
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 August 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): ____

On August 13, 2019, the Administrative Enforcement Committee (the “Committee”) of the Israel Securities Authority (“ISA”) approved an administrative enforcement agreement, titled Enforcement Arrangement (“Enforcement Arrangement”), entered into by and amongst ISA, Kitov Pharma Ltd. (the “Company” or the “Registrant”), Isaac Israel, the Company’s chief executive officer, Paul Waymack, the Company’s former chairman and Simcha Rock, the Company’s former chief financial officer, pursuant to which the Company and each of Messrs. Israel, Waymack and Rock settled the ISA’s claims that under Israeli Securities Laws the Company made negligent disclosures in a number of its historical reports filed with the ISA in 2014 and 2015, and the ISA decided to discontinue its criminal investigation and to cease all proceedings against the Company and its principals.

As noted by the Committee in its decision to accept and approve the Enforcement Arrangement, further continuation of the legacy matter of the ISA criminal investigation would have likely been protracted, burdensome, and expensive for the ISA, the Company and its principals. The Committee and the ISA, amongst other factors, recognized the Company’s cooperation and the fact that it had adopted internal policies and procedures in connection with public reporting even prior to the commencement of the investigation, and also noted that the Company is now reporting to ISA as a dual-listed Company primarily reporting under US Securities Laws. The Committee noted, amongst other factors (including the above), that in terms of the outcomes, no substantive damage was caused to the investing public as a result of the negligence of the Company and its principals as described in the Enforcement Arrangement, and the statistical results of the clinical trial were accepted by, and Consensi™ was, in fact, approved by the Food and Drug Administration.

As described in the Enforcement Arrangement, the Company and Mr. Israel made negligent disclosures in a number of historical reports filed with the ISA in 2014 and 2015 with respect to the impartiality of an external Data Monitoring Committee (“DMC”) that was appointed by the Company in connection with reviewing the Company’s Phase III clinical trial results for Consensi™. In addition, and as further described in the Enforcement Arrangement, in a number of historical reports filed with the ISA in 2015 the Company and each of Messrs. Israel, Waymack and Rock, negligently did not disclose that one of the members of the DMC did not receive and examine the results of the trial at such a time and manner as was reported by the Company.

The ISA allegations as described in the Enforcement Arrangement are not related to the validity of the results of the Phase III clinical trial data of Consensi™, which met its primary efficacy endpoint with statistical significance and was approved by the Food and Drug Administration, nor do they relate to any US securities laws or regulations.

As part of the Enforcement Arrangement, the ISA decided to discontinue its criminal investigation against the Company and to cease all proceedings against the Company and its principals in connection with this matter, including all proceedings regarding the ISA’s attempt to obtain documents and testimony in the US from Dr. Paul Waymack. In addition, the ISA agreed to discontinue the proceedings under the Israeli Securities Law against the Company and its principals with respect to the facts set out in the Enforcement Arrangement.

Specifically, as part of the Enforcement Arrangement:

- 1) The Company shall pay a fine of NIS 1,500,000 (approximately \$430,000), payable in 24 consecutive monthly payments;
 - 2) Mr. Isaac Israel shall (i) pay a fine of NIS 200,000, (approximately \$60,000) payable in 12 consecutive monthly payments, beginning thirty days after the approval of the Enforcement Arrangement by the Committee; and, (ii) be subject to a conditional prohibition to serve as a senior officer in a supervised body under the Israeli Securities Law for a period of 12 months, in the event that Mr. Israel violates certain sections under the Israeli securities laws within two years.
 - 3) Dr. Paul Waymack shall pay a fine of NIS 100,000 (approximately \$30,000), to be paid in one payment no later than sixty days after the approval of the Enforcement Arrangement by the Committee.
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4) Mr. Simcha Rock shall (i) pay fine of 80,000 NIS (approximately \$20,000), payable in 12 consecutive monthly payments, beginning thirty days after the approval of the Enforcement Arrangement by the Committee; and (ii) be subject to a conditional prohibition to serve as a senior officer in a supervised body under the Israeli Securities Law for a period of six months, in the event Mr. Rock violates certain sections under the Israeli securities laws within two years.

In order to put this matter to rest, remove uncertainty and focus on the future marketing of Consensi™ and on Kitov's other business, the Company, by vote of a committee consisting of independent members of the Board of Directors, and the above mentioned principals, agreed to the Enforcement Arrangement with the ISA.

