
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 April 2021

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 April 15, 2021 the registrant issued the press release which is filed as [Exhibit 1](#) to this Report on Form 6-K.

The first two paragraphs and the table under “summary data” 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: April 15, 2021



For Immediate Release

**BioLineRx Announces Presentation at 2021 American
Association for Cancer Research (AACR) Annual Meeting**

*- Poster includes analysis of results by liver metastases, further strengthening
results reported in December 2020 of the COMBAT/KEYNOTE-202 triple
combination study of motixafortide in metastatic pancreatic cancer -*

*- Company also on track to report final data from Phase 3 GENESIS trial of
motixafortide in stem cell mobilization in next few weeks -*

Tel Aviv, Israel, April 15, 2021 – BioLineRx Ltd. (NASDAQ/TASE: BLRX), a late clinical-stage biopharmaceutical Company focused on oncology, today announced that the Company has presented a poster at the AACR Annual Meeting, which is being held April 10-15 on a virtual basis.”

The poster, entitled: “A Multi-Center Phase 2a Trial of the CXCR4 inhibitor Motixafortide (BL-8040) in Combination with Pembrolizumab and Chemotherapy, in Patients with Metastatic Pancreatic Adenocarcinoma, the COMBAT Study,” includes new analyses from the Company’s Phase 2a COMBAT/KEYNOTE-202 triple combination study of motixafortide in metastatic pancreatic cancer, further detailing the clinical effect of the combination in patients with and without liver metastases.

The COMBAT/KEYNOTE-202 study evaluated BioLineRx’s lead clinical candidate, motixafortide, in combination with KEYTRUDA® and chemotherapy in patients with advanced pancreatic ductal adenocarcinoma, or PDAC. [Top-line results from the study](#) were announced in December 2020.

“Liver metastases are a critical factor driving poor prognoses for patients with metastatic PDAC,” stated Dr. Abi Vainstein, Chief Medical Officer of BioLineRx. “We are very pleased to present this additional analysis, which further strengthens the results reported from the COMBAT/KEYNOTE-202 trial in December 2020, since not only were substantially all patients initially diagnosed with stage 4 disease, but the vast majority (~80%) of the patients had liver metastases, emphasizing the extremely difficult patient population in this study. These data should be further confirmed in a randomized trial, and we continue to work diligently to define next steps for the program with potential collaboration partners.”

Summary data:

Endpoint	Evaluable Patients (N=38)	Liver Metastases (N=30)	No Liver Metastases (N=8)
mOS (months) (95% CI)	6.5 (4.5-9.6)	5.9 (4.4-9.6)	8.4 (3.5-10.8)
mPFS (months) (95% CI)	4.0 (1.5-5.6)	1.9 (1.5-5.7)	5.4 (1.5-8.0)
ORR (95% CI)	21.1% (8.1%-34.0%)	16.7% (3.3%-30.0%)	37.5% (4.0%-71.0%)
DCR (95% CI)	63.2% (47.8%-78.5%)	56.7% (38.9%-74.4%)	87.5% (64.6%-100.0%)

“We believe these incremental data provide strong support for continued development of motixafortide as the backbone of a new regimen for the treatment of PDAC and will likely prove beneficial as we advance discussions with potential collaboration partners,” stated Philip Serlin, Chief Executive Officer of BioLineRx. “At the same time, we are very much looking forward to final data from our Phase 3 GENESIS study in stem cell mobilization in the next few weeks, which we hope will give us a clear pathway to potential registration and highlight the versatility of motixafortide across both hematological and solid tumor cancer types.”

A copy of the poster is now available on the Company's website, www.biolinerx.com.

About BioLineRx

BioLineRx Ltd. (NASDAQ/TASE: BLRX) is a late clinical-stage biopharmaceutical company focused on oncology. The Company's business model is to in-license novel compounds, develop them through clinical stages, and then partner with pharmaceutical companies for further clinical development and/or commercialization.

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. Motixafortide was also successfully evaluated in a Phase 2a study for the treatment of pancreatic cancer in combination with KEYTRUDA® and chemotherapy under a clinical trial collaboration agreement with MSD (BioLineRx owns all rights to motixafortide), and is currently being studied in combination with LIBTAYO® and chemotherapy as a first-line PDAC therapy.

BioLineRx is 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.bioglinrx.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 "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. 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 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; risks related to the COVID-19 pandemic; and statements as to the impact of the political and security situation in Israel on BioLineRx's business. 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 February 23, 2021. 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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