
**UNITED STATES
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 2012

BioLineRx Ltd.

(Translation of Registrant's name into English)

**P.O. Box 45158
19 Hartum Street
Jerusalem 91450, 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** ☒

Item 1.01 Entry into a Material Definitive Agreement

BioLineRx Ltd. (the "Company") announced today that on September 2, 2012 it entered into an agreement (the "Agreement") with Biokine Therapeutics Ltd. ("Biokine") to in-license the rights to BL-8040 (formerly BKT-140), for the treatment of acute myeloid leukemia, as well as other types of hematological cancer (the "Drug"). Pursuant to the Agreement, Biokine granted the Company an exclusive, worldwide, sublicensable license to develop, manufacture, market and sell certain technology relating to a short peptide that functions as a high affinity antagonist for CXCR4 and the uses thereof (the "Licensed Technology"). Closing of the transaction is subject to formal approval of the Office of the Chief Scientist of Israel's Ministry of Industry, Trade and Labor.

There are no upfront payments due under the Agreement. The Company is obligated to pay a monthly development fee for certain development services that Biokine has committed to provide under the Agreement, as follows:

- during the initial 12-month period following execution of the Agreement; \$100,000 per month;
- after the initial 12-month period and continuing until the earlier of (i) completion of the clinical trials contemplated under the Agreement or (ii) grant of a sublicense; \$65,000 per month for the following 12 months, \$60,000 per month for the next six months and \$50,000 per month thereafter.

The Company is responsible for paying all development costs incurred by the parties in carrying out the development plan.

The Agreement contemplates two clinical trials, studying the effects of the Drug on two types of cancer. If both clinical trials contemplated under the Agreement are completed within a given period, the Company is obligated to pay Biokine a bonus of \$250,000. This is the sole milestone payment due under the Agreement.

Should the Company independently develop, manufacture and sell products (excluding sublicensing) containing the Licensed Technology, it is obligated to make royalty payments to Biokine of between 10-12% of net sales, subject to certain limitations.

The Agreement also grants the Company the right to grant sublicenses for the Licensed Technology. In such event, the Company is required to pay Biokine a royalty payment of between 40-60% of the amounts it receives as consideration in connection with any sublicensing, development, manufacture, marketing, distribution or sale of the Licensed Technology. The amount of the royalty for either direct sales or sublicensing is dependent on the aggregate amount of the Company's investment in connection with the Agreement, decreasing as the amount of the Company's investment in the project increases.

Under the Agreement, the Company is obligated to make commercially reasonable good faith efforts to sublicense or commercialize the Drug for fair consideration. If the Company does not fulfill this obligation within 24 months after completion of the Development Plan, all of the rights and responsibilities with respect to commercialization of the Licensed Technology will revert to Biokine, and the Company's obligation to pay royalties for sales of any licensed products or sublicensing as described above will revert to Biokine.

Pursuant to the Agreement, the Company has the first right to prepare, file, prosecute and maintain any patent applications and patents, in respect of the Licensed Technology and any part thereof, at its expense, provided that the Company is required to consult with Biokine regarding patent prosecution and patent maintenance. In addition, the Company has the right to take action in the prosecution, prevention, or termination of any patent infringement of the Licensed Technology. The Company is responsible for all the expenses of any patent infringement suit that it brings, including any expenses incurred by Biokine in connection with such suits, with such expenses reimbursable from any sums recovered in such suit or in the settlement thereof. After such reimbursement, if any funds remain, the Company and Biokine are each entitled to a certain percentage of any remaining sums.

The Agreement will remain in full effect until the expiration of all of the Company's royalty and sublicense revenue obligations to Biokine, determined on a product-by-product and country-by-country basis. The Company may terminate the Agreement for any reason on 90 days' prior written notice to Biokine. Either party may terminate the Agreement for a material breach by the other party if the breaching party is unable to cure the breach within 30 days after receiving written notice of the breach from the non-breaching party. With respect to any termination for a material breach, if the breach is not susceptible to cure within the stated period and the breaching party uses diligent, good faith efforts to cure such breach, the stated period will be extended by an additional 30 days. In addition, either party may terminate the Agreement upon the occurrence of certain bankruptcy events.