The above is a summary of the material terms of the Enforcement Arrangement. An English translation copy of the Enforcement Arrangement, is attached as an exhibit to this Report on Form 6-K. The Enforcement Arrangement has been attached to this Report on 6-K to provide you with information regarding its terms. The summary of the material terms of the Enforcement Arrangement herein is qualified in its entirety by reference to the Enforcement Arrangement. This summary may not contain all of the information about the Enforcement Arrangement that is important to you. We urge you to read the Enforcement Agreement carefully. The full binding Hebrew text of the Enforcement Arrangement and the Committee ruling are expected to be published by the ISA on its Administrative Enforcement Arrangements webpage at http://www.isa.gov.il/%d7%97%d7%a7%d7%99%d7%a7%d7%94%20%d7%95%d7%90%d7%9b%d7%99%d7%a4%d7%94/Enforcement/Admin_Enforcement/4562/Pages/default.aspx.

Exhibit 99.1 [English translation of the Enforcement Arrangement](#)

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.

August 13, 2019

By: /s/ Gil Efron
Gil Efron
Deputy CEO & CFO

Enforcement Arrangement

Signed on _____

Between: The Israel Securities Authority
22 Kanfei Nesharim St., Jerusalem
Telephone: 02-6556555 Fax: 02-6513646
By the Chairman of the Israel Securities Authority
(Hereinafter: "the ISA" or "the Authority")

And between: Kitov Pharma Ltd.
Isaac Israel
Through Adv. Dr. Zvi Gabbai
From Barnea, Jaffe, Lande & Co.
(Hereinafter: "Respondent 1")
(Hereinafter: "Respondent 2")

Paul Waymack
Through Adv. Navit Negev and/or Adv. Dafna Steinberg
of Sheinman Negev Niv Law office
(Hereinafter: "Respondent 3")

Simcha Rock
Through Adv. Pnina Sheffer and/or Adv. Michal Shalmon-Perlstein
From the office of S. Horowitz
(Hereinafter: "Respondent 4")

Whereas the ISA believed that there is reasonable basis to assume that the Respondents committed offences according to the Securities Law -1968 (hereinafter - "the Securities Law"), regarding including misleading information in the reports, and therefore commenced a criminal investigation.

And Whereas the Respondents proposed to enter into an Administrative Enforcement Arrangement with the ISA and agreed to admit to the following facts and violations, and recognize the authority of the ISA to reach an Administrative Enforcement Arrangement regarding these violations in lieu of the continuation of the criminal investigation, and to impose in the framework of such Administrative Enforcement Arrangement the enforcement measures listed in Article C of Chapter 8-D of the Securities Law, and the Respondents agreed to assume the agreed upon enforcement measures, as detailed below;

And Whereas the ISA has considered the matters set forth in Section 52 RR of the Securities Law, and it is of the opinion that this Arrangement satisfies the public interest, it has decided to discontinue the proceedings against the Respondents, including all proceedings in relation to the request for legal assistance regarding Respondent 3 currently active in the US, and in lieu of the continuation of proceedings¹ and the continuation of the criminal investigation, to enter with them into this Enforcement Arrangement, all in accordance with Section 54B of the Securities Law;

Therefore, the parties have reached the following Arrangement:

1. The Facts

The ISA and the Respondents agree that the following facts took place, which constitute the basis for entering this Arrangement:

The Respondents

- 1.1 KITOV PHARMA LTD. (hereinafter: “the Company” or “Respondent 1”) is a company that, at the relevant time, researched and developed combination drugs that treat two clinical conditions at the same time - pain resulting from degenerative arthritis and high blood pressure. The Company’s flagship drug, KIT 302 (hereinafter: “the drug”), is intended for the treatment of pain and the reduction of blood pressure in arthritis. The Company presently reports as a dual-listed reporting company, according to Chapter 5-C of the Securities Law. However, all the reports described in this Enforcement Agreement were made during a period in which the Company was a public Israeli company subject to the reporting duties set forth in the Israeli Securities Law.

¹ In this Arrangement, “proceedings” - as defined in section 54A of the Securities Law.

