
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 001-35948

Kamada Ltd.

(Translation of registrant's name into English)

**2 Holzman Street
Science Park, P.O. Box 4081
Rehovot 7670402
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): ____

Indicate by check mark whether the registrant by furnishing the information contained in this Form is also thereby furnishing the information to the Commission pursuant to Rule 12g3-2(b) under the Securities Exchange Act of 1934.

Yes ☐ No ☒

If "Yes" is marked, indicate below the file number assigned to the registrant in connection with Rule 12g3-2(b): 82- ____

This Form 6-K is being incorporated by reference into the Registrant's Form S-8 Registration Statements, File Nos. 333-192720, 333-207933, 333-215983 and 333-222891, and the Registrant's Form F-3 Registration Statement, as amended, File No. 333-214816.

The following exhibit is attached:

99.1 Press Release: **Kamada announces FDA acceptance of Inhaled AAT program path forward**

SIGNATURE

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 hereunto duly authorized.

Date: April 16, 2019

KAMADA LTD.

By: /s/ Orna Naveh

Orna Naveh

General Counsel and Corporate Secretary

EXHIBIT INDEX

EXHIBIT NO. DESCRIPTION

[99.1](#) [Press Release: Kamada announces FDA acceptance of Inhaled AAT program path forward](#)

Kamada announces FDA acceptance of Inhaled AAT program path forward

Company intends to submit an IND to the FDA and a CTA to the EMA, and expects to initiate the Inhaled AAT Phase 3 pivotal study during the second half of 2019

REHOVOT, Israel – April 16, 2019 – Kamada Ltd. (Nasdaq & TASE: KMDA), a plasma-derived protein therapeutics company, today announced receipt of a letter from the U.S. Food and Drug Administration (FDA or the Agency) stating that the Company has satisfactorily addressed the concerns and questions regarding its Inhaled Alpha-1-Antitrypsin (Inhaled AAT) program for the treatment of Alpha-1 Antitrypsin Deficiency (AATD), previously communicated by the Agency.

This most recent response from the FDA in connection with the development plan for Inhaled AAT follows positive scientific advice received in July 2018 from the Committee for Medicinal Products for Human Use of the European Medicines Agency (EMA) in Europe. Kamada intends to conduct a unified global pivotal Phase 3 clinical trial in the U.S. under an Investigational New Drug (IND) application and in Europe under a Clinical Trial Authorization (CTA) in order to submit marketing applications for regulatory approval in both regions. The Company expects to initiate the Phase 3 study during the second half of 2019, subject to a successful completion of a Human Factor Study (HFS), to be initiated during the current quarter. The HFS is required to support the combination product, consisting of Kamada's AAT for inhalation and the investigational eFlow nebulizer system of PARI Pharma GmbH.

The Phase 3 study protocol was designed to test the safety and efficacy of our inhaled AAT product in patients with AATD, and is meeting the requirements provided by the FDA and EMA. The protocol includes the enrollment of up to 250 subjects who will be randomized 1:1 to receive either Inhaled AAT at a dose of 80mg once daily, or placebo, during two years of treatment. The primary endpoint will be lung function measured by FEV1, and secondary endpoints will include lung density changes measured by CT densitometry, as well as other parameters of disease severity.

“We are extremely pleased to receive this feedback from the FDA regarding our Inhaled AAT for the treatment of AATD,” said Amir London, Kamada's Chief Executive Officer. “We expect to initiate the trial in the second half of 2019, subject to successfully completing the required human factor study. The current global intravascular AAT market is estimated at more than \$1 billion annually, and is growing at approximately 6-8% each year. We believe that our Inhaled AAT, if approved, could capture a significant share of this growing market due to the ability of our treatment to directly reach the lungs, as well as its enhanced convenience that would improve the quality of life for patients. We are encouraged by the strong support we continue to receive from the patient population and leading AATD physicians.”

About Kamada

Kamada Ltd. is focused on plasma-derived protein therapeutics for orphan indications, and has a commercial product portfolio and a late-stage product pipeline. The Company uses its proprietary platform technology and know-how for the extraction and purification of proteins from human plasma to produce Alpha-1 Antitrypsin (AAT) in a highly-purified, liquid form, as well as other plasma-derived Immune globulins. AAT is a protein derived from human plasma with known and newly-discovered therapeutic roles given its immunomodulatory, anti-inflammatory, tissue-protective and antimicrobial properties. The Company's flagship product is GLASSIA®, the first liquid, ready-to-use, intravenous plasma-derived AAT product approved by the U.S. Food and Drug Administration. Kamada markets GLASSIA® in the U.S. through a strategic partnership with Takeda Pharmaceuticals Company Limited and in other countries through local distributors. Kamada's second leading product is KamRAB, a rabies immune globulin (Human) for Post-Exposure Prophylaxis against rabies infection. KamRAB is FDA approved and is being marketed in the U.S. under the brand name KEDRAB and through a strategic partnership with Kedrion S.p.A. In addition to GLASSIA and KEDRAB, Kamada has a product line of four other plasma-derived pharmaceutical products administered by injection or infusion, that are marketed through distributors in more than 15 countries, including Israel, Russia, Brazil, India and other countries in Latin America and Asia. Kamada has late-stage products in development, including an inhaled formulation of AAT for the treatment of AAT deficiency, and in addition, its intravenous AAT is in development for other indications, such as GvHD, prevention of lung transplant rejection and type-1 diabetes. Kamada also leverages its expertise and presence in the plasma-derived protein therapeutics market by distributing more than 20 complementary products in Israel that are manufactured by third parties.

Cautionary Note Regarding Forward-Looking Statements

This release includes forward-looking statements within the meaning of Section 21E of the U.S. Securities Exchange Act of 1934, as amended, and the safe harbor provisions of the U.S. Private Securities Litigation Reform Act of 1995. Forward-looking statements are statements that are not historical facts, such as (without limitation) statements regarding the timing of the start of the unified global pivotal Phase 3 clinical trial in the second half of 2019 and successful results from such a clinical trial, the successful completion of the HFS in the second quarter of 2019 which is a necessary component to start the clinical trial, the AAT market growing at approximately 6-8% each year and Kamada's ability to capture significant market share through its Inhaled AAT, as well as the benefits of Inhaled AAT (e.g., directly reaching the lungs and enhanced convenience) being recognized in the market. Forward-looking statements are based on Kamada's current knowledge and its present beliefs and expectations regarding possible future events and are subject to risks, uncertainties and assumptions. Actual results and the timing of events could differ materially from those anticipated in these forward-looking statements as a result of several factors including, but not limited to, unexpected results of the HFS and/or the Phase 3 clinical study, delays with the studies, additional competition in the markets that Kamada competes, including AAT, regulatory delays, prevailing market conditions, and the impact of general economic, industry or political conditions in the U.S., Israel or otherwise. The forward-looking statements made herein speak only as of the date of this announcement and Kamada undertakes no obligation to update publicly such forward-looking statements to reflect subsequent events or circumstances, except as otherwise required by law.

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