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 2022

Commission file number: 001-35223

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 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 December 20, 2022, the registrant issued the press release which is filed as Exhibit 1 to this Report on Form 6-K.

The first three 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: December 20, 2022

Exhibit 1

For Immediate Release

BioLineRx Announces Results from Phase 1/2a Study of Investigational Anti-Tumor Vaccine AGI-134 in Metastatic Solid Tumors

- Study Met Primary Endpoint for Safety and Tolerability -

- First-in-Human, Single-Agent Study Demonstrated Immune Activity Across Multiple Biomarkers -

- Company to Seek Publication of Complete Data Analysis in 2023 -

TEL AVIV, Israel, December 20, 2022 – (PRNewswire) – BioLineRx Ltd. (NASDAQ/TASE: BLRX), a pre-commercial-stage biopharmaceutical company focused on oncology, today announced results from the Phase 1/2a study of intratumoral cancer vaccine candidate, AGI-134, designed to evaluate the safety and biological activity of AGI-134 in patients with unresectable metastatic solid tumors.

The study met its primary endpoint of AGI-134's safety and tolerability. In this first-in-human trial, a total of 38 patients were treated with AGI-134: 5 patients in part 1, the accelerated dose-escalation part of the study; and 33 patients in part 2, the dose expansion part of the study. Part 1 demonstrated that AGI-134 was safe and well tolerated, with no dose-limiting toxicities reported. The maximum tolerated dose was not reached and the recommended dose for part 2 of the study (RP2D) was determined to be up to 200mg. In the dose expansion part 2 of the study, AGI-134 was generally well-tolerated, with treatment-related adverse events being transient and mostly mild to moderate.

Generation of an immune response and markers of clinical efficacy were assessed as secondary endpoints. Most patients analyzed showed an increase in Alpha-Gal antibodies, indicating increased overall immune activity. Additionally, increases in antigen presenting cells (APCs) were observed in most tissue samples analyzed, and T cell and macrophage tumor infiltration was seen in approximately one-third of evaluable patients' injected tumors, and in approximately half of evaluable patients' un-injected lesions. Radiological assessments found that 29 percent of patients in the trial achieved best overall response of stable disease. Seven of the 11 patients who achieved stable disease had previously failed checkpoint-inhibitor therapy.

"In this first-in-human, single-agent trial, we were encouraged with AGI-134's safety profile and the observed initiation of immune activity in patients," said Philip Serlin, Chief Executive Officer of BioLineRx. "We plan to seek publication of our data at a medical congress in 2023, and in consultation with our scientific advisory board, we will determine the next steps for the program in the first half of next year. We want to thank the patients who participated in this important trial, their caregivers, and our physician collaborators."

The Phase 1/2a clinical trial was a multicenter, open-label study, which recruited a total of 38 patients in the UK, Spain and Israel. The study had two parts: part one was an accelerated dose-escalation study in five patients to determine the maximum tolerated dose and the recommended dose for part 2 of the study; part two was a dose expansion study at the recommended dose in 33 patients, designed to evaluate the safety and tolerability of AGI-134, and to validate AGI-134's mechanism of action using a wide array of biomarkers. For more information on this Phase 1/2a study, see NCT03593226.

PATIENT CHARACTERISTICS

- Total enrollment: 38 patients
- Gender: 21 Male, 17 Female
- Solid Tumor Cancer Type: Melanoma (21), Colon (5), Breast (4), Squamous Cell (3). Sarcoma (2), Cervical Node (1), Endometrial (1), Synovial (1)
- ECOG score: 0 to 1 with life expectancy not less than 3 months

SAFETY

- AGI-134 was generally well-tolerated, and adverse events (AEs) were mostly transient, mild to moderate in severity

CLINICAL RESPONSE

- Best overall response of stable disease (SD) was observed in 29 percent (11/38) of patients according to RECIST1.1 criteria
- 7 of the 11 patients who achieved stable disease had failed prior checkpoint inhibitor therapy

IMMUNE RESPONSE BIOMARKERS

Increase in Alpha-Gal antibodies

- Most patients analyzed showed an increase in Alpha-Gal antibodies as measured by IgG and IgM titers

Tumor infiltration following treatment with AGI-134

- 59 percent (10/17) of evaluable patients showed an increase in conventional dendritic cells (CD11c+ HLADR+) within or outside of the tumor
- 29 percent (5/17) of evaluable patients showed an increase in T helper cells (CD3+CD4+) in injected lesions and 47 percent (8/17) in un-injected lesions,
- 35 percent (6/17) of evaluable patients showed an increase in Cytotoxic T cells (CD3+CD8+) in injected lesions, and 47 percent (8/17) in un-injected lesions
- 24 percent (4/17) of evaluable patients showed an increase in macrophages (CD68+) in injected lesions and 47 percent (5/17) in un-injected lesions

About AGI-134

AGI-134 is a synthetic alpha-Gal glycolipid in development for solid tumors that is highly differentiated from other cancer immunotherapies. AGI-134 is designed to label cancer cells with alpha-Gal via intra-tumoral administration, thereby targeting the body's pre-existing, highly abundant anti-alpha-Gal (anti-Gal) antibodies and redirecting them to treated tumors. Binding of anti-Gal antibodies to the treated tumors results in activation of the complement cascade, which destroys the tumor cells and creates a pro-inflammatory tumor microenvironment that also induces a systemic, specific anti-tumor (vaccine) response to the patient's own tumor neo-antigens.

AGI-134 has been evaluated in numerous pre-clinical studies. In a mouse melanoma model, treatment with AGI-134 led to regression of established primary tumors and suppression of secondary tumor (metastases) development. Synergy has also been demonstrated in additional pre-clinical studies when combined with an anti-PD-1 immune checkpoint inhibitor, offering the potential to broaden the utility of such immunotherapies, and improve the rate and duration of responses in multiple cancer types. AGI-134 was obtained by BioLineRx through the acquisition of Agalimmune Ltd.

About BioLineRx

BioLineRx Ltd. (NASDAQ/TASE: BLRX) is a pre-commercial-stage biopharmaceutical company focused on oncology. The Company's lead development program, motixafortide, a novel selective inhibitor of the CXCR4 chemokine receptor, may support diverse therapeutic approaches in oncology and other diseases. APHEXDA® (motixafortide) was successfully evaluated in a Phase 3 study in stem cell mobilization for autologous transplantation in multiple myeloma patients, has reported positive results from a pre-planned pharmacoeconomic study in the U.S., and has had its NDA submission accepted by the FDA with a PDUFA date of September 9, 2023. Motixafortide was also successfully evaluated in a Phase 2a study for the treatment of pancreatic cancer (PDAC) in combination with KEYTRUDA® and chemotherapy and is currently being studied in combination with LIBTAYO® and chemotherapy as a first-line PDAC therapy. A randomized phase 2b study with 200 patients in combination with an anti-PD1 and chemotherapy as a first-line PDAC therapy will initiate in 2023. 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.

Forward Looking Statement

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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