- 1.2. Isaac Israel (hereinafter: "Respondent 2") has acted as CEO and a director of the Company as of 2012. Respondent 2, in his role as CEO of the company approved all of the Company's reports and signed them.
- 1.3. Paul Waymack (hereinafter: "Respondent 3") served as a director and as Chairman of the Board of Directors of the Company as of July 2013 and was its medical manager. In his position, Respondent 3 was responsible for the clinical trials conducted by the Company and for the Company's contact with the FDA.
- 1.4. Simcha Rock (hereinafter: "Respondent 4") served as a director and CFO of the Company as of July 2013. Respondent 4 was copied on the drafts of the Company's reports.

First Violation

- 1.5. On June 18, 2014, the Company reported the commencement of the Phase III clinical trial of the drug (hereinafter: "the trial"), as well as decisions taken at a meeting of the Company's Board of Directors regarding the format of the trial in accordance with the agreement signed between the Company and the FDA. The report said that the experiment would be conducted in the format of Adaptive Trial Design (ATD), in the first stage, 150 participants would be recruited. After the treatment of the 150 participants, the trial data would be disclosed to an impartial external committee – called the Data Monitoring Committee (DMC) (hereinafter: "the committee" or "DMC") which, according to the Company immediate report, would analyze the results and determine the number of additional patients that the Company should recruit in order to prove statistical significance. Also, according to the immediate report, the Company's Board of Directors authorized the company's Audit Committee to discuss and recommend to the Board of Directors concerning the identity of the members of the DMC, provided that among the members there would be at least one expert statistician and one senior professional in the company's field of activity.²

In the immediate report, the main goal of the trial was defined, as agreed in writing between the company and the FDA, as proving that the reduction in blood pressure in the group of patients treated with the drug was at least 50% of the reduction observed in the group treated only with a blood pressure medication.

² <https://maya.tase.co.il/reports/details/904174>

- 1.6. On September 24, 2015, the Company reported³ that following the recommendation of the company's Audit Committee, the company's Board of Directors appointed the members of the DMC, which included a statistical expert and a professional in the company's field of activity. In the report, the company described the identity and details of the two members of the committee:
- Dr. Gloria Crispino (hereinafter: "Dr. Crispino"), an expert in Bio-Statistics and Biological Mathematics from ITT University in Dublin, Ireland, who is also the founder and director of Statica Medica, a consulting company that operates in the field of bio-statistics and provides services to pharma companies.
 - Dr. Ofer Sachs, of the Department of Orthopedics at Rambam Hospital in Haifa.
- According to the immediate report, after the recruitment of the first 150 participants in the clinical trial, the results would be disclosed to the DMC, which would analyze the results and determine the number of patients, if any, that the company should recruit, in order to prove statistical significance and meet the primary goal of the trial. It should be noted that the Company referred to this immediate report and its contents also in the third quarterly report for 2014.⁴
- 1.7. On October 21, 2015, the Company reported⁵ the completion of the recruitment of the first 150 participants and repeated its previous reports regarding the committee.
- 1.8. On November 5, 2015, the Company reported⁶ the completion of treatment of the first participants, and that: "The trial data will now be collected and will be disclosed to the impartial external committee, Data Monitoring Committee... which will analyze the results and determine whether additional patients need to be recruited, in order to prove statistical significance and meet the main goal of the trial..." According to the report, the committee's examination and the publication of the interim results were expected to last up to eight weeks starting October 21, 2015, i.e. until December 15, 2015.
- 1.9. On November 17, 2015, the Company reported⁷ that following its reports, on November 16, 2015, the trial data of 152 participants in the clinical trial was submitted, together with an initial statistical analysis to the committee, which will examine the data. According to the immediate report, the Company does not and will not have access to such data until the completion of the examination by the committee. According to the immediate report, the publicizing of the interim results of the trial by the Company was expected by December 15, 2015.

³ <https://maya.tase.co.il/reports/details/993438>

⁴ <https://maya.tase.co.il/reports/details/933205> (See section 1.2.15, on page 6)

⁵ <https://maya.tase.co.il/reports/details/997086>

⁶ <https://maya.tase.co.il/reports/details/999996>

⁷ <https://maya.tase.co.il/reports/details/1001905>

1.10. On December 10, 2015, the Company reported⁸ that, following its previous reports, on Tuesday, December 15, 2015, the statistical analysis process is expected to be completed and the interim results of the Company's Phase III clinical trial will be publicized. According to the immediate report, immediately after the publication of the interim results to investors, the Company's management would hold a conference at the Hilton Hotel in Tel Aviv, in which it would disclose to the investing public the results of the trial.

