
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 October 2019

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 on October 11, 2019, the Company issued a press release “**Kitov Pharma Announces Amended Marketing and Distribution Agreement with Coeptis and Provides Update on the Upcoming Launch of Consensi™ in the U.S.**”, which is attached hereto as Exhibit 99.1.

Exhibits:

Exhibit 99.1 [Press Release](#)

This Form 6-K, including the entire Exhibit 99.1 attached hereto, is hereby 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), 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), the Registrant's Registration Statement on Form F-3, as amended, originally filed with the Securities and Exchange Commission on July 16, 2018 (Registration file number 333-226195), the Registrant's Registration Statement on Form S-8 filed with the Securities and Exchange Commission on March 28, 2019 (Registration file number 333-230584) and the Registrant's Registration Statement on Form F-3 filed with the Securities and Exchange Commission on September 16, 2019 (Registration file number 333-233795).

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.

October 11, 2019

KITOV PHARMA LTD.

By: /s/ Isaac Israel
Isaac Israel
CEO & Director

Kitov Pharma Announces Amended Marketing and Distribution Agreement with Coeptis and Provides Update on the Upcoming Launch of Consensi™ in the U.S

- *In the amended agreement with Coeptis, Kitov will receive up to \$99.5M in milestone and reimbursement payments plus 20% in royalties*
- *Coeptis Pharmaceuticals has engaged a distribution partner with an established sales network and access to thousands of pharmacies nationwide*

TEL AVIV, Israel, Oct. 11, 2019 (GLOBE NEWSWIRE) -- Kitov Pharma Ltd. ("Kitov") (NASDAQ/TASE: KTOV), a clinical-stage company advancing first-in-class therapies to overcome tumor immune evasion and drug resistance, today announced the amendment of the marketing and distribution agreement with Coeptis Pharmaceuticals and provided an update on the upcoming launch of Consensi in the U.S:

- Marketing and distribution agreement with Coeptis Pharmaceuticals for commercialization of Consensi™ in the U.S has been amended. Kitov will receive up to \$99.5M in milestone and reimbursement payments plus 20% in royalties, with a minimum aggregate of \$7 million in the next 3 years.
- Coeptis has engaged a distribution partner with an established sales network and access to thousands of pharmacies to drive the launch of the drug. In addition, a marketing plan and pricing strategy have been finalized.
- Manufacturing of the initial commercial batches is now in its latest phases and will soon be ready for packaging and shipping to the U.S.

"As we get closer to the launch of Consensi™ in the U.S., we are excited about Coeptis' commercialization strategy and welcome Coeptis' new partners who have an established distribution and operations infrastructure. We believe that their expertise and immense network will boost sales and will establish Consensi™ as an ideal therapeutic option for patients suffering from both osteoarthritis related pain and hypertension," said Isaac Israel, chief executive officer of Kitov. "In addition, the terms of the amended agreement create near-term revenue streams to support further development of our oncology pipeline – a key focus for Kitov."

"Our agreement with Kitov is mutually beneficial and the updated agreement is another solid example of the strong collaboration between Coeptis and Kitov. We look forward to continuing our close relationship with Kitov, especially as we gear up to launch Consensi™ in the US," said Modi Obochi, president and chief executive officer of Coeptis. "The recent selection of a distribution partner for Consensi™ illustrates our strong commitment to meet our business objectives and to provide therapeutic options to the patients. We look forward to leveraging the cash flow from Consensi™ to advance our portfolio."

Under the terms of the amended agreement Kitov will receive 20% in royalties on net sales of Consensi™ with minimum royalties of \$4.5M over the next 3 years. In addition, Kitov is entitled to receive up to \$99.5M in milestone and reimbursement payments, of which \$1M was previously received, \$1.5M is expected before the end of the year in connection with the manufacturing of the initial commercial batches, an additional \$1M is due following the first commercial sale of Consensi™ in the U.S. and \$96M which is subject to certain pre-defined commercial milestones.

