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 June 2022

Commission file number: 001-35223

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 if the registrant is submitting the Form 6-K in paper as permitted by Regulations S-T Rule 101(b)(1):_____

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulations S-T Rule 101(b)(7):_____

On June 28, 2022, the registrant issued the press release which is filed as Exhibit 1 to this Report on Form 6-K.

The first two paragraphs of the press release attached to this Form 6-K are 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: June 28, 2022

Exhibit 1

For Immediate Release

BioLineRx Announces Collaboration Agreement with GenFleet Therapeutics to Further Develop Motixafortide in Pancreatic Ductal Adenocarcinoma (PDAC)

- GenFleet to design and execute randomized Phase 2b triple combination trial of Motixafortide in first-line metastatic PDAC patients in China -

- BioLineRx to retain global rights to Motixafortide in all indications -

-Collaboration based on positive final results from Phase 2a COMBAT/KEYNOTE-202 study of Motixafortide in combination with anti-PD-1 and chemotherapy as second-line metastatic PDAC therapy -

Tel Aviv, Israel, June 28, 2022 – BioLineRx Ltd. (NASDAQ/TASE: BLRX), a late clinical-stage biopharmaceutical company focused on oncology, today announced that the Company has entered into a collaboration agreement with GenFleet Therapeutics, an immuno-oncology focused biopharmaceutical company based in China, to advance Motixafortide through a randomized Phase 2b clinical trial in pancreatic ductal adenocarcinoma, or PDAC.

Under the terms of the agreement, GenFleet will fully fund, design and execute a randomized Phase 2b clinical trial that will enroll approximately 200 first-line metastatic PDAC patients in China. This randomized controlled study will aim to evaluate the superiority of Motixafortide in combination with an anti-PD-1 and chemotherapy compared to chemotherapy alone, the current standard of care. As part of the collaboration, BioLineRx will supply Motixafortide, while GenFleet will supply the other study drugs for the trial. Trial oversight will be administered by a Joint Development Committee. GenFleet will be eligible to receive low-to-mid-single digit tiered percentage royalties on future Motixafortide sales, if approved.

“This collaboration is based on the highly encouraging results from our Phase 2a COMBAT/KEYNOTE-202 study of Motixafortide in combination with an anti-PD-1 and chemotherapy, which provide strong support for continued development in this very challenging disease,” stated Philip Serlin, Chief Executive Officer of BioLineRx. “With its broad solid tumor oncology pipeline and highly experienced development team, we believe we have found an outstanding partner in GenFleet to execute a rigorously designed randomized Phase 2b trial.”

“At the same time, we remain on track to submit our New Drug Application (NDA) for Motixafortide in stem cell mobilization in the U.S. in the next few months, and we are continuing our pre-launch activities in anticipation of potential FDA approval in 2023.”

“Together, these programs demonstrate the potential versatility of Motixafortide and its promise of new combination therapies targeting both hematological and solid tumor cancers,” Mr. Serlin concluded.

“The results of the COMBAT/KEYNOTE-202 Phase 2a study demonstrate the benefit of combining the CXCR4 inhibitor Motixafortide with an anti-PD-1 and chemotherapy in a second-line setting,” said Qiang Lu, Chairman of GenFleet. “We believe that this combination could be beneficial to patients in a first-line setting as well, and we hope to confirm this in a randomized trial. We are thrilled to be partners with BioLineRx in the development of this late-stage clinical asset, and look forward to initiating this important trial as quickly as possible.”

In parallel, BioLineRx is continuing its collaboration with Colombia University in an on-going Phase 2 investigator-initiated study (NCT04543071) to evaluate Motixafortide in combination with the anti-PD-1 LIBTAYO® (cemiplimab) and standard-of-care chemotherapy (gemcitabine and nab-paclitaxel) in first-line PDAC patients.

MSQ Ventures served as advisor to BioLineRx on this transaction.

About Pancreatic Cancer

Pancreatic cancer has a low rate of early diagnosis and a poor prognosis. Its incidence rate in the US is estimated at 3.2% of new cancer cases. In 2022, approximately 495,000 individuals globally are expected to be diagnosed with this condition, 62,000 of them in the US; and the incidence of pancreatic cancer is expected to continue to increase. Symptoms are usually non-specific and as a result, pancreatic cancer is often not diagnosed until it reaches an advanced stage. Surgical resection does not offer adequate treatment since only 20% of patients have resectable tumors at the time of diagnosis. Even among patients who undergo resection for pancreatic cancer and have tumor-free margins, the five-year survival rate is only 10-25%. The overall five-year survival rate among pancreatic cancer patients is 8%, which constitutes the highest mortality rate among solid tumor malignancies. The overall median survival is less than one year from diagnosis, highlighting the need for the development of new therapeutic options.

