
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 October 2021

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 October 13, 2021 the registrant issued the press release which is filed as [Exhibit 1](#) to this Report on Form 6-K.

The first five paragraphs of the press release attached to this Form 6-K are 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: October 13, 2021



For Immediate Release

**BioLineRx Announces Positive Results from
Pharmacoeconomic Study Positioning Motixafortide as
Potential Standard of Care in Stem Cell Mobilization**

*- Results demonstrate significant cost benefits of using Motixafortide in combination
with G-CSF as standard-of-care mobilization therapy for all multiple myeloma patients
undergoing autologous stem cell transplantation -*

*- Results from pre-planned study, on top of highly significant and clinically meaningful
results from Phase 3 GENESIS trial announced in May 2021, strongly support potential
use of Motixafortide as standard of care in stem cell mobilization -*

Tel Aviv, Israel, October 13, 2021 – BioLineRx Ltd. (NASDAQ/TASE: BLRX), a late clinical-stage biopharmaceutical company focused on oncology, today announced positive results from a pharmacoeconomic study evaluating the cost-effectiveness of using investigational drug Motixafortide as a primary stem cell mobilization (SCM) agent on top of granulocyte colony stimulating factor (G-CSF), versus G-CSF alone, in multiple myeloma patients undergoing autologous stem cell transplantation (ASCT). The study was performed by the Global Health Economics and Outcomes Research (HEOR) team of IQVIA, and was a pre-planned study conducted in parallel with the GENESIS Phase 3 trial. These results, together with the highly significant and clinically meaningful data from the GENESIS trial, strongly support the potential use of Motixafortide, on top of G-CSF, as the standard of care in SCM for ASCT.

The study concluded that the addition of Motixafortide to G-CSF (the current standard of care) is associated with a statistically significant decrease in health resource utilization (HRU) during the ASCT process, compared to G-CSF alone. Based on the significantly higher number of mobilized cells and the lower number of apheresis sessions, lifetime estimates show quality-adjusted-life-year (QALY) benefits and net cost savings of ~\$17,000 (not including the cost of Motixafortide), versus G-CSF alone. The study findings, combined with model estimates, suggest that the use of Motixafortide, on top of G-CSF, as the standard of care in mobilization for ASCT, could be a cost-effective option in the US, based on accepted willingness-to-pay (WTP) values for healthcare payers.

“The compelling cost savings identified by this rigorously designed study strongly support the Company’s view that Motixafortide, in combination with G-CSF, can become the new standard of care as an upfront, or primary, therapy for all multiple myeloma patients undergoing autologous stem cell transplantation,” stated Philip Serlin, Chief Executive Officer of BioLineRx. “Based on data from the GENESIS trial showing that nearly 90% of patients collected an optimal number of cells for transplantation following a single administration of Motixafortide and in only one apheresis session, versus less than 10% for G-CSF alone, the pharmacoeconomic study demonstrates that use of Motixafortide on top of G-CSF can save \$17,000 per patient, not including the cost of Motixafortide. These cost savings should leave substantial room in the future to optimize our pricing strategy for Motixafortide at product launch and thereafter, if approved.

“It is also important to note that fewer administrations and apheresis sessions confer meaningful safety and time benefits to patients. In addition, the significantly higher median number of cells collected in one apheresis session – ~11 million using Motixafortide on top of G-CSF versus ~2 million for G-CSF alone – not only enables transplantation of an optimal number of cells, with the potential to significantly save on time to engraftment, it also permits the retention of enough cells for cryopreservation in the event that an additional transplantation is required in the future. Lastly, higher levels of certainty regarding the number of apheresis sessions required for mobilization could enable more efficient utilization of apheresis units at transplantation institutions, where there is often a shortage of available machines.

“We believe the data from the GENESIS study, together with the results from this pharmacoeconomic study, set Motixafortide apart from all other mobilization agents either currently available or in development. If approved, Motixafortide represents a significant advancement in SCM to the benefit of patients and payers alike, and, to that end, we remain on track to submit a New Drug Application (NDA) to the FDA in the first half of next year,” Mr. Serlin concluded.

