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)

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 10, 2022, 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: November 10, 2022

Exhibit 1

For Immediate Release

BioLineRx Announces U.S. FDA Acceptance of New Drug Application for APHEXDA® (motixafortide) in Stem Cell Mobilization

- PDUFA target action date set for September 9, 2023 -

- NDA submission based on GENESIS Phase 3 trial data that met all primary and secondary endpoints with a high level of statistical significance -

- Company advancing preparations for robust commercial launch -

TEL AVIV, Israel, November 10, 2022 – BioLineRx Ltd. (NASDAQ/TASE: BLRX), a pre-commercial-stage biopharmaceutical company focused on oncology, today announced that the U.S. Food and Drug Administration (FDA) has accepted for review and filed the Company's New Drug Application (NDA) for APHEXDA® (motixafortide) in stem cell mobilization for autologous transplantation in multiple myeloma patients. The FDA has assigned the NDA a Prescription Drug User Fee Act (PDUFA) target action date of September 9, 2023.
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. With the trend toward more aggressive induction treatment protocols, there is a clear need amongst patients with multiple myeloma to be able to reliably and rapidly secure the necessary amount of stem cells to continue their treatment programs.

"APHEXDA has the potential to significantly improve outcomes and treatment experiences for patients with multiple myeloma, and the acceptance of our NDA brings us closer to this important goal," said Philip Serlin, Chief Executive Officer of BioLineRx. "The clinical outcomes demonstrated by our GENESIS Phase 3 study showed that nearly 90 percent of patients collected an optimal number of cells for transplantation following a single administration of APHEXDA and in only one apheresis session. We believe APHEXDA can become the standard of care in the multiple myeloma transplant setting, while also substantially decreasing healthcare resource utilization across a number of important areas. The Company is actively engaged in launch preparedness and excited about the potential of bringing this important therapeutic candidate to patients."

The NDA is supported by the results from the GENESIS Phase 3 trial of motixafortide on top of G-CSF (versus placebo on top of G-CSF) in stem cell mobilization for autologous transplantation in multiple myeloma patients. The study met all primary and secondary endpoints with a very high degree of statistical significance ($p<0.0001$). The combination was also found to be safe and well tolerated.

About the GENESIS Trial

The GENESIS trial (NCT03246529) was initiated in December 2017. GENESIS is 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 development program, motixafortide, a novel selective inhibitor of the CXCR4 chemokine receptor, may support diverse therapeutic approaches in oncology and other diseases. APHEXDA® (motixafortide) was successfully evaluated in a Phase 3 study in stem cell mobilization for autologous transplantation for multiple myeloma patients, has reported positive results from a pre-planned pharmacoeconomic study in the U.S., 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 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. In addition, 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.

Contacts:

United States

John Lacey
BioLineRx
+1-781-392-5514
johnl@biolinerx.com

Tim McCarthy
LifeSci Advisors, LLC
tim@lifesciadvisors.com

Israel

Moran Meir
LifeSci Advisors, LLC
+972-54-476-4945
moran@lifesciadvisors.com