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 2018

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 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 December 11, 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: December 11, 2018

Exhibit 1

For Immediate Release

BioLineRx Announces Initiation of Triple Combination Arm of Phase 2a COMBAT/KEYNOTE-202 Study in Pancreatic Cancer Under Immuno-Oncology Collaboration

Results of triple combination arm of BL-8040, KEYTRUDA® and chemotherapy expected in H2 2019

Tel Aviv, Israel, December 11, 2018 - BioLineRx Ltd. (NASDAQ/TASE:BLRX), a clinical-stage biopharmaceutical company focused on oncology and immunology, announced today the initiation of the triple combination arm of the Phase 2a COMBAT/KEYNOTE-202 study in patients with metastatic pancreatic cancer (PDAC) under its immuno-oncology collaboration with Merck & Co., Inc., Kenilworth, N.J., USA (known as MSD outside the United States and Canada). As previously announced, the triple combination arm will investigate the safety, tolerability and efficacy of BL-8040, KEYTRUDA and chemotherapy.

The triple combination arm will focus on second-line pancreatic cancer patients, and will include approximately 40 patients with unresectable metastatic pancreatic adenocarcinoma who have progressed following first-line therapy prior to enrollment. Patients will receive BL-8040 monotherapy priming treatment for 5 days, followed by ongoing cycles of the combination of chemotherapy (Onivyde®/5-fluorouracil/leucovorin – 5-FU/LV), KEYTRUDA and BL-8040 until progression. The primary endpoint of the study is the objective response rate (ORR) assessed by RECIST v1.1 criteria. Secondary endpoints will include overall survival, progression free survival, and the disease control rate.

“We are pleased to commence this triple combination arm of our Phase 2a pancreatic study, under the framework of our immuno-oncology collaboration with MSD,” stated Philip Serlin, Chief Executive Officer of BioLineRx. "We believe that the addition of chemotherapy may be synergistic with BL-8040 and KEYTRUDA, as chemotherapy has been shown to reduce overall tumor burden while inducing immunogenic cell death, leading to activation and expansion of new tumor-reactive T-cells. Based on its mechanism of action, we believe that BL-8040 may facilitate the infiltration of these T-cells into the tumor core, alongside the restoration of T-cell activity within the tumor by KEYTRUDA. We look forward to results of the study expected in the second half of 2019."

At the recent European Society for Medical Oncology 2018 Congress in Munich, Germany, BioLineRx disclosed top-line results from the dual combination arm of the Phase 2a COMBAT/KEYNOTE-202 study, evaluating PDAC patients treated with BL-8040 in combination with KEYTRUDA®. The results show encouraging disease control and extended overall survival, particularly in patients undergoing second-line treatment. In addition, the data also demonstrate that BL-8040 significantly improves T-cell infiltration into the tumor and reduces immunosuppression in the tumor microenvironment.

About the COMBAT/KEYNOTE-202 Study
The Phase 2a COMBAT/KEYNOTE-202 study was originally designed as an open-label, multicenter, single-arm trial 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 was primarily designed to evaluate the clinical response, safety and tolerability of the combination of these therapies, and was 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.

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 as part of the Phase 2a COMBAT/KEYNOTE-202 study. The triple combination arm will focus on second-line pancreatic cancer patients.

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.

Contact:

Tim McCarthy
LifeSci Advisors, LLC
+1-212-915-2564
tim@lifesciadvisors.com

or

Tsipi Haitovsky
Public Relations
+972-52-598-9892
tsipihai5@gmail.com