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 2020

Commission file number: 001-35223

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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 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 16, 2020, the registrant issued the press release which is filed as Exhibit 1 to this Report on Form 6-K.

The first, second, and third paragraphs, the table containing the data summary and the paragraph following immediately thereafter in 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 16, 2020

Exhibit 1

For Immediate Release

BioLineRx Announces Final Results from Phase 2a COMBAT/KEYNOTE-202 Triple Combination Study of Motixafortide in Second Line Metastatic Pancreatic Cancer (PDAC)

- Substantial improvement observed across all study endpoints, including overall survival, progression free survival and overall response rate, in the most challenging PDAC patients -

- Company plans to meet with regulatory authorities as it evaluates next development steps -

- Company to host Key Opinion Leader (KOL) webinar to discuss these results today, December 16, at 8:00 am EST; registration link below -

Tel Aviv, Israel, December 16, 2020 – BioLineRx Ltd. (NASDAQ/TASE:BLRX), a late clinical-stage biopharmaceutical Company focused on oncology, today announced results from the triple combination arm of the Company's COMBAT/KEYNOTE-202 clinical study evaluating motixafortide (BL-8040) in combination with KEYTRUDA® (pembrolizumab) and chemotherapy in patients with second-line stage IV pancreatic ductal adenocarcinoma (PDAC).

A total of 43 patients initially diagnosed with unresectable stage IV metastatic PDAC, who had progressed following first-line gemcitabine-based therapy, were enrolled in the triple combination arm. Patients received motixafortide monotherapy priming treatment for five days, followed by combination cycles of motixafortide, KEYTRUDA and chemotherapy (Onivyde®/5-fluorouracil/leucovorin) until progression. The primary endpoint of the study is the objective response rate (ORR); secondary endpoints include confirmed objective response rate (cORR), overall survival (OS), progression free survival (PFS), and disease control rate (DCR).

The results of the study showed substantial improvement as compared to historical results across all study endpoints. Data are summarized below for the evaluable patients in the study (n=38).

Data summary:

	COMBAT/KEYNOTE	HISTORICAL DATA
Median overall survival (mOS)	6.5 months	4.7 months[1]
Median progression free survival (mPFS)	4.0 months	2.7-3.1 months[2,3]
Confirmed overall response rate (cORR)	13.2%	7.7%[3]
Overall response rate (ORR)	21.2%	16%[1]
Disease control rate (DCR)	63.2%	29-52%[2,4]

The combination was generally well tolerated, with a safety profile consistent with the individual safety profile of each component alone; adverse event (AE) and severe adverse event (SAE) profiles were as expected with chemotherapy-based treatment regimens. Of note, certain safety advantages were demonstrated by the triple combination of motixafortide, KEYTRUDA and chemotherapy, when compared to historical data relating to the specific chemotherapy used in the study. These safety advantages include incidence of grade 3 neutropenia (7% versus historical data of 20%) and incidence of grade 3 infections (7% versus historical data of 17%).

“These results are highly encouraging in light of the extremely challenging population, even among PDAC patients, in this study cohort,” said Manuel Hidalgo, MD, PhD, Chief of the Division of Hematology and Medical Oncology and a Senior Member of the Sandra and Edward Meyer Cancer Center at Weill Cornell Medicine and New York-Presbyterian/Weill Cornell Medical Center, and principal investigator of this study. “All patients were initially diagnosed at stage IV, and greater than 70% had liver metastases, key contributing factors to very poor prognoses. I believe the results from this study strongly support further development.”

“We are extremely pleased with these results, which demonstrate a meaningful improvement versus historical data across all study endpoints,” stated Philip Serlin, Chief Executive Officer of BioLineRx. “The consistent improvement across all study endpoints represents a key differentiating factor relative to other compounds that showed improvement in only one endpoint in their initial studies and eventually failed in advanced studies. These positive results are further supported by a long-lasting median durability of clinical benefit of 5.6 months that we observed in this trial.

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1 Macarulla Mercade et al, Pancreas 2020
2 Petrelli et al Eu J Cancer 2017
3 Onivyde prescribing information
4 Wang Gilliam Eu J Cancer 2019

“Pancreatic cancer is one of the most difficult cancers to treat, with five-year survival rates of just 9% overall, and 3% for the greater-than-50% of patients initially diagnosed at stage IV. Therefore, even marginal improvements in survival endpoints in pivotal studies have been considered clinically meaningful and sufficient for regulatory approval. These positive efficacy results across all endpoints give us a high degree of confidence in their repeatability in a randomized trial and we plan to meet with the regulatory authorities in order to agree on the fastest pathway forward in this indication.

