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 19, 2018, 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 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 19, 2018

Exhibit 1

For Immediate Release

BioLineRx Presents Top-Line Results from Phase 2a COMBAT/KEYNOTE-202 Study in Pancreatic Cancer at ESMO 2018 Congress

BL-8040 in combination with KEYTRUDA® (pembrolizumab) demonstrated encouraging disease control and overall survival in patients with metastatic pancreatic cancer

Encouraging results support further development of combination and expansion of collaboration

Triple combination expansion cohort (BL-8040 + KEYTRUDA® (pembrolizumab) + chemotherapy) to commence by year-end

Tel Aviv, Israel, October 19, 2018 - BioLineRx Ltd. (NASDAQ/TASE:BLRX), a clinical-stage biopharmaceutical company focused on oncology and immunology, today announced top-line results from 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 show encouraging disease control and extended overall survival, particularly in patients undergoing second-line treatment. The data, entitled, "A Phase 2a Trial to Assess the Safety and Efficacy of BL-8040 and Pembrolizumab in Patients with Metastatic Pancreatic Adenocarcinoma (PDAC)," will be presented on October 20, 2018 at 5:15 pm CET at the immuno-oncology poster discussion session co-chaired by the principal investigator of the study at the European Society for Medical Oncology 2018 Congress, which is being held October 19-23, in Munich, Germany.

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 data show that the treatment regimen was safe and well tolerated. The disease control rate (patients exhibiting a response or stable disease) was 34.5% for the evaluable population (N=29), including 1 patient (3.4%) with a partial response showing a 40% reduction in tumor burden, as well as 9 patients (31%) with stable disease, with a median treatment time of 72 days (37-267). Median overall survival (OS) in all patients (N=37) was 3.3 months with a 6-month survival rate of 34.4%. A significant observation was made in the subpopulation of patients receiving the study drugs as a second-line treatment (N=17), where the median overall survival was 7.5 months, with a 6-month survival rate of 51.5%. This compares favorably with historical median overall survival data of 6.1 months for the only currently approved second-line PDAC treatment (a chemotherapy combination of Onivyde®, 5-FU and leucovorin).

The clinical activity correlates with previously announced partial pharmacodynamic results from the BL-8040 monotherapy period of this study, in which BL-8040 induced infiltration of T-cells into the core and periphery of metastatic lesions. Additional in-depth analyses of biopsies taken at screening and following monotherapy or combination treatment of BL-8040 and KEYTRUDA have now been completed and will be presented at the poster discussion session tomorrow, Saturday, October 20, 2018. Immediately following the presentation and lifting of the embargo on publication of the data, the Company will report these additional results in a press release.

Prof. Manuel Hidalgo, MD, PhD, Professor of Medicine at Harvard Medical School, Chief of Hematology Oncology and Co-Director, Pancreatic Cancer Research Program, at Beth Israel Deaconess Hospital, and principal investigator of this study, said, “Metastatic pancreatic cancer remains an area of very high unmet medical need, as currently approved treatments are limited by poor response rates and survival. Despite recent advances in cancer treatment with immune checkpoint inhibitors in many tumor types, pancreatic cancer remains refractory to these treatment options. It is therefore encouraging to see that the combination of BL-8040 and KEYTRUDA shows promising clinical activity, a robust pharmacodynamic effect and a very good safety and tolerability profile. I look forward to the next phase of this study, in which chemotherapy will be added to the combination of BL-8040 and KEYTRUDA in an expansion cohort. I believe that the addition of chemotherapy may boost the clinical response rate, while hopefully maintaining the favorable safety and tolerability profile observed in this arm of this trial.”

“We are extremely pleased with the top-line results from this ongoing study,” stated Philip Serlin, Chief Executive Officer of BioLineRx. “These data, which demonstrate that the combination of BL-8040 and KEYTRUDA is safe, with encouraging signs of clinical activity and proof of concept for the mechanism of action, support the combination’s potential to become an effective immunotherapy regimen for pancreatic cancer – a disease that has responded very poorly to available treatments, including immunotherapy. We look forward to expanding our collaboration with MSD and maximizing the potential of this combination through an additional study arm that will add chemotherapy to the regimen. We believe the addition of chemotherapy may be synergistic with the existing combination, 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 demonstrated mechanism of action, we believe BL-8040 can 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 commencing the triple combination arm of this important study 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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