
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 April 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): ____

FameWave Ltd. (“FameWave”), which is being acquired by Kitov Pharma Ltd. (the “Company” or the “Registrant”) as previously announced, subject to fulfillment of the closing conditions, announced the signing of a clinical collaboration with Bristol Myers Squibb Company to evaluate the combination of CM-24, FameWave’s monoclonal antibody targeting the novel immune checkpoint carcinoembryonic antigen-related cell adhesion molecule 1 (CEACAM1), with nivolumab (Opdivo®), a PD-1 inhibitor, in patients with non-small cell lung cancer (NSCLC). FameWave and Bristol Myers Squibb will coordinate on the protocol design for the Phase 1/2 clinical trial in a well-defined patient population with NSCLC. Under the terms of the agreement, FameWave will fund and sponsor the study and Bristol Myers Squibb will supply nivolumab. On April 12, 2019, FameWave issued a press release announcing the clinical collaboration, **“FameWave Announces Clinical Collaboration with Bristol Myers Squibb for the Planned Phase 1/2 Trial in Non-Small Cell Lung Cancer to Evaluate Immuno-Oncology Candidate CM-24 in Combination with Nivolumab (Opdivo®),”** which is attached hereto as Exhibit 99.1.

On April 12, 2019, the Company announced the execution of the clinical collaboration agreement between FameWave and Bristol Myers Squibb, a key milestone in the acquisition of FameWave, and issued a press release **“Kitov Announces Key Milestone in FameWave Acquisition,”** which is attached hereto as Exhibit 99.2.

Exhibit 99.1 [Press Release, issued by FameWave Ltd.](#)

Exhibit 99.2 [Press Release, issued by Kitov Pharma Ltd.](#)

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. Any forward-looking statement in this Report on Form 6-K 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>

This Form 6-K, excluding Exhibits 99.1 and 99.2, 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), 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.

April 12, 2019

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

FameWave Announces Clinical Collaboration with Bristol Myers Squibb for the Planned Phase 1/2 Trial in Non-Small Cell Lung Cancer to Evaluate Immuno-Oncology Candidate CM-24 in Combination with Nivolumab (Opdivo®)

TEL AVIV, Israel, April 12, 2019 (GLOBE NEWSWIRE) -- FameWave Ltd. a privately held biopharmaceutical company developing CM-24, which is being acquired by Kitov Pharma Ltd. (NASDAQ/TASE: KTOV), today announced the signing of a clinical collaboration with Bristol Myers Squibb Company (NYSE:BMJ) to evaluate the combination of CM-24, FameWave's monoclonal antibody targeting the novel immune checkpoint carcinoembryonic antigen-related cell adhesion molecule 1 (CEACAM1), with nivolumab (Opdivo®), a PD-1 inhibitor, in patients with non-small cell lung cancer (NSCLC).

FameWave and Bristol Myers Squibb will coordinate on the protocol design for the Phase 1/2 clinical trial in a well-defined patient population with NSCLC. Under the terms of the agreement, FameWave will fund and sponsor the study and Bristol Myers Squibb will supply nivolumab.

"FameWave's collaboration with Bristol-Myers Squibb, a global leader in immuno-oncology, is a crucial step to begin evaluation of CM-24 in combination with a PD-1 inhibitor," said Dr. Michael Schickler, chief executive officer of FameWave. "We look forward to evaluating CM-24 in NSCLC since we believe it has a great potential as a novel immune checkpoint to be used in combination therapies for a variety of hard-to-treat cancers."

About CEACAM1 and CM-24

CM-24 is a humanized monoclonal antibody directed against carcinoembryonic antigen-related cell adhesion molecule 1 (CEACAM1), an immune checkpoint protein belonging to the Human CEA (Carcino-Embryonic Antigen) protein family. Evidence has shown that CEACAM1 is expressed on tumor lymphocytes and is up-regulated in several cancer types. Preclinical studies have shown evidence that CM-24 enhances the cytotoxic activity of tumor-infiltrating lymphocytes (TILs) against various CEACAM1-positive tumor cell lines. CM-24 is being developed for multiple oncological indications according to the expression pattern of its target protein.

As part of the recently announced agreement for the acquisition of FameWave by Kitov Pharma Ltd. (NASDAQ/TASE: KTOV), cCAM BioTherapeutics Ltd., a wholly owned subsidiary of Merck Sharp and Dohme Corp., known as "MSD" in Israel, is returning the rights to CM-24 to former cCAM shareholders and founders of FameWave, following an initial Phase 1 dose ranging study of CM-24 as single agent. Kitov's acquisition of FameWave is pending completion of certain closing conditions, including FameWave entering this collaboration agreement for CM-24 with Bristol Myers Squibb.

