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 September 2019

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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)

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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 September 25, 2019, 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: September 25, 2019

Exhibit 1

For Immediate Release

BioLineRx Announces Dosing of First Patient in Part 2 of Phase 1/2a Clinical Study for AGI-134, a Novel Immunotherapy for Treatment of Solid Tumors

*- **Initial results of part 2 of the study expected by year-end 2020** -*

Tel Aviv**,** Israel – September 25, 2019 - BioLineRx Ltd. (NASDAQ/TASE: BLRX), a clinical-stage biopharmaceutical company focused on oncology, announced today dosing of the first patient in part 2 of the Phase 1/2a clinical study for AGI-134, a novel compound that evokes a direct anti-tumor response, as well as a vaccine effect, via a unique, multi-arm mechanism that targets patient-specific tumor neoantigens. In the dose-escalation part of the study completed earlier this month, AGI-134 was found to be safe and well tolerated, with no serious drug-related adverse events or dose-limiting toxicities reported.

“Following the successful completion of part 1 of the study and determination of the recommended dose, we are pleased to announce the initiation of part 2 of the Phase 1/2a study of AGI-134, our second lead oncology product,” said Philip Serlin, Chief Executive Officer of BioLineRx. “In preclinical trials, AGI-134 led to regression of established primary tumors, prevented growth of secondary tumors, and triggered a vaccine effect that may prevent the development of future metastases. We are looking forward to initial results from part 2 of the study expected by year-end 2020.”

The ongoing Phase 1/2a study is a multicenter, open-label study expected to take place at approximately 15 sites in the US, UK and Israel. The objectives of the study are to evaluate the safety and tolerability of AGI-134 at doses up to the recommended dose in multiple solid tumor types, to evaluate a wide array of biomarkers, and to validate AGI-134’s mechanism of action. Furthermore, efficacy will be assessed by clinical and pharmacodynamic parameters.

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 is a clinical-stage biopharmaceutical company focused on multiple oncology indications. The Company's lead program, BL-8040, is a cancer therapy platform currently being evaluated in a Phase 2a study in pancreatic cancer in combination with KEYTRUDA® and chemotherapy under a collaboration agreement with MSD. BL-8040 is also being evaluated in a Phase 2b study in consolidation AML and a Phase 3 study in stem cell mobilization for autologous bone-marrow transplantation. In addition, the Company has an ongoing collaboration agreement with Genentech, a member of the Roche Group, evaluating BL-8040 in combination with Genentech's atezolizumab in two Phase 1b/2 solid tumor studies.

BioLineRx is developing a second oncology program, AGI-134, an immunotherapy treatment for multiple solid tumors that is currently being evaluated 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. 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 28, 2019. 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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