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 March 2016

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 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 ☑

On March 29, 2016, 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: March 29, 2016

Exhibit 1

For Immediate Release

BioLineRx Reports Successful Top-Line Results in Phase 2 Trial for AML

Data identify a potential biomarker for future selection of BL-8040-responsive AML patients

Tel Aviv, March 29, 2016 – BioLineRx (NASDAQ/TASE: BLRX) announced today positive top-line results from BL-8040's Phase 2 clinical trial in relapsed or refractory acute myeloid leukemia (r/r AML). Detailed results are planned to be presented at an upcoming scientific conference.

The BL-8040 oncology platform is a short cyclic peptide that functions as a high-affinity antagonist for CXCR4, a chemokine receptor that is directly involved in tumor progression, angiogenesis, metastasis and cell survival. Results of the Phase 2 clinical trial showed that BL-8040, as a single agent and in combination with Cytarabine (Ara-C), was safe and well tolerated at all doses tested up to and including the highest dose level of 2.0 mg/kg, with no major adverse events (n=45). The composite complete remission rate, including both complete remission (CR) and complete remission with incomplete blood count recovery (CRi), was 38% in subjects receiving up to two cycles of BL-8040 treatment at doses of 1 mg/kg and higher (n=39). Patients included in the study were patients that had undergone a significant number of prior treatments or that were refractory to induction treatment. The data include three compassionate-use patients treated at the study sites under the identical treatment protocol.

Importantly, the data suggest, for the first time, a correlation between improved clinical response and patients with a high disease burden in the bone marrow, along with a lower peripheral circulation of AML blasts at baseline (indicative of potential CXCR4 disease dependency). This finding may serve as a biomarker for patient selection in future BL-8040 AML studies.

In addition, treatment with BL-8040 continues to show a triple effect on the leukemic cells. First, BL-8040 monotherapy triggered robust mobilization of AML cells from the bone marrow to the peripheral blood, thereby sensitizing these cells to the Ara-C chemotherapy and improving its efficacy. Second, BL-8040 monotherapy showed a direct apoptotic effect on the leukemia cells in the bone marrow. Last, BL-8040 induced leukemia progenitor cells towards differentiation, as evidenced by a decrease in the number of leukemia progenitor cells, along with a three-fold increase in differentiated granulocytes, in the bone marrow biopsy conducted on day 3 of the treatment cycle prior to the Ara-C treatment, as compared to the biopsy performed at baseline.

Dr. Jorge Cortes, Chief of the AML and CML Sections at the MD Anderson Cancer Center in Houston, stated, “The outlook for relapsed or refractory AML patients remains poor. I am therefore very encouraged by the response rate demonstrated using the combination of BL-8040 with Cytarabine in such patients, which is backed by a sound scientific rationale. The response rate is especially compelling for the identified sub-population. These impressive clinical results from the Phase 2 study support further development of the compound in the AML space.”

Dr. Kinneret Savitsky, CEO of BioLineRx, commented, “We are very enthusiastic about the positive results from the Phase 2 trial with BL-8040 for the treatment of relapsed or refractory AML. We are especially excited that for the first time, we see a direct correlation between clinical response and a specific subset of the study patient population. Given that AML is a heterogeneous disease, the ability to pre-define the population that may benefit from CXCR4 inhibition is very important for future development.”

“The results continue to demonstrate that BL-8040 not only significantly induces mobilization of leukemic cells from the protective microenvironment of the bone marrow into the peripheral blood, but also directly leads to apoptosis of leukemic progenitor cells and triggers terminal differentiation of the cells into granulocytes. Combined with the impressive remission rate reported from subjects receiving BL-8040 doses of 1 mg/kg or higher, the results strongly suggest that BL-8040 has potent anti-leukemic activity and, in combination with Cytarabine, may improve the response typically achieved in this advanced AML population. These successful results also reinforce our excitement about BL-8040’s overall potential in the AML space, including as an AML consolidation treatment that is currently being investigated in a large Phase 2b study at approximately 25 sites in Germany. Given these positive results, we now plan to meet with the regulatory authorities to discuss the next steps in the development of this promising program.”

“In order to further expand and enhance the potential of this unique oncology platform, we are continuing to perform and plan multiple additional clinical studies for BL-8040, including our recently announced immuno-oncology collaboration with Merck on a Phase 2 study to investigate BL-8040 in combination with KEYTRUDA® for the treatment of pancreatic cancer,” concluded Dr. Savitsky.

About the r/r AML Phase 2 study

The Phase 2 trial was a multicenter, open-label study under an IND, conducted at ten clinical sites in the U.S. and Israel, and was designed to assess the safety, efficacy pharmacodynamics and pharmacokinetic parameters of BL-8040 in combination with Cytarabine (Ara-C) for the treatment of adult relapsed or refractory AML patients. Forty-two patients with r/r AML were enrolled in the study (36 of which received a dose of 1 mg/kg and higher). The study included a dose escalation stage followed by an expansion stage. Each patient received a once daily dose of BL-8040 monotherapy (from 0.5 to 2.0 mg/kg) on days 1-2, followed by the same dose of BL-8040 plus Ara-C on days 3-7. Extensive pharmacodynamic parameters, such as mobilization of leukemic cells and induction of apoptosis, were assessed after monotherapy with BL-8040 using peripheral blood sampling and bone marrow aspirates at baseline and on Day 3 prior to Ara-C administration. Clinical response to treatment was evaluated by bone marrow biopsy on Day 30.

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 cyclic 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. 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 also 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). In addition, the recently completed Phase 2 clinical trial in AML patients has demonstrated robust mobilization and apoptosis of cancer cells, along with a clinically meaningful response rate. BL-8040 was licensed by BioLineRx from Biokine Therapeutics and was previously developed under the name BKT-140.

About Acute Myeloid Leukemia (AML)
Acute myeloid leukemia (AML) is a cancer of the blood and bone marrow and is the most common type of acute leukemia in adults. According to the American Cancer Society, approximately 19,000 new cases of AML were diagnosed in the United States in 2014, and the median age of AML patients was 67 years old. The first treatment line for patients with AML includes a combination of chemotherapy drugs and is called induction treatment. The median survival for AML patients receiving induction chemotherapy is less than two years, with shorter survival for patients over the age of 60 or for those with certain gene or chromosome aberrations. Due to relapsed or refractory disease (where the disease is not responsive to standard treatments), the overall five-year survival rate for AML is between 10 and 40 percent.

About BioLineRx
BioLineRx is a 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 leading therapeutic candidates are: BL-8040, a cancer therapy platform, which has successfully completed 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 and gluten sensitivity, which has successfully completed a Phase 1/2 study. In addition, BioLineRx has a strategic collaboration with Novartis for the co-development of selected Israeli-sourced novel drug candidates, and has recently signed a collaboration agreement with MSD (known as Merck in the US and Canada) to run a Phase 2 study in pancreatic cancer using the combination of BL-8040 and Merck's KEYTRUDA®.

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. BioLineRx industry updates are also regularly updated on Facebook, Twitter, and LinkedIn.

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 10, 2016. 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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