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 2018

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 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 ☐ **No ☑**

On October 20, 2018, the registrant issued 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 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 22, 2018

Exhibit 1

For Immediate Release

BioLineRx Discloses Additional Data from Phase 2a COMBAT/KEYNOTE-202 Study in Pancreatic Cancer at ESMO 2018 Congress

Results presented today demonstrate that BL-8040 significantly improves T-cell infiltration into the tumor and reduces immunosuppression in the tumor microenvironment

Tel Aviv, Israel, October 20, 2018 - BioLineRx Ltd. (NASDAQ/TASE:BLRX), a clinical-stage biopharmaceutical company focused on oncology and immunology, today disclosed additional data from the in-depth analyses of biopsies of the dual combination arm of the Phase 2a COMBAT/KEYNOTE-202 study, evaluating patients with metastatic pancreatic adenocarcinoma (PDAC) treated with BL-8040 in combination with KEYTRUDA® (pembrolizumab), an anti-PD-1 therapy marketed by Merck & Co., Inc., Kenilworth, N.J., USA (known as MSD outside of the United States and Canada). The results presented today at a poster discussion session at the European Society for Medical Oncology 2018 Congress, in Munich, Germany, demonstrate that BL-8040 significantly improves T-cell infiltration into the tumor and reduces immunosuppression in the tumor microenvironment. These data follow top-line results of the COMBAT/KEYNOTE-202 study announced yesterday, October 19, 2018, showing encouraging disease control and extended overall survival, particularly in patients undergoing second-line treatment.

The study included 37 patients with metastatic PDAC who had disease progression after one or more previous lines of treatment. Study treatment consisted of an initial 5-day priming period of BL-8040 monotherapy, followed by repeated 3-week cycles of BL-8040 in combination with KEYTRUDA. In addition to clinical efficacy assessments, the study included a number of pharmacodynamic assessments to support BL-8040's mechanism of action as an immuno-oncology agent.

The additional data from in-depth analyses of biopsies taken at screening and following monotherapy or combination treatment of BL-8040 and KEYTRUDA demonstrate that in 75% of the available biopsies, BL-8040 treatment promotes an increase in the number of infiltrating CD4+, CD8+ and CD8+Granzyme B+ cytotoxic T-cells. The greatest improvement in T-cell infiltration was observed following combination treatment of BL-8040 and KEYTRUDA and was correlated with stable disease for 8 cycles of treatment. Furthermore, increased infiltration of activated CD4 and CD8 T-cells was accompanied by a pronounced decrease in the number of tumor cells, as well as by a decrease in myeloid-derived suppressor cells, a cell type known to impede the anti-tumor immune response.

Philip Serlin, Chief Executive Officer of BioLineRx, commented. “The data we disclosed today further support BL-8040 as a powerful immune modulating agent, which promotes infiltration of T-cells into the tumor and decreases immuno-suppressive cells in the tumor microenvironment, even more so when combined with KEYTRUDA. This, once again, attests to the potential of the combination treatment as an effective immunotherapy for pancreatic cancer. We look forward to commencing the triple combination arm through the addition of chemotherapy expected by the end of this year, with results expected in the second half of 2019.”

About the COMBAT/KEYNOTE-202 Study

The Phase 2a COMBAT/KEYNOTE-202 study is currently an open-label, multicenter, single-arm trial designed to evaluate the safety and efficacy of the combination of BL-8040 and KEYTRUDA® (pembrolizumab), an anti-PD-1 therapy marketed by Merck & Co., Inc., Kenilworth, N.J., USA (known as MSD outside the United States and Canada), in over 30 subjects with metastatic pancreatic adenocarcinoma. The study is primarily designed to evaluate the clinical response, safety and tolerability of the combination of these therapies, and is being carried out in the US, Israel and additional territories. The study is being conducted by BioLineRx under a collaboration agreement signed in 2016 between BioLineRx and MSD, through a subsidiary, to support a Phase 2a program investigating BioLineRx’s BL-8040 in combination with KEYTRUDA in patients with metastatic pancreatic cancer.

In July 2018, the Company announced the expansion of its immuno-oncology collaboration with MSD to include a triple combination arm investigating the safety, tolerability and efficacy of BL-8040, KEYTRUDA and chemotherapy. The triple combination arm will focus on second-line pancreatic cancer patients. Thirty to fifty patients will be enrolled in this arm, planned for initiation in the fourth quarter of 2018.

BL-8040, BioLineRx’s lead oncology platform, is a CXCR4 antagonist that has been shown in several clinical trials to be a robust mobilizer of immune cells to peripheral blood and to be effective at inducing direct tumor cell death. In addition, clinical findings have demonstrated the ability of BL-8040 to mediate infiltration of T-cells into tumors that were previously immunologically “cold” and devoid of immune cell infiltrate. Immune checkpoint inhibitors (such as KEYTRUDA) produce anti-cancer effects by increasing the activity of T-cells through blockade of the interaction between the immune checkpoint receptor PD-1, on T-cells, and its ligand PD-L1, on tumor cells. Pancreatic cancers have very little T-cell infiltrate, making them less susceptive to checkpoint blockade than other tumors that are infiltrated by T-cells. Therefore, combining BL-8040 with immune checkpoint blockade is predicted to increase the responsiveness of pancreatic cancer patients to immunotherapy. Further increase in the sensitivity of pancreatic cancer cells to BL-8040 and KEYTRUDA may be achieved by chemotherapy-mediated immunogenic cell death and exposure of new tumor antigens, resulting in activation of new anti-cancer T cell clones.

About BL-8040

BL-8040 is a short synthetic peptide for the treatment of hematological malignancies, solid tumors, and stem cell mobilization. It functions as a high-affinity best-in-class antagonist for CXCR4, a chemokine receptor that is directly involved in tumor progression, angiogenesis, metastasis and cell survival. CXCR4 is over-expressed in more than 70% of human cancers and its expression often correlates with disease severity. In a number of clinical and pre-clinical studies, BL-8040 has shown robust mobilization of cancer cells and immune-cells, sensitization of cancer cells to chemo- and bio-based anti-cancer therapies, and direct anti-cancer effect by inducing programmed cell death (apoptosis). BL-8040 was licensed by BioLineRx from Biokine Therapeutics and was previously developed under the name BKT-140.

About BioLineRx

BioLineRx is a clinical-stage biopharmaceutical company focused on oncology and immunology. The Company in-licenses novel compounds, 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 2a study for relapsed/refractory AML, is in the midst of a Phase 2b study as an AML consolidation treatment and has initiated a Phase 3 study in stem cell mobilization for autologous transplantation; and AGI-134, an immunotherapy treatment in development for multiple solid tumors, which has recently initiated a Phase 1/2a study. In addition, BioLineRx has a strategic collaboration with Novartis for the co-development of selected Israeli-sourced novel drug candidates; a collaboration agreement with MSD, on the basis of which the Company is conducting a Phase 2a study in pancreatic cancer using the combination of BL-8040 and KEYTRUDA® (pembrolizumab), and a collaboration agreement with Genentech, a member of the Roche Group, to investigate the combination of BL-8040 and Genentech's atezolizumab in several Phase 1b/2 studies for multiple solid tumor indications and AML.

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 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 6, 2018. 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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