Termination of the Agreement will result in a loss of all of the Company's rights to the Drug and the Licensed Technology, which will revert to Biokine. In addition, any sublicense of the Company of the Licensed Technology will terminate provided that, upon such termination and at the request of the sublicensee, Biokine will be required to enter into a separate license agreement with the sublicensee on substantially the same terms as those contained in the applicable sublicense agreement.

A copy of the press release announcing the Agreement is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

Exhibit 99.1 Press release dated September 4, 2012

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 Serlin
Philip Serlin
Chief Financial and Operating Officer

Date: September 4, 2012



FOR IMMEDIATE RELEASE

**BioLineRx In-Licenses a Novel, Phase II Ready Drug
for the Treatment of Leukemia and Other
Hematological Cancers**

- Phase II clinical trials are expected to commence in H1 2013 -

Jerusalem, Israel, September 4, 2012 --- BioLineRx Ltd. (NASDAQ: BLRX) (TASE: BLRX), a biopharmaceutical drug development company, announced today that it has signed an exclusive, worldwide license agreement with Biokine Therapeutics Ltd., a Clal Biotechnology Industries (TASE: CBI) portfolio company, for the development and commercialization of BL-8040 (formerly BKT-140), a Phase II ready drug candidate for the treatment of acute myeloid leukemia (AML), as well as other types of hematological cancer.

BL-8040 is a short peptide that functions as a high-affinity antagonist for CXCR4, a chemokine receptor that is directly involved in tumor progression, angiogenesis (growth of new blood vessels in the tumor), metastasis (spread of the disease to other organs or organ parts) and cell survival. CXCR4 is over-expressed in more than 70% of human cancers and its expression often correlates with disease severity. In a Phase I/II, open-label, dose escalation, safety and efficacy clinical trial in 16 multiple myeloma patients, BL-8040 demonstrated an excellent safety profile and was well tolerated at all doses tested. On the basis of data obtained from this study, the FDA has approved an IND application.

BL-8040 has been shown to induce the mobilization of healthy hematopoietic stem cells from the bone marrow into the peripheral blood. BL-8040 also mobilizes cancer cells from the bone marrow and other sites and may therefore expose these cells to chemo- and bio-based anti-cancer therapy and induce apoptosis (cell death). Pre-clinical studies show that BL-8040 is efficient, both alone and in combination with the anti-cancer drug Rituximab, in reducing bone marrow metastasis of lymphoma cells and stimulating lymphoma cell death.

Dr. Kinneret Savitsky, CEO of BioLineRx, commented, "BioLineRx has made a strategic decision to enter the field of oncology, where there is clearly an urgent need for next generation anti-cancer therapies utilizing novel biological pathways. We are therefore extremely pleased to in-license this promising Phase II ready drug, which we will initially develop for the treatment of acute myeloid leukemia, a true unmet medical need with very low survival rates. AML is a recognized orphan indication both in the U.S. and the EU; therefore, we plan to seek orphan designation status from the regulatory authorities in order to accelerate its development plan. In addition, based on BL-8040's promising pre-clinical data, as well its mechanism of action, we believe it can be utilized for several other related oncology indications and we intend to explore these possibilities as well. We look forward to the upcoming Phase II clinical study for evaluating BL-8040's efficacy on AML patients, which is expected to commence in the first half of 2013."

"We are very happy that BioLineRx will further develop this promising anti-cancer agent, and are confident that BioLineRx's experience and expertise will advance BL-8040 through the clinical development stages in the most efficient manner," said Professor Amnon Peled, from the Gene Therapy Institute, Hadassah Medical Center - Jerusalem, founder and CEO of Biokine Therapeutics.