Forward-Looking Statements and Safe Harbor Statement

Certain statements in this press release are forward-looking statements within the meaning of 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. 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.

For further information, contact:

Dr. Michael Schickler
CEO

Kitov Announces Key Milestone in FameWave Acquisition

TEL AVIV, Israel, April 12, 2019 (GLOBE NEWSWIRE) -- Kitov Pharma Ltd. (NASDAQ/TASE: KTOV), an innovative pharmaceutical company developing first-in-class combination oncology therapies, today announces a key milestone in the acquisition of FameWave Ltd., following signature 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, a monoclonal antibody targeting the novel immune checkpoint carcinoembryonic antigen-related cell adhesion molecule 1 (CEACAM1) with nivolumab (Opdivo®), a PD-1 inhibitor, in patients with non-small cell lung cancer (NSCLC).

“We look forward to completing the acquisition of FameWave and advancing CM-24 studies in the clinic,” said Isaac Israel, chief executive officer of Kitov. “Our goal is to assess the innovative combination of CM-24 with Opdivo® in NSCLC patients. Since we believe CM-24 has great potential as a novel checkpoint inhibitor to be used in combination therapies to provide new options to address the significant unmet medical need in hard-to-treat cancers.”

Preclinical studies have shown a strong synergetic anti-cancer effect using CM-24 in combination with a PD-1 antibody. Based on Kitov’s review of the initial Phase I dose ranging study of CM24 as a single agent, performed by Merck Sharpe & Dohme, Kitov plans to explore higher doses in order to reach receptor saturation.

Kitov is acquiring FameWave, pending completion of certain additional closing conditions, including approval by the shareholders of Kitov of the acquisition.

Conference Call and Webcast Information:

The Company will host a conference call **Monday, April 15, 2019, at 8:30 a.m. EDT** to discuss the FameWave acquisition deal and new asset CM-24.

The conference call will be broadcast live and will be available for replay for 30 days on the Company's website. Please access the webcast and conference line dial-in at least 15 minutes ahead of the conference call to register. Conference ID: 13689863; U.S dial in: 877-705-6003; Israel dial in: 1 809 406 247; International dial in: 201-493-6725. Webcast: <http://public.viavid.com/index.php?id=134109>

About CEACAM1 and CM-24

CM-24 is a humanized monoclonal antibody directed against carcinoembryonic antigen-related cell adhesion molecule 1 (CEACAM1), an immune checkpoint protein belonging to the Human CEA (Carcino-Embryonic Antigen) protein family. Evidence has shown that CEACAM1 is expressed on tumor lymphocytes and is up-regulated in several cancer types. Preclinical studies have shown evidence that CM-24 enhances the cytotoxic activity of tumor-infiltrating lymphocytes (TILs) against various CEACAM1-positive tumor cell lines. CM-24 is being developed for multiple oncological indications according to the expression pattern of its target protein.

As part of the recently announced agreement for the acquisition of FameWave by Kitov, cCAM BioTherapeutics Ltd., a wholly owned subsidiary of Merck Sharp and Dohme Corp., known as “MSD” in Israel, has returned the rights to CM-24 to former cCAM shareholders and founders of FameWave, following an initial Phase 1 dose ranging study of CM-24 as single agent.

About Kitov Pharma

Kitov Pharma (Kitov Pharma Ltd.; NASDAQ/TASE: KTOV) is an innovative pharmaceutical 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 combination drug, Consensi™, treating osteoarthritis pain and hypertension simultaneously, was approved by the FDA for marketing in the U.S and is partnered in the U.S, China and South Korea. In addition, Kitov’s NT219, 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 novel late-stage 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>.

Forward-Looking Statements and Kitov's Safe Harbor Statement

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Examples of forward-looking statements include, among others, statements we make regarding: (i) the therapeutic and commercial potential of CM-24; (ii) research and development plans related to the CM-24 therapies; (iii) the potential of CM-24 for the treatment of against various CEACAM1-positive tumor cell lines; (iv) the potential for the collaboration between Kitov (FameWave) and Bristol Myers Squibb; and (v) the closing of the transactions between the shareholders of FameWave and Kitov, which is subject to closing conditions, including approval of the transactions by Kitov shareholders. 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, including conditions related to Kitov shareholder approvals; the plans, strategies and objectives of management for future operations; product development for 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; 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, 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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