About the Pharmacoeconomic Study

The pharmacoeconomic study analyzed healthcare resource utilization (HRU) observed during the Phase 3 GENESIS trial, which randomized 122 patients into two arms: Motixafortide plus G-CSF (n=80) or placebo plus G-CSF (n=42). HRU data points collected include: (1) the number of Motixafortide and G-CSF doses, as well as the number of apheresis sessions performed, in primary mobilization; (2) the percentage of patients needing rescue mobilization due to poor primary mobilization, including the number of apheresis sessions needed and the number of G-CSF and plerixafor doses required; and (3) hospitalization costs related to conditioning and transplantation, including length of stay. Quality-adjusted life years gained (QALY) from published literature were also incorporated into the model. Motixafortide plus G-CSF was associated with a statistically significant HRU decrease during the autologous stem cell transplantation process compared to standard-of-care G-CSF alone. Given the higher number of mobilized cells and lower number of apheresis sessions, lifetime estimates show quality-adjusted-life-year (QALY) benefits and net cost savings of ~\$17,000 (not including the cost of Motixafortide), versus the current standard of care.

About the GENESIS Phase 3 Trial

The GENESIS Phase 3 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. Additional objectives included time to engraftment of neutrophils and platelets and durability of engraftment, as well as other efficacy and safety parameters. The study successfully met all primary and secondary endpoints with an exceptionally high level of statistical significance ($p < 0.0001$), including approximately 90% of patients who mobilized the target number of cells for transplantation with only one administration of Motixafortide and in only one apheresis session.

About Stem Cell Mobilization for 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, non-Hodgkin's lymphoma and other lymphomas. In eligible patients, ASCT is performed after initial (induction) therapy, and, in most cases, requires consecutive-day clinic visits for the mobilization and apheresis (harvesting) phases, and full hospitalization for the conditioning chemotherapy and transplantation phases until engraftment. The associated burden is therefore significant – patients experience clinically relevant deteriorations in their quality of life during ASCT, and healthcare resource use throughout the ASCT phases is particularly intense. Therefore, new interventions impacting the ASCT process have the potential for relieving some of the clinical burden for transplanted patients, the logistical burden for the apheresis units, and the financial burden for healthcare providers and payers.

Described simply, ASCT consists of: (1) mobilizing the patient's own stem cells from his/ her bone marrow to the peripheral blood for removing (harvesting) via an apheresis procedure; (2) freezing and storing the harvested cells until they are needed for transplantation; (3) providing a conditioning treatment, such as high-dose chemotherapy or radiation, to kill the remaining cancer cells the day before transplant; and (4) infusing the stored stem cells back to the patient intravenously via a catheter.

To mobilize the patient's stem cells from the bone marrow to the peripheral blood for harvesting, the current standard of care includes the administration of 5-8 daily doses of granulocyte colony stimulating factor (G-CSF), 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 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 late clinical-stage biopharmaceutical company focused on oncology. The Company's business model is to in-license novel compounds, develop them through clinical stages, and then partner with pharmaceutical companies for further clinical development and/or commercialization.

The Company's lead program, Motixafortide (BL-8040), is a cancer therapy platform that was successfully evaluated in a Phase 3 study in stem cell mobilization for autologous bone-marrow transplantation, as well as reporting positive results from a pre-planned pharmacoeconomic study, and is currently in preparations for an NDA submission. Motixafortide was also successfully evaluated in a Phase 2a study for the treatment of pancreatic cancer in combination with KEYTRUDA® and chemotherapy under a clinical trial collaboration agreement with MSD (BioLineRx owns all rights to Motixafortide), and is currently being studied in combination with LIBTAYO® and chemotherapy as a first-line PDAC therapy.

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.

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 "may," "expects," "anticipates," "believes," and "intends," and describe opinions about future events. These forward-looking statements involve known and unknown risks and uncertainties 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 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 the COVID-19 pandemic; 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 February 23, 2021. 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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