
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 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 October 16, 2020, Kitov Pharma Ltd. (the “Company” or the “Registrant”) issued a press release, “**New Mechanism of Action Data for NT219 Presented at Epigenetics and Metabolism AACR Special Virtual Conference**”, 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.

October 16, 2020

KITOV PHARMA LTD.

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

New Mechanism of Action Data for NT219 Presented at Epigenetics and Metabolism AACR Special Virtual Conference

Data Further Support Potential of NT219 to Overcome Cancer Drug Resistance

TEL AVIV, Israel, Oct. 16, 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, announced new data supporting the mechanism of action of NT219, a dual inhibitor, novel small molecule targeting IRS1/2 and STAT3 is being presented in a video recorded presentation at the Epigenetics and Metabolism AACR Special Virtual Conference by researchers at Tel-Aviv University. The data was generated as part of the Company's collaboration with Professor Ido Wolf, Head of the Oncology Division, Tel Aviv Sourasky Medical Center.

The new data demonstrates IRS2-amplified colorectal cancer (CRC) cells upregulate β -catenin expression, and treatment with NT219 significantly decreased the β -catenin transcriptional activity in these cells. In addition, NT219 markedly inhibited cell viability in a dose-dependent manner. Moreover, there was a unique role for IRS2 in promoting brain metastasis of CRC, suggesting AKT and β -catenin pathways downstream of IRS2 may be involved in mediating the enhanced aggressive phenotype of IRS2-amplified CRC cells in the brain microenvironment. β -catenin signaling by Wnt has been shown to have a number of different cellular influences. Besides cellular proliferation via protein stabilization to promote cellular growth, Wnt/ β -catenin has demonstrated a role in the establishment of the blood brain barrier and impacts the tumor microenvironment, associated with the therapeutic resistance of cancer cells (Dzobo et al, 2019).

"These new mechanism of action data, together with the compelling results from our preclinical studies of NT219, further support the rationale behind combining NT219 with various targeted and immune oncology approaches, both in peripheral and nervous system tumor tissues," said Bertrand Liang, M.D., Ph.D., Chief Medical Officer of Kitov. "We are currently enrolling patients in our Phase 1/2 clinical trial of NT219 as monotherapy for the treatment of advanced solid tumors, as well as in combination with cetuximab, an epithelial growth factor receptor (EGFR) blocking monoclonal antibody, for the treatment of recurrent and/or metastatic solid tumors and head and neck cancer or colorectal adenocarcinoma. We expect top-line data from the first part of this important study in the second half of 2021."

Previously completed preclinical studies demonstrated NT219's ability to overcome cancer drug resistance in patient-derived xenograft (PDX) models of various advanced cancer types, and to revert resistance to pembrolizumab (Keytruda®). Mice treated concomitantly with a combination of pembrolizumab and NT219 demonstrated complete blockage of tumor progression. Similarly, the combination of NT219 with cetuximab sensitized resistant tumors to this 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-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 CM24 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: 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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