
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 July 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 July 2, 2020, Kitov Pharma Ltd. (the “Company” or the “Registrant”) issued a press release, “**Kitov Pharma Issues CEO Shareholder Letter Providing Business Update**”, 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 SEC on December 12, 2016 (Registration file numbers [333-207117](#) and [333-211477](#)), the Registrant’s Registration Statement on [Form S-8](#) filed with the SEC on May 20, 2016 (Registration file number 333-211478), the Registrant’s Registration Statement on [Form S-8](#) filed with the SEC on June 6, 2017 (Registration file number 333-218538), the Registrant’s Registration Statement on [Form F-3](#), as amended, originally filed with the SEC on July 16, 2018 (Registration file number 333-226195), the Registrant’s Registration Statement on [Form S-8](#) filed with the SEC on March 28, 2019 (Registration file number 333-230584), the Registrant’s Registration Statement on [Form F-3](#) filed with the SEC on September 16, 2019 (Registration file number 333-233795), the Registrant’s Registration Statement on [Form F-3](#) filed with the SEC on December 2, 2019 (Registration file number 333-235327), the Registrant’s Registration Statement on [Form F-3](#) filed with the SEC on May 13, 2020 (Registration file number 333- 238229), and the Registrant’s Registration Statement on [Form S-8](#) filed with the SEC on May 18, 2020 (Registration file number 333-238481), 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.

July 2, 2020

KITOV PHARMA LTD.

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

Kitov Pharma Issues CEO Shareholder Letter Providing Business Update

- **Emerging oncology pipeline continues to advance**
- **Strong balance sheet with over \$60M in cash**

TEL AVIV, July 02, 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, is pleased to provide the following letter to shareholders from its Chief Executive Officer, Isaac Israel.

Dear Shareholders,

Following our recently closed \$35 million financing, we believe we have successfully completed our evolution to an oncology focused biotechnology company, and wanted to provide our shareholders and other stakeholders with an update on our business and strategic plans. As of the end of June 2020, we had over \$60 million in cash, which we believe positions us well to conduct the two clinical studies we intend to initiate this year, and provides us with the resources to expand these development programs, as appropriate, as well as potentially acquire additional promising drug candidates that we may identify to further expand our pipeline.

Moreover, we continue to support our distribution partners for CONSENSI[®] indicated for the simultaneous treatment of hypertension and osteoarthritis pain in the U.S. and the Far East. Importantly, following the recent launch of CONSENSI[®] in the U.S., this drug is expected to begin generating royalty revenue for Kitov this year. With this launch underway, our strategic focus has shifted to the development of innovative therapeutics to treat cancer patients with significant unmet medical needs.

We are focused on building a pipeline of first-in-class oncology assets based on our three core values of Innovation - we have assembled a team of world-class oncology drug developers, Collaboration - we strive to establish beneficial relationships with our partners to best progress our mission, and Agility - we are focused on advancing our pipeline as expeditiously as possible. Our emerging oncology pipeline currently consists of CM24, a monoclonal antibody targeting CEACAM1, a novel immune checkpoint that supports tumor immune evasion and survival through multiple pathways, in patients with advanced cancer, and NT219, a dual inhibitor, novel small molecule targeting IRS1/2 and STAT3, important oncogenic drivers and major drug resistance pathways in many hard-to-treat cancers.

In addition, with a strong balance sheet that includes no debt, we have the flexibility to enhance our growth through smart acquisitions and/or in-licensing activity that we may identify in our core focus area of oncology. We expect to identify promising drug candidates with unique differentiation that have the potential to create exciting new treatment paradigms for the benefit of cancer patients. Our core objective is to become a recognized leader in the oncology field and to make a significant impact on patients' lives.

An important aspect of our strategy is to collaborate with third-parties. As a result of our recent financing activity, our current balance sheet provides us with the ability to maximize the value of the strategic opportunities that we are pursuing. We look forward to providing you with further updates on these ongoing activities as events warrant.

I would like to provide an update on our current pipeline and CONSENSI[®]:

CM24:

On May 14, 2020, we announced that the positive results of a previously reported Phase 1 trial of CM24 were presented in a poster presentation at the American Society of Clinical Oncology (ASCO) 2020 Virtual Scientific Program.

These Phase 1 results are encouraging and indicate that CM24 at higher doses warrants further evaluation in a larger clinical study. Importantly, pharmacokinetic modelling suggests that higher doses of CM24 of up to 20mg/kg administered every two weeks would be required for target saturation. We look forward to the anticipated initiation of our planned Phase 1/2 clinical trial to evaluate the combination of CM24 with the PD-1 inhibitor, nivolumab (OPDIVO[®]), to be conducted in collaboration with Bristol Myers Squibb, which we expect to initiate in the second half of this year. In order to maximize the potential of the trial to demonstrate a strong efficacy signal, we intend to include expansion cohorts that will follow the dose escalating phase: an expansion cohort in non-small cell lung cancer patients, and an additional expansion cohort in pancreatic cancer patients. This new arm of the trial in pancreatic cancer patients is designed to evaluate the CEACAM1/PD-1 combination in addition to standard of care chemotherapy.