1.11. The Company, in its' reports, defined the committee as impartial, without considering that a reasonable investor could have understood this term as incompatible with the fact that Statistica Medica, which was established and run by Dr. Crispino, performed the statistical analysis of the results of the trial through two of its employees, and Dr. Crispino was in contact with persons on behalf of the Company in regard with the framework of the trial.

It should be clarified that the ISA does not claim that the Company's agreement with the FDA, or any part of it, was not fulfilled.

1.12. In doing so, Respondent 1, by virtue of Respondent 2's actions, and Respondent 2 negligently included a misleading item in the immediate report dated September 24, 2015 regarding the committee being impartial, when they should have known that this could mislead a reasonable investor.

Second Violation

1.13. On December 13, 2015 the Company received the results of the trial, which fulfilled the goal of the trial and even showed particularly high statistical significance. Soon afterwards, it became known to Respondents 2-4 that Dr. Ofer Sachs, one of the members of the committee, did not receive the relevant material at such time as was reported by the Company and that he did not examine the results of the trial as required according to his role as part of the committee. Respondents 2-3 decided, in light of the results of the trial, and despite the fact that the committee did not act at the time and in the manner which the Company intended and reported to the public, to publicize the results of the trial "as is" and to hold the investors' conference as planned.

⁸ <https://maya.tase.co.il/reports/details/1007359>

- 1.14. On December 15, 2015, the Company reported⁹ that, further to its previous reports to which it refers, on Tuesday, December 15, 2015, upon completion of the process of statistical analysis of the interim results of the Company's Phase III clinical trial, it was found that the main goal of the trial was achieved in full in a statistically significant manner. As a result of achieving the goal of the trial in full, there is no need to recruit additional patients and the results of the trial were declared as final. According to the immediate report, the Company intends to continue as planned in the chemical development process of the product, to conduct a final trial during the first half of 2016 and to submit to the FDA a request to approve the marketing of the drug (NDA) during the second half of 2016. According to the immediate report, the Company would hold a conference at the Hilton Hotel in Tel Aviv at 14:00 (Israel time), in which it would disclose to the investing public the results of the trial. It should be clarified that the ISA has no claim regarding the results of the trial, which were also approved by the FDA. The Company did not report to the public that the committee did not convene and did not act in the manner which was reported.
- 1.15. On December 20, 2015, the Company reported¹⁰ additional information about the results of the Phase 3 clinical trial, while referring to its previous immediate reports on the matter.
- 1.16. The Company's reports of December 15th and December 20th, 2015, which referred to previous immediate reports concerning the procedure of the committee, were incorrect, since in practice the committee did not convene and did not act in the manner which was reported.
- 1.17. In so doing, Respondent 1, by virtue of the actions of its officers described above, and Respondents 2-4 negligently included a misleading item in the Company's immediate report dated December 15, 2015 with regard to the committee as described above, when they should have known that this could have misled a reasonable investor.

⁹ <https://maya.tase.co.il/reports/details/1008116>

¹⁰ <https://maya.tase.co.il/reports/details/1009161>

2. The Legal Framework

- 2.1. On the basis of section 1 above, the ISA finds and Respondents 1 and 2 admit that they negligently committed two violations of including a misleading item under subsection 4 of Part C of the Seventh Schedule to the Securities Law: including a misleading item in a report when they should have known it could mislead a reasonable investor.
- 2.2. On the basis of sections 1.13-1.17 above, the ISA finds and Respondents 3 and 4 admit that they negligently committed a violation of including a misleading item under subsection 4 of Part C of the Seventh Schedule to the Securities Law: including a misleading item in a report when they should have known it could mislead a reasonable investor.

3. Enforcement Measures

In light of the above, the Respondents undertake upon themselves the following enforcement measures and undertake to carry out the actions imposed on them by virtue of the same means of enforcement:

3.1. Respondent 1

- 3.1.1. A monetary sanction in the sum of NIS 1,500,000 (NIS 1.5 million) to be paid in 24 consecutive monthly payments, beginning thirty days after the approval of the Arrangement by the Administrative Enforcement Committee.

