# 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 2015***

---

# 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 x Form 40-F o**

Indicate by check mark whether the registrant by furnishing the information contained in this form is also thereby furnishing the information to the Commission pursuant to Rule 12g3-2(b) under the Securities Exchange Act of 1934:

**Yes o No x**

On December 14, 2015, the registrant will issue the press release which is filed as Exhibit 1 to this Report on Form 6-K.

This Form 6-K, including all exhibits hereto, is hereby incorporated by reference into all effective registration statements filed by the Company 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 Serlin
Philip Serlin
Chief Financial and Operating Officer

Dated: December 14, 2015

**Exhibit 1**

**For immediate release**

# BioLineRx Announces Regulatory Submission for Phase 2 Trial of BL-8040 as Novel Stem Cell Mobilization Treatment

***Study will be conducted in collaboration with Washington University School of Medicine, Division of Hematology and Oncology***

Tel Aviv**,** Israel, December 14, 2015 - BioLineRx Ltd. (NASDAQ/TASE:BLRX), a clinical-stage biopharmaceutical company dedicated to identifying, in-licensing and developing promising therapeutic candidates, announced today the filing of regulatory submissions required to commence a Phase 2 trial for BL-8040 as a novel approach for mobilization and collection of bone marrow stem cells from the peripheral blood circulation. The trial is expected to commence shortly after receipt of regulatory approval, anticipated in the first quarter of 2016.

The Phase 2 open-label study will be conducted as an investigator-initiated study in collaboration with Washington University School of Medicine, Division of Oncology and Hematology, and will enroll up to 24 donor/recipient pairs. The study submission was made following a meeting with the FDA in October 2015 to discuss the BL-8040 stem cell mobilization development program. The trial will evaluate the ability of BL-8040 to promote stem cell mobilization as a single agent in the allogeneic transplantation setting. Donors between 18 and 70 years of age and their HLA-matching recipients, diagnosed with advanced hematological malignancies that require stem cell transplantation, will be recruited to the study. On the donor side, the primary endpoint of the study is the ability of a single injection of BL-8040 to mobilize sufficient amounts of cells for transplantation following up to two leukapheresis collections. On the recipient side the study aims to evaluate the functionality and engraftment following transplantation of the BL-8040 collected graft.

The safety and tolerability of BL-8040 in the healthy donors will be evaluated. In addition, graft durability, the incidence of grade 2-4 acute graft versus host disease (GvHD), and other recipient related parameters will be evaluated in the patients who have undergone transplantation of hematopoietic cells mobilized with BL-8040.

Dr. Kinneret Savitsky, Chief Executive Officer of BioLineRx, stated, “Stem cell mobilization is used increasingly as a method of collecting hematopoietic stem cells for transplantation, forming part of the treatment regimen for certain types of hematological cancers, as well as for severe anemia or immune deficiency disorders. We have already completed a successful Phase 1 safety and efficacy study in healthy volunteers, supporting BL-8040 as one-day, single-dose collection regimen, with the capacity to rapidly mobilize substantial amounts of stem cells, representing a significant improvement upon the current standard of care. Following a productive meeting with the FDA regarding the development program for BL-8040 as a stem cell mobilizer for allogeneic transplantation, and in light of the fact that there are no approved drugs for stem cell mobilization to support allogeneic transplant, we are looking forward to shortly commencing yet another Phase 2 trial for our lead oncology platform.”

“In parallel, BL-8040 is also undergoing a Phase 2 study for treating relapsed and refractory acute myeloid leukemia patients, and has recently initiated a Phase 2b study as an AML consolidation treatment and a Phase 1/2 study as a novel treatment for hMDS and AA, two bone marrow failure conditions. In addition, as we recently announced, we are also performing an extensive evaluation of BL-8040’s potential in the immuno-oncology space, as a combination treatment with immune checkpoint inhibitors,” added Dr. Savitsky.

