
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 May 2018

Commission File Number: 001-37643

KITOV PHARMA LTD.
(Translation of registrant's name into English)

**One Azrieli Center, Round Tower,
132 Menachem Begin Road, Tel Aviv 6701101, Israel**
(Address of principal executive offices)

Indicate by check mark whether the registrant files or will file annual reports under cover 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 Regulation S-T Rule 101(b)(1): _____

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(7): _____

Kitov Pharma Ltd. (the “Company” or the “Registrant”) is announcing that it has signed a definitive License, Development and Commercialization Agreement for its lead product candidate, Consensi™ (formerly KIT-302), which was developed to simultaneously treat pain caused by osteoarthritis and to treat hypertension, for the territory of China with Hebei Changshan Biochemical Pharmaceutical Co., Ltd. (Changshan Pharma), a Chinese public company traded on the Shenzhen Stock Exchange. Upon receipt of marketing authorization in China, Changshan Pharma will have the exclusive right and license to import, manufacture, distribute and sell Consensi™ in China, Taiwan, Hong Kong and Macao. Changshan Pharma will be responsible for seeking regulatory approval for Consensi™ in China. Under the terms of the agreement, Kitov is entitled to receive up to an aggregate of \$3.5 million for U.S. FDA approval of Consensi™, which has a PDUFA date of May 31, 2018, and for China regulatory milestones; up to an aggregate of \$6.0 million for predefined commercial milestones; and up to 12% royalties on net sales. The initial term of the definitive agreement with Changshan Pharma is for ten years from the date of first commercial sale and shall automatically renew for additional one-year terms. On May 11, 2018, the Company issued a press release in connection with the agreement with Changshan Pharma, “**Kitov Announces Consensi™ Commercialization Agreement for China**”, which is attached hereto as Exhibit 99.1.

Exhibit 99.1 [Press Release](#)

Forward-Looking Statements and the Company’s Safe Harbor Statement

Certain statements in this Report on Form 6-K are forward-looking statements within the meaning of the safe harbor provisions of the Private Securities Litigation Reform Act of 1995 and other applicable securities laws. Forward-looking statements can be identified by the use of forward-looking words such as “believe”, “expect”, “intend”, “plan”, “may”, “should”, “could”, “might”, “seek”, “target”, “will”, “project”, “forecast”, “continue” or “anticipate” or their negatives or variations of these words or other comparable words or by the fact that these statements do not relate strictly to historical matters. You should not place undue reliance on these forward-looking statements, which are not guarantees of future performance. Forward-looking statements reflect our current views, expectations, beliefs or intentions with respect to future events, and are subject to a number of assumptions, involve known and unknown risks, many of which are beyond our control, as well as uncertainties and other factors that may cause our actual results, performance or achievements to be significantly different from any future results, performance or achievements expressed or implied by the forward-looking statements. Important factors that could cause or contribute to such differences include, among others, risks relating to: the fact that drug development and commercialization involves a lengthy and expensive process with uncertain outcomes; our ability to successfully develop and commercialize our pharmaceutical products; the expense, length, progress and results of any clinical trials; the lack of sufficient funding to finance the clinical trials; the impact of any changes in regulation and legislation that could affect the pharmaceutical industry; the difficulty in receiving the regulatory approvals necessary in order to commercialize our products; the difficulty of predicting actions of the U.S. Food and Drug Administration or any other applicable regulator of pharmaceutical products; the regulatory environment and changes in the health policies and regimes in the countries in which we operate; the uncertainty surrounding the actual market reception to our pharmaceutical products once cleared for marketing in a particular market; the introduction of competing products; patents attained by competitors; dependence on the effectiveness of our patents and other protections for innovative products; our ability to obtain, maintain and defend issued patents with protective claims; the commencement of any patent interference or infringement action; our ability to prevail, obtain a favorable decision or recover damages in any such action; and the exposure to litigation, including patent litigation, and/or regulatory actions; the uncertainty surrounding an investigation by the Israel Securities Authority into our historical public disclosures and the potential impact of such investigation on the trading of our securities or on our clinical, commercial and other business relationships, or on receiving the regulatory approvals necessary in order to commercialize our products, and other factors that are discussed in our in our Annual Report on Form 20-F for the year ended December 31, 2017 and in our other filings with the SEC, including our cautionary discussion of risks and uncertainties under ‘Risk Factors’ in our Registration Statements and Annual Reports. These are factors that we believe could cause our actual results to differ materially from expected results. Other factors besides those we have listed could also adversely affect us. Any forward-looking statement in this Report on Form 6-K speaks only as of the date which it is made. We disclaim any intention or obligation to publicly update or revise any forward-looking statement, or other information contained herein, whether as a result of new information, future events or otherwise, except as required by applicable law. You are advised, however, to consult any additional disclosures we make in our reports to the SEC, which are available on the SEC’s website, <http://www.sec.gov>

This Form 6-K, excluding Exhibit 99.1, is incorporated by reference into each of the Registrant’s Registration Statements on Form F-3 filed with the Securities and Exchange Commission on December 12, 2016 (Registration file numbers 333-207117, 333-211477 and 333-215037), the Registrant’s Registration Statement on Form S-8 filed with the Securities and Exchange Commission on May 20, 2016 (Registration file number 333-211478), and the Registrant’s Registration Statement on Form S-8 filed with the Securities and Exchange Commission on June 6, 2017 (Registration file number 333-218538).