About Consensi™

Consensi™ is a fixed-dose combination of celecoxib, a non-steroidal anti-inflammatory drug (NSAID) for the treatment of pain caused by osteoarthritis, and amlodipine besylate, a drug designed to treat hypertension. The U.S. Food & Drug Administration (FDA) approved Consensi™ oral tablets for marketing on May 2018 and partnered in the U.S, China and South Korea. Consensi™ is under patent protection in the U.S. until 2030 and will be the only NSAID whose labeling indicates a reduction of blood pressure and consequent risk reduction of heart attack, stroke and death.

Full US Prescribing Information, including BOXED WARNING and Medication Guide is available at: www.consensi.com.

Indications and Usage:

Consensi™ is a combination of amlodipine besylate, a calcium channel blocker, and celecoxib, a nonsteroidal anti-inflammatory drug (NSAID), indicated for patients for whom treatment with amlodipine for hypertension and celecoxib for osteoarthritis are appropriate. Lowering blood pressure reduces the risk of fatal and nonfatal CV events, primarily strokes and myocardial infarctions.

Limitations of Use:

Consensi™ is only available in a celecoxib strength of 200 mg and is only to be taken once daily.

Important Safety Information (ISI) for Consensi™

The following ISI is based on the Highlights section of the U.S. Prescribing Information for Consensi™. Please consult the full Prescribing Information for all of the labelled safety information for Consensi™.

Nonsteroidal anti-inflammatory drugs (NSAIDs) cause an increased risk of serious cardiovascular (CV) thrombotic events, including myocardial infarction and stroke, which can be fatal. This risk may occur early in the treatment and may increase with duration of use.

Consensi™ is contraindicated in the setting of coronary artery bypass graft (CABG) surgery.

NSAIDs cause an increased risk of serious gastrointestinal (GI) adverse events, including bleeding, ulceration and perforation of the stomach or intestines, which can be fatal. These events can occur at any time during use and without warning symptoms. Elderly patients and patients with a prior history of peptic ulcer disease and/or GI bleeding are at greater risk for serious GI events.

Consensi™ is contraindicated in patients with a known hypersensitivity to amlodipine, celecoxib or any of its inactive ingredients.

Consensi™ is contraindicated in patients with a known history of asthma, urticaria or other allergic-type reactions after taking aspirin or other NSAIDs and in the setting of CABG surgery.

Consensi™ is contraindicated in patients with known demonstrated allergic-type reactions to sulfonamides.

Significant warnings and precautions related to Consensi™ include the following:

Patients should be warned about the potential signs and symptoms of hepatotoxicity and hepatic failure. Physicians should discontinue Consensi™ if abnormal liver tests persist or worsen, or if clinical signs and symptoms of liver disease develop.

Patients taking some antihypertensive medications may have impaired response to these therapies when taking NSAIDs. Physicians should carefully monitor blood pressure.

Symptomatic hypotension is possible, particularly in patients with severe aortic stenosis.

Worsening angina and acute myocardial infarction, particularly in patients with severe obstructive coronary artery disease, is possible.

Physicians should avoid use of Consensi™ in patients with severe heart failure.

Physicians should monitor renal function in patients with renal or hepatic impairment, heart failure, dehydration, or hypovolemia, and avoid the use of Consensi™ in patients with advanced renal disease.

Patients should seek emergency help if an anaphylactic reaction occurs.

Consensi™ is contraindicated in patients with aspirin-sensitive asthma. Monitor patients with preexisting asthma (without aspirin sensitivity).

Physicians should discontinue Consensi™ at the first appearance of skin rash or other signs of hypersensitivity.

NSAIDs such as Consensi™ can cause premature Closure of Fetal Ductus Arteriosus.

Avoid use in pregnant women starting at 30 weeks of gestation.

Physicians should monitor hemoglobin or hematocrit in patients with any signs or symptoms of anemia.

Consensi™ is not recommended in patients with moderate or severe hepatic impairment or severe renal insufficiency.

Consensi™ is not recommended in Poor Metabolizers of CYP2C9 Substrates.