NT219:

On May 22, 2020, we announced that the U.S. Food and Drug Administration had accepted our Investigational New Drug application to conduct a Phase 1/2 clinical trial of NT219. The study is designed to evaluate NT219 as a monotherapy treatment for advanced solid tumors and in combination with cetuximab, an epithelial growth factor receptor (EGFR) blocking monoclonal antibody, for the treatment of recurrent or metastatic solid tumors and head and neck cancer or colorectal adenocarcinoma.

Based on the encouraging pre-clinical data generated in various studies with NT219, as both monotherapy and in combination with cetuximab, we believe this promising drug candidate has the potential to be a safe and effective therapy for multiple hard-to-treat cancers. In addition to U.S. clinical sites, and in order to mitigate a potential COVID-19 pandemic-related slowdown in patient recruitment into the study, we are also including additional clinical sites in Canada.

The primary objectives of the open-label Phase 1/2 trial are to evaluate safety, assess pharmacokinetics, identify the appropriate dose to be studied in the Phase 2 portion, and establish preliminary efficacy of NT219. The Phase 1 portion of the study will encompass a dose escalation evaluation of NT219 monotherapy administered in patients with refractory advanced solid tumors. A second cohort of patients, with either recurrent or metastatic squamous cell carcinoma of the head and neck or colorectal adenocarcinoma, will be dosed with NT219, dose escalated, in combination with cetuximab. Upon completion of the Phase 1 monotherapy and combination dose escalation portion of the trial, we plan to commence the expansion Phase 2 components of the study at the recommended Phase 2 dose of NT219 in combination with cetuximab. In addition, based on the data obtained in the Phase 1 monotherapy portion, we intend to pursue an expansion Phase 2 study in a yet to be defined indication for NT219 as monotherapy.

The principal investigator of the Phase 1/2 study is Dr. Ezra Cohen, Chief, Division of Hematology-Oncology at the University of California San Diego, and a distinguished key opinion leader. We expect to activate up to eight sites in the U.S. and Canada over the next few months and that our first clinical site will be initiated shortly.

CONSENSI®:

On May 20, 2020, we announced the U.S. commercial launch of CONSENSI®, a fixed-dose combination of celecoxib and amlodipine besylate, designed for the simultaneous treatment of hypertension and osteoarthritis pain. CONSENSI® is being sold in the U.S. by Burke Therapeutics, the marketing partner of Kitov's U.S. distributor, Coepris Pharmaceuticals.

Burke Therapeutics' sales team is growing steadily, and is expected to soon include about 50 sales representatives, with plans to increase this number further. We believe the team is highly-motivated to introduce this once-a-day treatment for hypertension and osteoarthritis pain in the U.S. market. In addition, we believe Burke is taking the necessary actions to overcome the short-term challenges imposed by the COVID-19 pandemic and we look forward to sales beginning to ramp up in the next few months, which will result in royalty revenue to us of 20% of sales, pursuant to our marketing and distribution agreement with Coepris. According to the agreement for CONSENSI®, Kitov is eligible to receive up to \$99.5 million in milestone and reimbursement payments, in addition to royalties. We expect to receive aggregate milestone and royalty revenues of between \$28 million and \$36 million from 2020 through 2022.

In summary, we look forward to further advancing our commercial and clinical activities by leveraging our strong cash position. Our current cash runway is expected to support our currently planned activities into at least 2024, beyond multiple anticipated clinical milestones, and we believe we are well-funded to execute our strategic plans.

We thank you for your continued support of Kitov.

Wishing you and yours good health,

Isaac Israel

Chief Executive Officer

About Kitov Pharma

Kitov Pharma (Kitov Pharma Ltd.; 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 NT-219 and CM-24. NT-219 is a small molecule targeting the novel cancer drug resistance pathways IRS1/2 and STAT3. Kitov is currently advancing NT-219 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 planned phase 1/2 study. CM-24 is a monoclonal antibody blocking CEACAM1, a novel immune checkpoint that supports tumor immune evasion and survival through multiple pathways. Kitov plans to advance CM-24 as a combination therapy with anti-PD1 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 NSCLC and pancreatic cancer. Kitov has entered into a clinical collaboration agreement with Bristol Myers Squibb Company for the planned phase 1/2 clinical trials to evaluate the combination of CM-24 with the PD-1 inhibitor nivolumab (Opdivo®). 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: different results from the expected benefit and synergies of the acquisition of FameWave by Kitov; management plans relating to the transaction; 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 therapeutic candidates such as NT219 and CM-24 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 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, 2019 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>.

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