SIGNATURES

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.

KITOV PHARMA LTD.

May 11, 2018

By: /s/ Simcha Rock
Simcha Rock
CFO & Director

Kitov Announces Consensi™ Commercialization Agreement for China

Kitov to receive milestone payments of up to \$9.5 million, as well as potential double-digit royalties

Consensi™ PDUFA date of May 31, 2018, Upcoming

TEL AVIV, Israel, May 11, 2018 / GlobeNewsWire/ --

Kitov Pharma Ltd. (NASDAQ: KTOV; TASE: KTOV), an innovative biopharmaceutical company, announced today that the Company has signed a definitive license and commercialization agreement for the Chinese market, granting exclusive rights to import, manufacture and distribute its lead drug candidate, Consensi™, in China to Hebei Changshan Biochemical Pharmaceutical Co., Ltd. (Changshan Pharma), a Chinese public company traded on the Shenzhen Stock Exchange.

Consensi™, formerly known as KIT-302, is a combination drug intended to simultaneously treat pain caused by osteoarthritis, and hypertension, which is a common side effect of stand-alone drugs that treat osteoarthritis pain. Consensi™ is comprised of two FDA-approved drugs, celecoxib (Celebrex®), a non-steroidal anti-inflammatory COX-2 inhibitor (NSAID) for the treatment of pain caused by osteoarthritis, and amlodipine besylate (Norvasc®), a calcium channel blocker for lowering blood pressure.

Upon receipt of marketing authorization in China, Changshan Pharma will have the exclusive right and license to import, manufacture, distribute, and sell Consensi™ in China, Taiwan, Hong Kong, and Macao. Changshan Pharma will be responsible for financing and seeking regulatory approval for Consensi™ in China. Under the terms of the agreement, Kitov is entitled to receive up to an aggregate of \$3.5 million for U.S. FDA approval of Consensi™, which has a PDUFA date of May 31, 2018, and for China regulatory milestones; up to an aggregate of \$6.0 million for predefined commercial milestones; and up to 12% royalties on net sales.

“We are extremely pleased to enter into this commercialization agreement for Consensi™ and look forward to building a long-term relationship with Changshan Pharma in China. Changshan Pharma has a strong track record of successfully launching and marketing pharmaceutical products in China,” said Dr. Gil Ben-Menachem, Kitov’s Vice President - Business Development. “This is the second commercialization agreement for Consensi™ in Asia, further confirming its global sales potential. Kitov continues to work diligently towards finalizing additional commercialization agreements in the U.S. and in other territories.”

“We believe that Consensi™ has substantial commercial potential in China and will provide significant benefit to Chinese patients. We are well-positioned to maximize the value of this product in the Chinese market, and look forward to seeking regulatory approval and launching Consensi™ in China,” said Mr. Shuhua Gao, Chairman and General Manager of Changshan Pharma.

The total annual NSAID market in China is estimated at hundreds of millions of dollars, according to IMS. Moreover, celecoxib sales in China represented 25% of the total NSAID market. In recent years, sales of selective COX-2 inhibitors (coxibs), and especially Celebrex® (Pfizer’s branded celecoxib), have been increasing in China at an annual rate of 25 percent.

About Kitov Pharma

Kitov Pharma (Kitov Pharma Ltd.; NASDAQ/TASE: KTOV) is an innovative biopharmaceutical drug development group of companies. Leveraging deep regulatory and clinical-trial expertise, Kitov's veteran team of healthcare and business professionals maintains a proven track record in streamlined end-to-end drug development and approval. Kitov's flagship combination drug, Consensi™, intended to treat osteoarthritis pain and hypertension simultaneously, achieved the primary efficacy endpoints for its Phase III and Phase III/IV clinical trials. NT219, which is developed by its majority-owned subsidiary, TyrNovo Ltd., is a novel patented small molecule designed to overcome cancer drug resistance that is currently in pre-clinical development. By lowering development risk and cost through fast-track regulatory approval of novel late-stage therapeutics, Kitov plans to deliver rapid ROI and long-term potential to investors, while making a meaningful impact on people's lives. For more information on Kitov, the content of which is not part of this press release, please visit <http://www.kitovpharma.com>.

About Changshan Pharma

Hebei Changshan Biochemical Pharmaceutical Co., Ltd. (Changshan Pharma) is a fully-integrated, publicly-traded (stock code: 300255) pharmaceutical company with headquarters in Shijiazhuang, Hebei, China. Changshan Pharma is a leading supplier of Heparin and Low Molecular Weight Heparin pharmaceutical products from its state-of-the-art manufacturing facilities. Changshan Pharma has a long history of international collaborations leading to a deep and diverse pipeline of innovative products across various therapeutic categories and dosage forms.

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