
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 2018

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 September 18, 2018, Kitov Pharma Ltd. (the “Company” or the “Registrant”) issued a Press Release: “**Kitov Pharma Updates on Motions in USA Initiated by Kitov Chairman.**” A copy of this press release is furnished herewith as Exhibit 99.1.

Exhibits

99.1 [Press Release](#)

This Form 6-K, including the entire Exhibit 99.1 attached hereto, are all 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), and the Registrant’s Registration Statement on Form F-3 filed with the Securities and Exchange Commission on July 16, 2018 (Registration file number 333-226195).

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 19, 2018

By: /s/ Simcha Rock

Simcha Rock
CFO and Director

Kitov Pharma Updates on Motions in USA Initiated by Kitov Chairman

Tel Aviv, Israel, Sept. 18, 2018 (GLOBE NEWSWIRE) -- Kitov Pharma Ltd. (NASDAQ/TASE: KTOV), an innovative biopharmaceutical company, today announced that, following a filing by Kitov's Chairman of the Board and Chief Medical Officer, Dr. Paul Waymack, of a motion to quash a subpoena for documents and testimony served on Dr. Waymack by the Securities and Exchange Commission ("SEC"), the SEC has commenced an action to enforce the subpoena.

As stated by the SEC, "The application does not reflect a determination by the SEC or its staff that Waymack or Kitov Pharmaceuticals has violated any provisions of the federal securities laws or any provisions at issue in the Israel Securities Authority's investigation". The formal order issued by the SEC, which authorizes the SEC Staff to issue subpoenas and take testimony, states that the Israel Securities Authority ("ISA") has requested assistance in connection with an investigation and does not cite any other reason for issuing the formal order. Furthermore, counsel for the SEC has confirmed to Dr. Waymack's counsel that the sole purpose of the SEC's involvement in this matter is to facilitate obtaining documents and testimony from Dr. Waymack on behalf of the ISA, pursuant to the assistance memorandums between the SEC and ISA, which, as previously announced by Kitov, is conducting an ongoing investigation of Kitov and certain of its principals.

Kitov Pharma's board of directors has expressed its full support of our management, including Dr. Waymack. Kitov looks forward to the conclusion of this Israeli investigation by ISA in the most expeditious manner possible.

According to Dr. Waymack's filing, the SEC subpoena should be quashed because the SEC's assistance to the ISA in this matter would prejudice the public interest of the United States; that in conducting the underlying investigation, the ISA has violated both Israeli and United States law that would normally prohibit the ISA's conduct in certain matters in connection with the investigation; that Dr. Waymack's rights under American law as an American citizen and a respected member of the medical community would not be respected and preserved by the SEC providing assistance to the ISA; that to allow the SEC's subpoena to stand would result in an abuse of process; and, that the subpoena is also overly broad and unduly burdensome to both Dr. Waymack and Kitov.

While this matter is between the SEC, acting for the ISA, and Dr. Waymack, Kitov fully understands Dr. Waymack's position and reaffirms its full support for Dr. Waymack, who is one of the founders of Kitov, a former transplant surgeon and FDA Medical Officer who has over twenty years of experience in drug development and in conducting and overseeing clinical trials, and also previously served as an Associate Professor of Surgery at leading medical schools in the USA, and as a major in the U.S. Army Medical Corps.

As previously announced by Kitov, it has not yet been advised by the ISA of the full scope and focus of the ISA investigation; however, as previously disclosed by Kitov, it is Kitov's understanding that the ISA is investigating certain circumstances surrounding the post-trial internal dissemination of the statistical analysis of the Phase III clinical trial data of Consensi™, and whether or not, according to Israeli Law, this led to any misleading disclosures in any of the Company's public filings.

Kitov believes that the ISA's concerns are misguided and not consistent with industry accepted U.S. Food and Drug Administration ("FDA") regulatory requirements, nor with the procedures for the conduct of clinical trials for the purposes of New Drug Application submissions to the FDA. Furthermore, Kitov believes that the ISA is not the regulatory body authorized to evaluate the materiality of events and the completeness of public disclosures made by us in compliance with United States federal securities laws.

In addition, Kitov strongly disputes the legal ramifications of any possible concerns of the ISA with respect to its disclosures in these matters. Kitov firmly believes that the information relating to the post-trial internal dissemination of the statistical analysis of the Phase III clinical trial data of Consensi™ is not material, and was not material at the time of the Company's announcement of the final clinical trial results. This matter had no impact whatsoever on the validity of the analysis of the Consensi™ Phase III clinical trial data, which successfully met its primary efficacy endpoint with statistical significance. In addition, the statistical analysis was further validated by the Consensi™ Phase III/IV renal function clinical trial data, which had a similar primary efficacy endpoint. Finally, the statistical analysis was included in the final Phase III clinical study report which was part of Kitov's NDA submission for Consensi™ subsequently filed and approved for marketing by the FDA in May 2018.

Kitov has previously announced commercialization agreements for Consensi™ with leading pharmaceutical companies in China and South Korea, and is focused on securing an optimal U.S. commercialization partner for Consensi™ in the U.S.

About Kitov Pharmaceuticals

Kitov Pharma (Kitov Pharma Ltd.; NASDAQ/TASE: KTOV) is an innovative biopharmaceutical drug development company. Leveraging deep regulatory and clinical-trial expertise, Kitov's veteran team of healthcare and business professionals maintains a proven track record in streamlined end-to-end drug development and approval. Kitov's flagship combination drug, Consensi™ achieved the primary efficacy endpoints for its Phase III and Phase III/IV clinical trials, and was approved by the FDA for patients suffering from osteoarthritis pain and hypertension. NT219, which is developed by its majority-owned subsidiary, TyrNovo Ltd., is a novel patented small molecule designed to overcome cancer drug resistance that is currently in pre-clinical development. By lowering development risk and cost through fast-track regulatory approval of innovative therapeutic candidates, Kitov is committed to delivering rapid ROI and long-term potential to investors, while making a meaningful impact on people's lives.

Forward-Looking Statements

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. Forward-looking statements may be identified by the use of forward-looking 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: risks and uncertainties associated with obtaining court approval of the proposed settlement of the two U.S. shareholder class-action lawsuits, the number of plaintiffs who may opt-out of the proposed settlement, and whether any proposed settlement is appealed; 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; the continued uncertainty surrounding an investigation by the Israel Securities Authority into our historical public disclosures and the potential impact of such investigation on the trading of our securities or on our clinical, commercial and other business relationships; or on receiving the regulatory approvals necessary in order to commercialize our products; the uncertainty of the impact of such investigation and/or the proposed settlement of the two U.S. shareholder class-action lawsuits on the Israeli class action civil litigation in connection with the investigation which is still continuing, and other factors that are discussed in our in our Annual Report on Form 20-F for the year ended December 31, 2017 and in our other filings with the SEC, including our cautionary discussion of risks and uncertainties under 'Risk Factors' in our Registration Statements, Prospectuses 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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