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 August 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 August 1, 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: August 1, 2018

Exhibit 1

For Immediate Release

BioLineRx Initiates Phase 1/2a Clinical Study for AGI-134, a Novel Immunotherapy for Treatment of Solid Tumors

Tel Aviv**,** Israel – August 1, 2018 - BioLineRx Ltd. (NASDAQ/TASE: BLRX), a clinical-stage biopharmaceutical company focused on oncology and immunology, announced today that it has initiated a 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, universally applicable, multi-arm mechanism that targets patient-specific tumor neoantigens.

AGI-134 is a synthetic, intratumorally administered glycolipid designed to label cancer cells with alpha-Gal, which then become the target of pre-existing anti-Gal antibodies, effectively triggering an immediate local anti-tumor response, as well as a follow-on systemic anti-tumor response targeting both the primary injected tumor and distal secondary tumors.

The Phase 1/2a study is a multicenter, open-label study that will take place in the UK and Israel, with possible expansion to the US and additional countries in Europe in 2019. The study is primarily designed to evaluate the safety and tolerability of AGI-134, given both as monotherapy and in combination with an immune checkpoint inhibitor, in unresectable metastatic solid tumors. Additional objectives are to perform a wide array of biomarker studies and to demonstrate the mechanism of AGI-134. Furthermore, efficacy will be assessed by clinical and pharmacodynamic parameters.

The study will be comprised of two parts: (i) an accelerated dose-escalation part to assess the safety and tolerability of intratumorally injected AGI-134 as a monotherapy, as well as to determine the maximum tolerated dose and the recommended dose for part 2 of the study; and (ii) a dose expansion part at the recommended dose, comprised of three cohorts and designed to assess the safety, tolerability and anti-tumor activity of AGI-134 as a monotherapy in a basket cohort of multiple solid tumor types, as well as in two additional cohorts in combination with an immune checkpoint inhibitor – in metastatic colorectal cancer and head and neck squamous cell carcinoma.

Prof. Mark Middleton of the University of Oxford, the study's principal investigator, stated, "We are very excited to be launching a first-in-human clinical trial assessing AGI-134 for the treatment of solid tumors. AGI-134 represents a new mechanistic class of cancer immunotherapies, with a unique and highly differentiated mode of action, harnessing pre-existing immune machinery to trigger a systemic anti-tumor response and create a pro-inflammatory tumor microenvironment. More treatment options are urgently needed for cancer patients and we are optimistic that AGI-134's encouraging pre-clinical results are going to translate to an efficacious and safe treatment for humans."

"We are pleased to enter the clinic with our second lead oncology project," said Philip Serlin, Chief Executive Officer of BioLineRx. "Numerous pre-clinical studies to date have demonstrated that treatment with AGI-134 leads to regression of established primary tumors, prevents growth of untreated distal secondary tumors, and triggers a vaccine effect that may prevent the development of future metastases. Furthermore, a combination of AGI-134 and an anti-PD-1 immune checkpoint inhibitor has demonstrated synergistic effect in protection from secondary tumor growth. We look forward to the first results of the Phase 1/2a study expected by the end of 2020."

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 intratumoral 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 completed 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 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 (known as Merck in the US and Canada), on the basis of which the Company is conducting a Phase 2a study in pancreatic cancer including the combination of BL-8040 and Merck's KEYTRUDA®; 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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