undergoing autologous stem cell transplantation -

- Phase 1 trial design of novel hematopoietic stem cell mobilization regimen including motixafortide for gene therapy in patients with sickle cell disease to be presented; a potential new development area -

TEL AVIV, Israel, November 3, 2022 – (PRNewswire) – BioLineRx Ltd. (NASDAQ/TASE: BLRX), a pre-commercial-stage biopharmaceutical company focused on oncology, today announced that its full pharmacoeconomic study that indirectly evaluated the cost-effectiveness of using the investigational drug motixafortide as a primary stem cell mobilization (SCM) agent in combination with granulocyte colony stimulating factor (G-CSF), against plerixafor in combination with G-CSF, in multiple myeloma (MM) patients undergoing autologous stem cell transplantation, will be presented at the 64th American Society of Hematology (ASH) Annual Meeting held from December 10-13 in New Orleans, LA. The analysis demonstrated significant net cost savings with motixafortide plus G-CSF and a greater proportion of patients achieving successful mobilization of optimal amounts of stem cells in a single apheresis day. The company has submitted a new drug application to the FDA for motixafortide in this indication.

Collaborating investigators will also present a Phase 1 trial design of a novel mobilization regimen combining motixafortide and a VLA-4 inhibitor. The clinical trial will evaluate the regimen's ability to safely produce the significant quantity of hematopoietic stem cells (HSC) required for the genetic manipulation processes used in gene therapy development in patients with sickle cell disease (SCD). Sickle cell disease is one of the most common inherited genetic diseases globally and HSC -based gene therapies now offer curative potential; however, effective HSC-based gene therapy depends on the collection of sufficient HSCs. Currently, the most widely used mobilization strategies include G-CSF and CXCR4 inhibition with plerixafor. However, G-CSF is contra-indicated in SCD and short-acting CXCR4 inhibition with plerixafor alone does not reliably yield optimal HSC numbers for SCD gene therapy applications. Developing novel HSC mobilization regimens to rapidly and reliably mobilize optimal CD34+ HSCs for gene therapy in SCD represents an unmet need.

"We are pleased to publish our full pharmacoeconomic data at ASH which demonstrates that the combination of motixafortide plus G-CSF significantly lowers healthcare resource utilization in patients with multiple myeloma in the U.S. undergoing autologous stem cell transplantation," said Philip Serlin, Chief Executive Officer of BioLineRx. "Importantly, motixafortide plus G-CSF had significantly greater successful mobilization of the optimal number of cells following a single administration of motixafortide and in only one apheresis session, improving the patient journey. If approved, we believe motixafortide has the potential to become the new standard of care for all patients with multiple myeloma undergoing autologous stem cell transplantation. We are also excited to introduce the design of a Phase 1 study by investigators who are targeting unmet needs in both quantity and quality of cells harvested for cell engineering and administration. Our team is working diligently to develop motixafortide in different areas of stem cell mobilization with the objective of becoming the standard of care in these settings."

Major Findings of Cost-Effectiveness Analysis
The study was performed by the Global Health Economics and Outcomes Research (HEOR) team of IQVIA. For this study, an adjusted indirect comparison was undertaken, using data from the relevant phase 3 trials. This included finding and extracting efficacy data for both motixafortide (from GENESIS Phase 3 trial patient-level data) and plerixafor (aggregate data from literature), estimating plerixafor efficacy as if it had been one arm of the GENESIS trial (Bucher method), and implementing the results in the cost-effectiveness model.

- Healthcare resource utilization (HRU) outcomes significantly favored motixafortide plus G-CSF during primary mobilization, including less frequent administration of G-CSF, lower G-CSF doses, and fewer apheresis sessions
- The proportion of patients with successful mobilization of≥$6x10^6$ CD34+ cells/kg within 1 apheresis day was significantly greater with motixafortide plus G-CSF than with plerixafor plus G-CSF
- Motixafortide plus G-CSF was dominant to plerixafor plus G-CSF over a lifetime horizon, resulting in additional QALYs and lower total costs as per base case deterministic results. The key cost drivers were the probability of successful transplantation, long-term maintenance costs, and the time to engraftment in poor mobilizers

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PRESENTATIONS AT ASH

Title: *Cost-Effectiveness Analysis of Motixafortide Versus Plerixafor in Stem Cell Mobilization for Autologous Transplantation in Patients with Multiple Myeloma*
Presenting Author: Mark Lamotte, MD, Global Health Economics & Outcomes Research, IQVIA
Date/Time: Poster 4848, Monday, December 12, 2022, 6:00 PM - 8:00 PM

Title: *A Phase I Safety and Feasibility Study to Evaluate Motixafortide (CXCR4/SDF-1 Inhibition) and Natalizumab (VLA-4/VCAM-1 Inhibition) As a Novel Regimen to Mobilize CD34+ Hematopoietic Stem Cells for Gene Therapy in Sickle Cell Disease*
Presenting Author: Zachary Crees, MD, Division of Oncology, Washington University School of Medicine, St. Louis, MO
Date/Time: Poster 4679, Monday, December 12, 2022, 6:00 PM - 8:00 PM

About the GENESIS Trial
The GENESIS trial (NCT03246529) was initiated in December 2017. GENESIS was a randomized, placebo-controlled, multicenter study, evaluating the safety, tolerability 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 only one dose of motixafortide on top of G-CSF is superior to G-CSF alone in the ability to mobilize ≥ 6 million CD34+ cells in up to two apheresis sessions. A key secondary objective of the study was to demonstrate that only one dose of motixafortide on top of G-CSF is superior to G-CSF alone in the ability to mobilize ≥ 6 million CD34+ cells in only one apheresis session. In this regard, ~90% of patients in the GENESIS study went directly to transplantation after mobilizing the optimal number of stem cells following only one administration of motixafortide on top of G-CSF and in only one apheresis session, compared to less than 10% of those receiving G-CSF alone. Additional objectives included time to engraftment of neutrophils and platelets and durability of engraftment, as well as other efficacy and safety parameters.

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. In 2022, it is estimated that more than 34,000 people will be diagnosed with multiple myeloma, and more than 12,000 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. In light of this, an agent with superior mobilization activity may significantly reduce the mobilization and harvesting burden and associated risks of the ASCT process and lead to significant clinical and resource benefits.

About BioLineRx

BioLineRx Ltd. (NASDAQ/TASE: BLRX) is a pre-commercial-stage biopharmaceutical company focused on oncology. The Company's lead program, APHEXDA® (motixafortide), is a cancer therapy platform that was successfully evaluated in a Phase 3 study in stem cell mobilization for autologous bone-marrow transplantation, has reported positive results from a pre-planned pharmacoeconomic study in the U.S., has successfully completed a pre-NDA meeting with the FDA, and has completed an NDA submission. APHEXDA® was also successfully evaluated in a Phase 2a study for the treatment of pancreatic cancer (PDAC) in combination with KEYTRUDA® and chemotherapy and is currently being studied in combination with LIBTAYO® and chemotherapy as a first-line PDAC therapy. A randomized phase 2b study with 200 patients in combination with PD1 and chemotherapy as a first-line PDAC therapy will initiate in 2023. BioLineRx is also developing a second oncology program, AGI-134, an immunotherapy treatment for multiple solid tumors that is currently being investigated in a Phase 1/2a study. 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 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; 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; 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 and the Russian invasion of Ukraine, 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 16, 2022. 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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