“In addition, we believe these results clearly support investigating the motixafortide/immune-checkpoint-inhibitor platform with other standard-of-care chemotherapies in earlier PDAC treatment lines, as well as in other ‘cold’ solid tumors. To that end, we are currently investigating motixafortide in combination with an anti-PD-1 and chemotherapy (gemcitabine and nab-paclitaxel) in first-line pancreatic cancer, and we are assessing potential combinations in other solid-tumor indications as well.

“These data are particularly exciting in light of the strikingly positive results of the interim analysis from our Phase 3 GENESIS study of motixafortide in stem cell mobilization that we recently announced in October. Motixafortide has now demonstrated clinical utility in two therapeutic areas through multiple mechanisms of action, supporting our belief that it can serve as the backbone of a number of promising combination therapies to treat a broad range of cancer types,” Mr. Serlin concluded.

BioLineRx plans to present the full data set at an upcoming medical conference.

KOL Webinar Information

BioLineRx will host a KOL webinar **today, December 16, 2020 at 8:00 a.m. EST**. The webinar will feature presentations by Key Opinion Leaders (KOLs) Gulam Manji, M.D., Ph.D. (Columbia University Medical Center), Manuel Hidalgo, M.D., Ph.D. (Weill Cornell Medicine), and Talia Golan, M.D. (Sheba Medical Center), who will discuss the current treatment landscape and unmet medical need in treating patients with pancreatic cancer, and the COMBAT study data. BioLineRx's management team will also discuss the COMBAT results. Drs. Hidalgo and Golan will be available to answer questions following the formal presentations.

Interested parties can register for the webinar here.

About COMBAT/KEYNOTE-202

The Phase 2a COMBAT/KEYNOTE-202 study was originally designed as an open-label, multinational, multicenter, single-arm trial to evaluate the safety, tolerability and efficacy of the dual combination of motixafortide and KEYTRUDA®, an anti-PD-1 therapy marketed by Merck & Co., Inc., Kenilworth, N.J., USA (known as MSD outside the United States and Canada), in 37 subjects with metastatic pancreatic adenocarcinoma (2L-5L). The dual combination study was conducted under a clinical trial collaboration agreement signed in 2016 between BioLineRx and MSD, through a subsidiary, where MSD provided KEYTRUDA® and BioLineRx was the study sponsor and owns all rights to motixafortide.

In July 2018, the Company announced the expansion of the collaboration with MSD to include a triple combination arm, as part of the COMBAT/KEYNOTE-202 study investigating the safety, tolerability and efficacy of motixafortide, KEYTRUDA and chemotherapy in 43 patients initially diagnosed with unresectable stage IV metastatic PDAC, who had progressed following first-line gemcitabine-based therapy. These results are being announced today.

The study was carried out primarily in the US, Spain and Israel.

About Motixafortide in Cancer Immunotherapy

Motixafortide is targeting CXCR4, a chemokine receptor and a well validated therapeutic target that is over-expressed in many human cancers including PDAC. CXCR4 plays a key role in tumor growth, invasion, angiogenesis, metastasis and therapeutic resistance, and CXCR4 overexpression has been shown to be correlated with poor prognosis.

Motixafortide is a short synthetic peptide used as a platform for cancer immunotherapy with unique features allowing it to function as a best-in-class antagonist of CXCR4. It shows high-affinity, long receptor occupancy and acts as an inverse agonist.

In a number of clinical and preclinical studies, motixafortide has been shown to affect multiple modes of action in 'cold' tumors, including immune cell trafficking, tumor infiltration by immune effector T cells, and reduction in immunosuppressive cells (such as MDSCs) within the tumor microenvironment, turning 'cold' tumors, such as pancreatic cancer, into "hot" (i.e., sensitizing them to immune checkpoint inhibitors and chemotherapy).

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 2018, approximately 450,000 individuals globally were diagnosed with this condition, 55,000 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 9%, 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 no new approved therapies 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 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.biolinerx.com, where you can review the Company's SEC filings, press releases, announcements and events.

Dr. Hidalgo is a paid consultant for InxMed, Agenus, and Tolero Pharmaceuticals, which are clinical-stage companies focused on treatments for cancer and other diseases. Dr. Hidalgo also has stock in Agenus, Inxmed, PharmaCyte Biotech Inc., as well as Champions Oncology Inc., a company that supports oncology drug development.

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 coronavirus outbreak; 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 March 12, 2020. 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.

Contact:
Tim McCarthy
LifeSci Advisors, LLC
+1-212-915-2564
tim@lifesciadvisors.com

or

Moran Meir
LifeSci Advisors, LLC
+972-54-476-4945
moran@lifesciadvisors.com