Despite advances in chemotherapeutics and immunotherapy, increases in median and overall survival rates in pancreatic cancer have been modest. Pancreatic cancer remains an area of unmet medical need, with very limited new approved therapies for the majority of PDAC patients since the approval of nab-paclitaxel (Abraxane®) in combination with gemcitabine for first-line treatment in 2013 and Onivyde® in combination with fluorouracil and leucovorin for second-line treatment in 2015. The limited clinical benefits demonstrated by these existing standard treatment options reinforce the need for additional approaches.

About COMBAT/KEYNOTE-202

In December 2020, BioLineRx announced final positive results from its Phase 2a COMBAT/KEYNOTE-202 triple combination study of Motixafortide in second line PDAC. The highly encouraging results demonstrated improvement across all study endpoints, including overall survival, progression free survival and overall response rate, in the most challenging PDAC patients, as compared to historical data. All patients were diagnosed at Stage IV, and greater than 70% had liver metastases, a key determinant of poor prognoses in this patient population.

About GenFleet Therapeutics

GenFleet Therapeutics is a clinical-stage biotechnology company focusing on cutting-edge therapies in oncology and immunology, founded in 2017 by veteran drug developers with the support from top-tier venture capital investors. Dedicated to serving significant unmet medical needs, GenFleet Therapeutics established its proprietary R&D platform based on a deep understanding of disease biology and translational medicine, as well as on research into the latest biological mechanisms of cancer pathways, the tumor microenvironment and human immunoregulation. GenFleet's rich and diversified pipeline highlights multiple cutting-edge products with novel mechanisms and global IP.

For additional information on GenFleet, please visit the Company's website at www.genfleet.com/en.

About BioLineRx

BioLineRx Ltd. (NASDAQ/TASE: BLRX) is a late clinical-stage biopharmaceutical company focused on oncology. The Company's lead program, Motixafortide (BL-8040), is a cancer therapy platform that was successfully evaluated in a Phase 3 study in stem cell mobilization for autologous bone-marrow transplantation, has reported positive results from a pre-planned pharmacoeconomic study, has successfully completed a pre-NDA meeting with the FDA, and is currently in preparations for an NDA submission. Motixafortide was also successfully evaluated in a Phase 2a study for the treatment of pancreatic cancer in combination with KEYTRUDA® and chemotherapy and is currently being studied in combination with LIBTAYO® and chemotherapy as a first-line PDAC therapy.

BioLineRx is also developing a second oncology program, AGI-134, an immunotherapy treatment for multiple solid tumors that is currently being investigated in a Phase 1/2a study.

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.

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 "anticipates," "believes," "could," "estimates," "expects," "intends," "may," "plans," "potential," "predicts," "projects," "should," "will," and "would," and describe opinions about future events. These forward-looking statements involve known and unknown risks, uncertainties and other factors 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. Factors that could cause BioLineRx's actual results to differ materially from those expressed or implied in such forward-looking statements include, but are not limited to: the initiation, timing, progress and results of BioLineRx's preclinical studies, clinical trials and other therapeutic candidate development efforts; BioLineRx's ability to advance its therapeutic candidates into clinical trials or to successfully complete its preclinical studies or clinical trials; BioLineRx's receipt of regulatory approvals for its therapeutic candidates, and the timing of other regulatory filings and approvals; the clinical development, commercialization and market acceptance of BioLineRx's therapeutic candidates; BioLineRx's ability to establish and maintain corporate collaborations; BioLineRx's ability to integrate new therapeutic candidates and new personnel; the interpretation of the properties and characteristics of BioLineRx's therapeutic candidates and of the results obtained with its therapeutic candidates in preclinical studies or clinical trials; the implementation of BioLineRx's business model and strategic plans for its business and therapeutic candidates; the scope of protection BioLineRx is able to establish and maintain for intellectual property rights covering its therapeutic candidates and its ability to operate its business without infringing the intellectual property rights of others; estimates of BioLineRx's expenses, future revenues, capital requirements and its needs for and ability to access sufficient additional financing; risks related to changes in healthcare laws, rules and regulations in the United States or elsewhere; competitive companies, technologies and BioLineRx's industry; statements as to the impact of the political and security situation in Israel on BioLineRx's business; and the impact of the COVID-19 pandemic and the Russian invasion of Ukraine, which may exacerbate the magnitude of the factors discussed above. 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 16, 2022. 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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