
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 December 2017

Commission File Number: 001-37643

KITOV PHARMACEUTICALS HOLDINGS 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 December 14, 2017, Kitov Pharmaceuticals Holdings Ltd. (the “Company” or the “Registrant”) announced that the U.S. Food and Drug Administration (the “FDA”) has granted permission to use the brand name Consensi™ for marketing KIT-302, its lead drug candidate, subject to receipt of marketing approval from the FDA. As previously announced by the Company, in connection with its determination that the Company’s New Drug Application application is sufficiently complete to permit a substantive review, the FDA, under the Prescription Drug User Fee Act (PDUFA), has set a target date of May 31, 2018 to complete its review. On December 14, 2017, the Company issued a press release in connection with the permission of the FDA to use the brand name Consensi™ for marketing KIT-302, “**Kitov Announces Consensi™ as Brand Name for KIT-302**”, which is attached hereto as Exhibit 99.1

The Company has applied to the United States Patent and Trademark Office (“USPTO”) for registered trademark protection for Consensi™, and the application has been published in the Trademark Official Gazette. The Company has been informed by the USPTO that should no one file an opposition or extension request to the trademark within 30 days of November 28, 2017, then a Notice of Allowance should be issued within 11 weeks following November 28, 2017.

Attached hereto are the following exhibits:

Exhibit 99.1 [Press Release](#)

This Form 6-K, excluding Exhibit 99.1, is 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), and 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).

Forward-Looking Statements and the Company’s Safe Harbor Statement

Certain statements in this Report on Form 6-K are forward-looking statements within the meaning of the safe harbor provisions of the Private Securities Litigation Reform Act of 1995 and other applicable securities laws. Forward-looking statements can 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: 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 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, and other factors that are discussed in our in our Annual Report on Form 20-F for the year ended December 31, 2016 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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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 PHARMACEUTICALS HOLDINGS LTD.

December 14, 2017

By: /s/ Simcha Rock
Simcha Rock
CFO and Director

Kitov Announces Consensi™ as Brand Name for KIT-302

TEL AVIV, Israel, December 14, 2017 /PRNewswire/ --

Kitov Pharmaceuticals (NASDAQ: KTOV) (TASE: KTOV), an innovative biopharmaceutical company, announced today that the U.S. Food & Drug Administration (FDA) has granted permission to Kitov to use the brand name Consensi™ for marketing KIT-302, subject to receipt of marketing approval from the FDA.

"The receipt of the FDA's permission to use Consensi as the brand name for our lead drug is another important step in executing on our corporate strategy and will facilitate the commercialization of KIT-302, once approved by the FDA," stated J. Paul Waymack, M.D., Sc.D., Kitov's Chairman of the Board and Chief Medical Officer.

Consensi™ is a combination drug that is intended to simultaneously treat pain caused by osteoarthritis, as well as hypertension, which is a common side effect of stand-alone drugs that treat osteoarthritis pain. Consensi™ is comprised of two FDA approved drugs, celecoxib (Celebrex®), a COX-2 inhibitor, for the treatment of pain caused by osteoarthritis, and amlodipine besylate (Norvasc®), a calcium channel blocker for lowering blood pressure.

In September 2017, the FDA filed Kitov's New Drug Application (NDA) for Consensi™ and, under the Prescription Drug User Fee Act (PDUFA), set a target date of May 31, 2018 to complete its review.

About Kitov Pharmaceuticals

Kitov Pharmaceuticals (NASDAQ: KTOV, TASE: KTOV) is an innovative biopharmaceutical drug development company. Leveraging deep regulatory and clinical-trial expertise, Kitov's veteran team of healthcare professionals maintains a proven track record in streamlined end-to-end drug development and approval. Kitov's flagship combination drug, Consensi™ (previously referred to as KIT-302), intended to treat osteoarthritis pain and hypertension simultaneously, achieved the primary efficacy endpoints for its Phase III and Phase III/IV clinical trials. Kitov's newest drug, NT219, which is developed by its majority-owned subsidiary, TyrNovo Ltd., is a small molecule that presents a new concept in cancer therapy, and in combination with various approved oncology drugs, demonstrated potent anti-tumor effects and increased survival in various cancer models. By lowering development risk and cost through fast-track regulatory approval of novel therapeutics, Kitov plans to deliver rapid ROI and long-term potential to investors, while making a meaningful impact on people's lives. For more information on Kitov, the content of which is not part of this press release, please visit <http://www.kitovpharma.com>.

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