**About BL-8040**

BL-8040 is a clinical-stage drug candidate for the treatment of acute myeloid leukemia, as well as other hematological indications. It is a short peptide that functions as a high-affinity antagonist for CXCR4, a chemokine receptor that is directly involved in tumor progression, angiogenesis (growth of new blood vessels in the tumor), metastasis (spread of the disease to other organs or organ parts) and cell survival. CXCR4 is over-expressed in more than 70% of human cancers and its expression often correlates with disease severity. BL-8040 is currently in the midst of a Phase 2 study for relapsed/refractory acute myeloid leukemia (AML) and has recently initiated a Phase 2b study as an AML consolidation treatment and a Phase 1/2 study in hMDS and AA,. In addition, in a Phase 1/2, open-label, dose escalation, safety and efficacy clinical trial in 18 multiple myeloma patients, BL-8040, when combined with G-CSF, demonstrated an excellent safety profile at all doses tested and was highly effective in the mobilization of hematopoietic stem cells and white blood cells from the bone marrow to the peripheral blood. Additionally, in a Phase 1 stem-cell mobilization study in healthy volunteers, BL-8040 as a single agent was safe and well tolerated at all doses tested and resulted in efficient stem-cell mobilization and collection in all study participants. Importantly, the results of this study support the use of BL-8040 as one-day, single-dose collection regimen, which is a significant improvement upon the current standard of care.

BL-8040 effectively mobilizes cancer cells from the bone marrow and may therefore sensitize these cells to chemo- and bio-based anti-cancer therapy. Importantly, BL-8040 has also demonstrated a direct anti-cancer effect by inducing apoptosis. Pre-clinical studies show that BL-8040 inhibits the growth of various tumor types including multiple myeloma, non-Hodgkin’s lymphoma, leukemia, non-small cell lung carcinoma, neuroblastoma and melanoma. BL-8040 also significantly and preferentially stimulated apoptotic cell death of malignant cells (multiple myeloma, non-Hodgkin’s lymphoma and leukemia). Significant synergistic and/or additive tumor cell killing activity has been observed in vitro and in vivo when tumor cells were treated with BL-8040 together with Rituximab, Bortezomib, Imatinib, Cytarabine and the FLT-3 inhibitor AC-220 (in NHL, MM, CML, AML, and AML-FLT3-ITD models, respectively). BL-8040 was licensed by BioLineRx from Biokine Therapeutics and was previously developed under the name BKT-140.

**About Stem Cell Mobilization**
High-dose chemotherapy followed by stem cell transplantation has become an established treatment modality for a variety of hematologic malignancies, including multiple myeloma, as well as various forms of lymphoma and leukemia. Modern peripheral stem-cell harvesting often replaces the use of traditional surgical bone marrow stem-cell harvesting. In the modern method, stem cells are mobilized from the bone marrow using granulocyte colony-stimulating factor (G-CSF), often with the addition of a mobilizing agent such as Plerixafor (Mozobil), harvested from the donor's peripheral blood by apheresis, and infused to the patient after chemotherapy ablation treatment. This treatment is highly effective, the peripheral stem cells are easier to collect, and the treatment allows for a quicker recovery time and fewer complications.

**About BioLineRx**
BioLineRx is a publicly-traded, clinical-stage biopharmaceutical company dedicated to identifying, in-licensing and developing promising therapeutic candidates. The Company in-licenses novel compounds primarily from academic institutions and biotech companies based in Israel, develops them through pre-clinical and/or clinical stages, and then partners with pharmaceutical companies for advanced clinical development and/or commercialization.

BioLineRx's current portfolio consists of a variety of clinical and pre-clinical projects, including: BL-8040, a cancer therapy platform, which is in the midst of a Phase 2 study for relapsed/refractory AML, has recently initiated a Phase 2b study as an AML consolidation treatment, has recently initiated a Phase 1/2 study in hMDS and AA, and has successfully completed a Phase 1 study in stem cell mobilization; and BL-7010 for celiac disease, which has successfully completed a Phase 1/2 study.

In December 2014, BioLineRx entered into a strategic collaboration with Novartis for the co-development of selected Israeli-sourced novel drug candidates. The companies intend to co-develop a number of pre-clinical and early clinical therapeutic projects through clinical proof-of-concept for potential future licensing by Novartis.

For more information on BioLineRx, please visit www.biolinerx.com or download the investor relations mobile device app, which allows users access to the Company's SEC documents, press releases, and events. BioLineRx's IR app is available on the iTunes App Store as well as the Google Play Store.

*Various statements in this release concerning BioLineRx's future expectations, including specifically those related to the development and commercialization of BL-8040, 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. Some of these risks are: changes in relationships with collaborators; the impact of competitive products and technological changes; risks relating to the development of new products; and the ability to implement technological improvements. 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 23, 2015. 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.*

**Contact:**
PCG Advisory
Vivian Cervantes
Investor Relations
212-554-5482
vivian@pcgadvisory.com

or

Tsipi Haitovsky
Public Relations
+972-3-624-0871
tsipihai5@gmail.com