3.2. Respondent 2

- 3.2.1. A monetary sanction in the amount of NIS 200,000 (two hundred thousand New Israeli Shekels), to be paid in 12 consecutive monthly payments, beginning thirty days after the approval of the Arrangement by the Administrative Enforcement Committee.
- 3.2.2. A conditional prohibition to serve as a senior officer in a supervised body under section 52 FFF for a period of 12 months to be imposed on him, to the extent that within two years from the date of approval of this Arrangement by the administrative enforcement committee, he will commit a violation of subsection 4 of Part C of the Seventh Schedule to the Securities Law.

3.3. Respondent 3

- 3.3.1. A monetary sanction in the sum of NIS 100,000 (one hundred thousand New Israeli Shekels), to be paid in one payment, to be made within sixty days of the approval of the Arrangement by the Administrative Enforcement Committee.¹¹

¹¹ It should be noted that on May 2nd, 2019, during the negotiations, the Company reported that Respondent 3 had announced his resignation from his position as a director and chairman of the board of directors of the company. This resignation will take effect upon appointment of his replacement(s) and by no later than July 1, 2019.

3.4. Respondent 4

- 3.4.1. A monetary sanction in the sum of 80,000 NIS (eighty thousand New Israeli Shekels) to be paid in 12 consecutive monthly payments, beginning thirty days after the approval of the Arrangement by the Administrative Enforcement Committee.
- 3.4.2. A conditional prohibition to serve as a senior officer in a supervised body under section 52 FFF for a period of six months, to be imposed on him to the extent that within two years from the date of approval of this Arrangement by the Administrative Enforcement Committee, he will commit a violation of subsection 4 of Part C of the Seventh schedule to the Securities Law.
4. The Respondents are aware that under Section 56H of the Securities Law, insurance and indemnification, directly or indirectly, are not permitted with respect to the monetary sanctions they each agreed to bear.
5. Respondent 1 confirms that all the approvals required for it to enter into this Arrangement have been received.
6. The Respondents undertake to refrain, directly or by anyone acting on their behalves, from any publication and / or public expression which includes a denial of all or part of the provisions of this Arrangement.
7. The ISA undertakes to refrain from continuing the conduct of the criminal investigation against the Respondents, including all proceedings in relation to the request for legal assistance regarding Respondent 3 currently active in the US, and to refrain from conducting any enforcement proceeding under the Securities Law against the Respondents with respect to the facts set out above in Section 1 which created the violations that are the subject of this Arrangement; Subject to the circumstances specified in section 54B (e) of the Securities Law.¹²

¹² Section 54B (e) states as follows: "If it is proven to the ISA Chairman that the suspect has violated any of the terms of the arrangement or that the arrangement was obtained fraudulently, the ISA Chairman may, with the approval of a panel the Chairman will appoint for such purpose, order that proceedings be initiated against the suspect after the suspect is given a notice of the ISA's Chairman to do so, and after the suspect is given an opportunity to present arguments within 30 days from the date on which the notice was delivered; if the ISA Chairman has issued such an order, the arrangement will be deemed to be void and the suspect will not be required to carry out those terms of the arrangement that the suspect has not yet carried out, other than the terms that apply to the suspect by virtue of the application of conditional enforcement measures, pursuant to the arrangement."

8. The consent of the Respondents to entering into this Arrangement shall not serve as evidence against them in a criminal or administrative proceeding concerning the violations which are the subject of the Arrangement and evidence provided for the purpose of the Arrangement shall not be used against them in any criminal and administrative proceedings, unless the circumstances specified in section 54B (e) of the Securities Law are met.
9. The purpose of this Arrangement is not to grant rights or derogate from the rights of a person or entity who is not a party to it.
10. Nothing in this Arrangement shall prevent the Respondents from taking different legal positions in other legal proceedings or before any other regulatory body or agency.
11. The parties agree and are aware that the content of this Arrangement is subject to the approval of the Administrative Enforcement Committee under section 54B of the Securities Law. As a result, this Arrangement, including the parties' undertakings herein, will enter into force only after the approval of the Administrative Enforcement Committee.
12. The decision of the Administrative Enforcement Committee, accompanied by this Arrangement, will be publicized on the ISA's website after it has been signed and after the approval of the Administrative Enforcement Committee, in accordance with section 54C (a) of the Securities Law.

In witness whereof the parties have signed:

ISA

KITOV PHARMA LTD

ISAAC ISRAEL

SIMCHA ROCK

PAUL WAYMACK