
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 September 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 September 9, 2019, the Company issued a press release “**Kitov Pharma Presents Newly Released Data for NT-219 in Reversing Pancreatic Cancer Drug Resistance**,” which is attached hereto as Exhibit 99.1.

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](#)), and 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](#)).

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.

September 9, 2019

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

Kitov Pharma Presents Newly Released Data for NT-219 in Reversing Pancreatic Cancer Drug Resistance

- *Data validates NT-219 mechanism of action in reversing resistance to various FDA-approved treatments in pancreatic tumor models of mice implanted with biopsies from patients (PDX)*
- *NT-219's novel mechanism of action may open new avenues for combination therapies with targeted therapies and chemotherapies in pancreatic and other hard-to-treat cancers*

TEL AVIV, Israel, Sept. 09, 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, presented newly released proof-of-concept data showing evidence of NT-219 mechanism of action in reversing cancer drug resistance in *PDX* models. The data was presented in a poster at the American Association for Cancer Research's (AACR) Pancreatic Cancer: Advances in Science and Clinical Care conference in Boston on September 8, 2019.

NT-219 is a first-in-class small molecule bi-specific inhibitor of two key cancer resistance pathways STAT3 and IRS1/2. As previously disclosed, the preclinical study initially evaluated the efficacy of NT-219 in combination with the approved chemotherapy agent gemcitabine on four *PDX* models of mutated KRAS pancreatic cancer. Data demonstrated reversal of gemcitabine-resistant tumors in all *PDX* models following treatment with NT-219 and gemcitabine. One of these models demonstrated complete response in about half of the animal group upon addition of NT-219 to gemcitabine. The study was then extended to define an optimal dose regimen and future clinical protocol.

Newly released data from the NT-219 poster showed:

- The combination of NT-219 with the targeted therapies trametinib (MEK inhibitor) or folfinirox (chemotherapy) reversed tumor resistance to the treatments.
- Administering NT-219 prior to chemotherapy suppressed activation of two key cancer survival pathways, STAT3 and IRS. The sequence of administering the therapies had a remarkable impact on the efficacy of NT-219 in reversing resistance.
- Gene expression analysis of the tumors in a *PDX* model of KRAS mutated pancreatic cancer revealed an average 80% reduction in IRS1 levels compared to the control group following a single treatment with NT-219 and gemcitabine combined therapy. Similar reductions were observed in the expression of STAT3-regulated genes and the proliferation marker Ki67, confirming NT-219 mechanism of action.
- A dose-dependent therapeutic effect of NT-219 was demonstrated on tumor-growth and correlated with NT-219 levels in plasma.

"STAT3 and IRS play an important role in KRAS-induced pancreatic tumorigenesis and drug resistance. Demonstrating efficacy of NT-219 in pancreatic cancer models is in line with previous results in other cancer types. We believe that targeting IRS and STAT3 may be a tumor-agnostic solution to combat resistance to multiple oncology drugs," said Hadas Reuveni, PhD, VP Research and Development of Kitov. "NT-219 is a first-in-class small molecule which suppresses both targets using a unique mechanism of action, and is crucial for overcoming cancer drug resistance."

"We are encouraged by the results of the study which demonstrate the potential of NT-219 to reverse resistance to oncology therapies in a wide range of *PDX* models. We plan to clinically explore its efficacy in multiple hard-to-treat oncology indications including squamous cell carcinoma of the head and neck in a planned clinical study to be launched soon. We are also exploring its potential in pancreatic cancer," said Isaac Israel, CEO of Kitov. "Resistance to chemotherapy and targeted therapies is a major problem facing oncology patients. Kitov is now strategically focused on developing first-in-class oncology therapies, including such which are targeted to overcome drug resistance and tumor immune evasion, and to ultimately provide patients long-lasting treatment alternatives."

Kitov plans to submit an Investigational New Drug Application (IND) to the U.S Food and Drug Authority (FDA) for a clinical study on NT-219 in combination with cetuximab in patients with recurrent or metastatic squamous cell carcinoma of the head and neck before the end of 2019, and to initiate the trial immediately following FDA's clearance.

The poster is available on the "Investor Relations" section on the Kitov website: <http://kitovpharma.investorroom.com/index.php?s=151>

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 their 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 the third quarter of 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. at the end of 2019 by its partner 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 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>

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