
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 November 2020
Commission File Number: 001-37643

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

One Azrieli Center, Round Tower, 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): ☐

On November 9, 2020, Kitov Pharma Ltd. (the “Company” or the “Registrant”) issued a press release, “**Kitov Expands Planned Phase 1/2 Clinical Trial of CM24 in Non-Small Cell Lung Cancer with New Cohort to Evaluate CM24 in Patients with Pancreatic Cancer Conducted with Bristol Myers Squibb**”, which is attached hereto as Exhibit 99.1.

Exhibits

99.1 [Press Release](#)

Incorporation by Reference

This Form 6-K, including all exhibits 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](#) and [333-211477](#)), 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), 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), the Registrant’s Registration Statement on [Form F-3](#) filed with the Securities and Exchange Commission on December 2, 2019 (Registration file number 333-235327), the Registrant’s Registration Statement on [Form F-3](#) filed with the Securities and Exchange Commission on May 13, 2020 (Registration file number 333- 238229), the Registrant’s Registration Statement on [Form S-8](#) filed with the Securities and Exchange Commission on May 28, 2020 (Registration file number 333-238481) and each of the Registrant’s Registration Statements on Form F-3 filed with the Securities and Exchange Commission on July 10, 2020 (Registration file numbers [333-239807](#) and [333-233793](#)), to be a part thereof from the date on which this report is submitted, to the extent not superseded by documents or reports subsequently filed or furnished.

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.

November 9, 2020

KITOV PHARMA LTD.

By: /s/ Isaac Israel
Isaac Israel
Chief Executive Officer

Kitov Expands Planned Phase 1/2 Clinical Trial of CM24 in Non-Small Cell Lung Cancer with New Cohort to Evaluate CM24 in Patients with Pancreatic Cancer Conducted with Bristol Myers Squibb

The new cohort will explore the combination of CM24, Opdivo (“nivolumab”) and Abraxane (“albumin-bound paclitaxel; nab-paclitaxel”) in patients with pancreatic cancer

TEL AVIV, Israel, Nov. 09, 2020 (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 that the company and Bristol Myers Squibb have amended their Clinical Trial Collaboration and Supply Agreement to reflect the expansion of the planned Phase 1/2 clinical trial evaluating CM24 in advanced non-small cell lung cancer (NSCLC) with a new cohort to also evaluate CM24 in patients with pancreatic cancer.

The Phase 1/2 clinical trial will evaluate CM24, a monoclonal antibody targeting CEACAM1, in combination with nivolumab (Opdivo®) in patients with advanced non-small cell lung cancer. With this expansion, the trial is now also planned to evaluate CM24 in combination with nivolumab in addition to nab-paclitaxel (ABRAXANE®) in patients with pancreatic cancer.

In an initial Phase 1 study consisting of a monotherapy dose escalating IV administration of CM24 administered every two weeks, in 27 patients with advanced malignancies, CM24 was found to be safe and well-tolerated in all patients, with no discontinuations of study drug or dose limiting toxicities (up to 10mg/kg). In the efficacy evaluable patients (n=24), subjects were highly refractory to therapy, having received between two and eight prior therapies (with a median of four). Eight of the evaluable patients (33%) achieved stable disease, with most of these patients responding at the higher dose levels of 3mg/kg and 10mg/kg. Pharmacokinetic analysis revealed non-linearity, and modeling suggested that a higher dose level is required to achieve full saturation of CEACAM1 receptors.

“We are excited to announce this important expansion of our planned Phase 1/2 trial for CM24,” said Bertrand Liang, M.D., Ph.D., Chief Medical Officer of Kitov. “Based on the encouraging Phase 1 results for CM24, which were presented in a poster presentation at this year’s American Society of Clinical Oncology (ASCO) 2020 Virtual Scientific Program, we look forward to evaluating this compelling drug candidate at higher doses and in a larger clinical study. We anticipate starting this Phase 1/2 trial, which is being conducted with Bristol Myers Squibb, before the end of 2020. We expect the availability of top-line Phase 1 results from the study in the second half of 2021.”

The Phase 1/2 clinical study will encompass a dose escalation of CM24 from 10mg/kg to 20mg/kg with nivolumab for the treatment of refractory cancer patients with NSCLC, pancreatic cancer, ovarian carcinoma, melanoma or thyroid carcinoma, in order to determine a recommended Phase 2 dose. Subsequently, two expansion arms will be opened: the first in patients with NSCLC who have become refractory to first-line immunotherapy, and will receive CM24 in combination with nivolumab, and the second in metastatic pancreatic adenocarcinoma patients who have progressed after first-line chemotherapy treatment, and will receive CM24 in combination with nab-paclitaxel and nivolumab. Study endpoints will include both safety and preliminary efficacy in these refractory patients.

“Collaborating with Bristol Myers Squibb has allowed us to design a clinical study that reflects some of the most current available data in both NSCLC and pancreatic cancer,” noted Michael Schickler, Ph.D., Head of Clinical and Regulatory Affairs of Kitov. “CM24 targets CEACAM1, which has been found to be correlated with poor prognosis in these tumor types, and the creation of neoantigens with the use of a cytotoxic agent, such as nab-paclitaxel, could potentiate the activity of immuno-oncology agents. I would like to thank the respective teams at Kitov and Bristol Myers Squibb for their significant efforts in preparing for this important study and I look forward to the initiation of the study before the end of the year. Our focus is on efficiently advancing the program, and establishing CM24 as a potential first-in-class anti-CEACAM1 therapy.”

About Kitov Pharma

Kitov Pharma Ltd. (“Kitov”; NASDAQ/TASE: KTOV) is a clinical-stage company focusing on 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 NT219 and CM24. NT219 is a small molecule targeting the novel cancer drug resistance pathways IRS1/2 and STAT3. Kitov is currently advancing NT219 as a monotherapy treatment of advanced solid tumors and in combination with cetuximab for the treatment of recurrent or metastatic squamous cell carcinoma of head and neck cancer (SCCHN) in a phase 1/2 study. CM24 is a monoclonal antibody blocking CEACAM1, a novel immune checkpoint that supports tumor immune evasion and survival through multiple pathways. Kitov plans to advance CM24 as a combination therapy with anti-PD-1 checkpoint inhibitors in selected cancer indications in a phase 1 study followed by a phase 2 for the treatment of non-small cell lung cancer and pancreatic cancer. Kitov has entered into a clinical collaboration agreement, as amended, with Bristol Myers Squibb for the planned phase 1/2 clinical trials to evaluate the combination of CM24 with the PD-1 inhibitor nivolumab (Opdivo®) in patients with non-small cell lung cancer and in combination with nivolumab in addition to nab-paclitaxel (ABRAXANE®) in patients with pancreatic cancer. Kitov is also the owner of Consensi®, a fixed-dose combination of celecoxib and amlodipine besylate, for the simultaneous treatment of osteoarthritis pain and hypertension that was approved by the FDA for marketing in the U.S. Consensi® is being sold in the U.S. by Burke Therapeutics, the marketing partner of Kitov’s U.S. distributor, Coepris 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 plans, strategies and objectives of management for future operations; product development for NT219 and CM24; the process by which early stage therapeutic candidates such as NT219 and CM24 could potentially lead to an approved drug 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 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 obtained by competitors; dependence on the effectiveness of our patents and other protections for innovative products; our ability to obtain, maintain and defend issued patents; the commencement of any patent interference or infringement action against our patents, and 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 Annual Report on Form 20-F for the year ended December 31, 2019 and in our other filings with the U.S. Securities and Exchange Commission (“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>.

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