To report SUSPECTED ADVERSE REACTIONS, contact Coeptis Pharmaceuticals at 1-800-651-6606 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch

About Coeptis Pharmaceuticals

Coeptis Pharmaceuticals, Inc. is a privately held biopharmaceutical company engaged in the acquisition, development and commercialization of innovative products that utilizes the 505(b)2 pathways. Coeptis licensed FDA-approved Consensi™ (a combination of amlodipine and celecoxib), which is indicated for patients for whom treatment with amlodipine for hypertension and celecoxib for osteoarthritis are appropriate. It is in the process of launching Consensi™ in the US through a distribution partner with an established sales network to thousands of pharmacies nationwide. Headquartered near Pittsburgh, PA, Coeptis has put together seasoned pharmaceutical executives with demonstrated successes growing revenues and shareholder value and has a robust pipeline of 505(b)2 products at various stages of development. For more information, please visit www.coeptispharma.com.

About Kitov Pharma

Kitov Pharma (Kitov Pharma Ltd.; NASDAQ/TASE: KTOV) is a clinical-stage company advancing first-in-class therapies to overcome tumor immune evasion and drug resistance, to create successful long-lasting treatments for people with cancer. Kitov's oncology pipeline includes NT-219, a small molecule targeting the novel cancer drug resistance pathways IRS1/2 and STAT3. Kitov is currently advancing NT-219 in combination with cetuximab as a third-line or second-line treatment option for the treatment of recurrent and metastatic squamous cell carcinoma of head & neck cancer (SCCHN). Kitov is also under contract to acquire 100% of FameWave Ltd. which owns CM-24, a monoclonal antibody blocking CEACAM1, a novel immune checkpoint that supports tumor immune evasion and survival through multiple pathways. Kitov will advance CM-24 as a combination therapy with anti-PD1 checkpoint inhibitors for the treatment of non-small cell lung cancer (NSCLC). Following the receipt of the approval of Kitov's shareholders for the acquisition of FameWave, and the finalization of a clinical collaboration agreement between FameWave and Bristol Myers Squibb (NYSE:BMJ) for the planned Phase 1/2 clinical trials to evaluate the combination of CM-24 with the PD-1 inhibitor nivolumab (Opdivo®), the acquisition is expected to close during 2019, subject to fulfillment of certain additional closing conditions. Consensi, a fixed-dose combination of celecoxib and amlodipine besylate, for the simultaneous treatment of osteoarthritis pain and hypertension was approved by the FDA for marketing in the U.S in May 2018 and is expected to be launched in the U.S. by early 2020 by its partner Copeptis Pharmaceuticals. Kitov has also partnered to commercialize Consensi in China and South Korea. The company is headquartered in Tel Aviv, Israel. For more information, please visit <http://www.kitovpharma.com>.

Forward-Looking Statements and Kitov's Safe Harbor Statement

Certain statements in this press release that are forward-looking and not statements of historical fact are forward-looking statements within the meaning of the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. Such forward-looking statements include, but are not limited to, statements that are not statements of historical fact, and may be identified by 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 manner in which the parties to the transaction for the acquisition of FameWave by Kitov plan to effect the transaction; the expected benefits, synergies and costs of the transaction; management plans relating to the transaction; the expected timing of the completion of the transaction; the parties' ability to complete the transaction considering the various closing conditions; the plans, strategies and objectives of management for future operations; product development for NT219 and CM-24; the potential future financial impact of the transaction; and any assumptions underlying any of the foregoing; the process by which early stage products such as CM-24 could potentially lead to an approved product is long and subject to highly significant risks, particularly with respect to a joint development collaboration; 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, and other factors that are discussed in our in our Annual Report on Form 20-F for the year ended December 31, 2018 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 press release 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>

Investor Contact

Gil Efron
Deputy & Chief Financial Officer
IR@kitovpharma.com
+972-3-933-3121 ext. #105

Media Contact:

Gloria Gasaatura
ggsaatura@lifescipublicrelations.com
+1 646 627 8387