



BioLineRx Acquires Rights to leading Schizophrenia Drug Candidate BL-1020

May 11, 2011 9:30 AM IDT

Jerusalem, Israel, May 11, 2011 – BioLineRx Ltd. (TASE: BLRX), a biopharmaceutical development company dedicated to building a portfolio of products for unmet medical needs or with advantages over currently available therapies, announced today the signing of an agreement with Cypress Bioscience Inc. for the reacquisition of rights to BL-1020.

BioLineRx had previously reported in June 2010 the signing of an agreement with Cypress, pursuant to which Cypress was granted an exclusive sub-license to BL-1020 (for the treatment of schizophrenia) in North America (US, Canada and Mexico) for its continued development and commercialization. Pursuant to a request by Cypress, BioLineRx has agreed to reacquire, effective June 1, 2011, all of the development and commercialization rights to BL-1020 in North America, and to terminate the license agreement with Cypress. Based on the understandings reached, on May 10, 2011, the parties signed an agreement for the reacquisition of the above rights.

"Since the signing of the license agreement in June 2010, Cypress has put forth significant efforts to advance the development of BL-1020 and is currently finalizing preparations for the commencement of a clinical trial in India and Romania," commented Dr. Kinneret Savitsky, CEO of BioLineRx. "We would like to point out that the clinical preparatory and regulatory activities performed by Cypress to date have been carried out to our satisfaction. We expect recruitment of the first patient in the trial during June 2011, after completion of final preparations by Cypress and receipt of the required regulatory approvals. Pursuant to our agreement, the parties are to cooperate fully in order to avoid any delays to commencement of the trial."

"We reached the decision to enter into this agreement as a result of discussions recently held with Royalty Pharma, the parent company of Cypress, and Cypress," continued Dr. Savitsky. "During such discussions, Royalty Pharma and Cypress indicated that as a result of a recent change in their strategy, they believe it is in the best interest of the product's future commercial potential to consolidate the worldwide rights with BioLineRx. Cypress expressed its desire that development of the product continue in a manner that both optimized its investment in the product and provided the best long-term commercialization potential."

Dr. Savitsky concluded, "Our Board of Directors held a number of discussions regarding the new circumstances created. As a result of such discussions, our Board concluded that the agreement, which ensures that the product's development will continue without delay and that BioLineRx will hold worldwide rights, is the best alternative for the Company at this point and represents a significant opportunity. This conclusion was reached in light of the Board's belief in the importance of BL-1020, as well as the clinical and pre-clinical results that have been achieved to date."

"Based on information received from Cypress, through the date of this announcement, approximately \$10 million has been invested in preparation for the trial (in addition to the \$30 million upfront payment that was paid to the Company upon signing of the License Agreement), and it is estimated that an additional \$10-12 million will be required to complete the trial. As of the date of this announcement, BioLineRx has the financial resources to complete the trial. We intend to seek, in the near term, additional funding sources to cover the remaining cost of the trial, in a manner that will not delay the start of the trial, and that will allow the Company to continue to develop the rest of its product portfolio without any significant change in our current operating plan. In addition, concurrent with the advancement of the trial and in accordance with our business strategy, BioLineRx intends to renew its efforts to seek an out-licensing partner for the continued development and commercialization of the product at its more advanced stages."

Agreement Terms

In consideration for the reacquisition of rights by BioLineRx, the Company will pay Cypress a 1% royalty on worldwide net sales of the product up to an aggregate cumulative royalty of \$80 million. In addition, the Company will pay Cypress 10% of all future one-time payments, not to exceed a total of \$10 million, as reimbursement for costs that Cypress has incurred in developing the intellectual property portfolio, designing the trial and conducting substantially all the preparations to launch the trial.

About BL-1020

BL-1020 is a novel, first in class, oral therapeutic for schizophrenia. Pre-clinical and clinical trials to date have shown that BL-1020 is effective at treating schizophrenia symptoms and has a good safety profile. These trials have shown that BL-1020 blocks activity of the neurotransmitter dopamine and enhances the activity of another neurotransmitter, GABA. These characteristics may contribute to the efficacy and safety of the drug. In addition, clinical trials have shown that BL-1020 improves cognitive function in schizophrenia patients. Many schizophrenia patients suffer from a significant decrease in cognitive function, which is an unmet medical need not addressed by current therapies.

Preparations are currently being finalized for an additional clinical trial focusing on cognitive function in schizophrenia. The trial is planned to be a randomized, double-blind, placebo-controlled clinical trial to examine both acute (6 weeks) and long-term (6 months) antipsychotic and cognitive efficacy, safety and tolerability of BL-1020 on patients with acute schizophrenia.

About BioLineRx

BioLineRx Ltd. is a publicly-traded (TASE: BLRX) 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 business model is based on acquiring molecules, mainly from biotechnological incubators and Israeli academic institutions. The next stages, which include feasibility assessment studies and development through pre-clinical and clinical stages, are performed with partial funding from the Israeli Government's Office of the Chief Scientist (OCS). The final stage includes partnering with medium to large pharma companies to continue advanced clinical development and commercialization.

BioLineRx's current portfolio consists of three clinical stage candidates (BL-1040, BL-1020 and BL-5010), as well as nine products in various pre-clinical development stages spanning a variety of indications, including central nervous system diseases, oncology, infectious diseases, cardiovascular and autoimmune diseases. BioLineRx also operates a unique Early Development Program (EDP) to develop innovative early-stage projects until sufficient data is obtained for entry into the Company's main portfolio. In July 2009, BL-1040, for treatment following acute myocardial infarction, was out-licensed to Ikaria Inc. for a total deal value of \$282.5 million, in addition to sales royalties.

For more information about BioLineRx, please visit our website at www.biolinerx.com.

Forward Looking Statements

The estimates and judgments included in this release are considered forward-looking statements, which involve certain risks and uncertainties, and are based on information available to the Company at the time of this release. Such estimates, including clinical trial commencement dates, may not be realized or may be only partially realized, due to the significant uncertainty characterizing research and development activities in general, particularly those of drug development, including changes in regulation or uncertainty relating to the application of regulation, unexpected delays in obtaining regulatory approval, unexpected delays in patient recruitment for clinical trials, unexpected delays in other clinical trial preparatory activities, inefficiencies, inability to manufacture, toxicity, a high level of risk/reward in comparison to current treatments available, as well as new information regarding intellectual property rights which may affect the economic viability of continued product development. The Company assumes no responsibility for updating forward-looking statements made herein or otherwise.