"CXCR4 is one of the most important cancer targets discovered in recent years. It is essential for multiple aspects of cancer progression in over 70% of all cancers, including leukemia, breast, lung, colon, and prostate cancer. BL-8040, as a CXCR4 antagonist, therefore has the potential to target and kill various cancer cells, and studies in animal models of the disease have shown that this agent may stimulate hematological cancer cell death. In addition, for many blood cancers, the bone marrow provides protection for malignant cells from chemotherapeutic agents. Therefore, by inducing mobilization of these cells into the peripheral blood, CXCR4 antagonists literally 'flush out' the malignant cells from their hiding places.

"We have demonstrated in pre-clinical studies that BL-8040 is very effective in mobilizing cells out of the bone marrow, thus sensitizing chemo-resistant cells and improving treatment with other anti-cancer drugs," concluded Professor Peled.

Terms of the License Agreement

There are no upfront payments due pursuant to the agreement. BioLineRx is obligated to pay a monthly development fee ranging from \$50K to \$100K for certain development services that Biokine has committed to provide under the agreement. If the agreed-upon clinical development plan is completed within certain defined timelines, BioLineRx is obligated to pay Biokine a milestone payment of \$250K. The agreement does not contain any other milestone payments. Upon any sub-licensing transaction to a third party, BioLineRx is required to pay Biokine a royalty payment on a sliding scale, beginning at 60% of the amounts received as consideration in connection with the sublicensing, and decreasing to 40% of such consideration, based on the aggregate amount of BioLineRx's investment in the project. Closing of the transaction is subject to formal approval of the Office of the Chief Scientist of Israel's Ministry of Industry, Trade and Labor.

About Acute Myeloid Leukemia (AML)

AML is a very aggressive form of leukemia, characterized by uncontrolled proliferation of immature white blood cells called myeloid cells in the bone marrow and peripheral circulation. AML is the most common form of adult acute leukemia, accounting for 80% of all diagnosed cases, with approximately 13,000 new cases diagnosed in the U.S., as well as 30,000 new cases diagnosed in the seven leading markets, in 2011. The incidence of AML is expected to further increase as the population of developed countries continues to age.

AML is currently treated with a combination of chemotherapeutic agents and stem cell transplantation. However, the past 20 years have seen little improvement in overall patient survival rates, which are less than 25% within five years from diagnosis. Accordingly, AML is considered a true unmet medical need and there is a significant urgency for developing more effective and tolerable treatments for AML patients, particularly those with relapsed or refractory disease. The AML therapeutics market was estimated at \$200 million in 2010, and it is projected to significantly grow with the development of new targeted therapies, reaching over \$600 million by 2017. The total leukemia therapeutics market was valued at \$6.3 billion in 2010, and is expected to reach \$11.3 billion by 2020.

About BioLineRx

BioLineRx is a publicly-traded biopharmaceutical development company. BioLineRx is dedicated to building a portfolio of products for unmet medical needs or with advantages over currently available therapies. BioLineRx's current portfolio consists of six clinical stage candidates: BL-1020 for schizophrenia is currently undergoing a Phase II/III study; BL-1040, for prevention of pathological cardiac remodeling following a myocardial infarction, which has been out-licensed to Ikaria Inc., is currently undergoing a pivotal CE-Mark registration trial; BL-5010 for non-surgical removal of skin lesions has completed a Phase I/II study; BL-1021 for neuropathic pain is in Phase I development, BL-7040 for treating inflammatory bowel disease (IBD) has commenced a Phase II trial, and BL-8040 for treating acute myeloid leukemia (AML) has completed Phase I. In addition, BioLineRx has nine products in various pre-clinical development stages for a variety of indications, including central nervous system diseases, infectious diseases, cardiovascular and autoimmune diseases.

BioLineRx's business model is based on acquiring molecules mainly from biotechnological incubators and academic institutions. The Company performs feasibility assessment studies and development through pre-clinical and clinical stages, with partial funding from the Israeli Government's Office of the Chief Scientist (OCS). The final stage includes partnering with medium and large pharmaceutical companies for advanced clinical development (Phase III) and commercialization. For more information on BioLineRx, please visit www.biolinerx.com.

Various statements in this release concerning BioLineRx's future expectations, plans and prospects, including specifically those related to the development and commercialization of BL-8040, 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 22, 2012. 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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