
**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 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, 333-222891 and 333-233267, 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 Enrollment of First Patient into its Pivotal Phase 3 InnovAATe Clinical Trial of Inhaled AAT for the Treatment of Alpha-1 Antitrypsin Deficiency

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: December 16, 2019

KAMADA LTD.

By: /s/ Orna Naveh
Orna Naveh
General Counsel and Corporate Secretary

EXHIBIT INDEX

<u>EXHIBIT NO.</u>	<u>DESCRIPTION</u>
<u>99.1</u>	<u>Kamada Announces Enrollment of First Patient into its Pivotal Phase 3 InnovAAATe Clinical Trial of Inhaled AAT for the Treatment of Alpha-1 Antitrypsin Deficiency</u>

**Kamada Announces Enrollment of First Patient into its Pivotal Phase 3 InnovAAte Clinical Trial
of Inhaled AAT for the Treatment of Alpha-1 Antitrypsin Deficiency**

Rehovot, Israel, December 16, 2019 -- Kamada Ltd. (NASDAQ & TASE: KMDA), a plasma-derived protein therapeutics company, announced today that the first patient has been randomized in Europe into its pivotal Phase 3 InnovAAte clinical trial evaluating the safety and efficacy of the Company's proprietary inhaled Alpha-1 Antitrypsin (AAT) therapy for the treatment of Alpha-1 Antitrypsin Deficiency (AATD). The study is being led by Jan Stolk, M.D., Department of Pulmonology, Member of European Reference Network LUNG, Leiden University Medical Center, The Netherlands.

"I am very excited to lead the InnovAAte study" stated Dr. Stolk. "I believe that this Phase 3 trial of inhaled AAT includes all relevant endpoints which characterize AATD lung disease, and utilizes a sample size that I believe enables the demonstration of clinically meaningful effects on both FEV1 and CT densitometry. As presented in our recent manuscript (ERJ November 2019) describing the results of Kamada's previously completed Phase 2/3 study, AATD patients with severe lung disease treated with inhaled AAT for one year demonstrated slower FEV1 decline. This finding signals inhaled AAT's ability to potentially reduce lung inflammation and destruction, which will be measured in the InnovAAte study by lung function, CT densitometry, symptoms, exacerbations and other disease outcomes."

"The initiation of this Phase 3 clinical trial represents a significant milestone for our inhaled AAT development program," said Amir London, Kamada's Chief Executive Officer. "We are excited about the potential market opportunity for the product, which, if approved, will enter a market currently valued at approximately \$1 billion and growing 6% to 8% annually. We believe that our program is the most advanced of those evaluating potential new AATD treatments in terms of clinical development, and we are encouraged by the strong support we continue to receive from the patient community and leading AATD physicians."

InnovAAte is a randomized, double-blind, placebo-controlled, pivotal Phase 3 trial designed to assess the efficacy and safety of inhaled AAT in patients with AATD and moderate lung disease. Up to 250 patients will be randomized 1:1 to receive either inhaled AAT at a dose of 80mg once daily, or placebo, over two years of treatment. The primary endpoint of the InnovAAte trial is lung function measured by FEV1. Secondary endpoints include lung density changes as measured by CT densitometry, as well as other parameters of disease severity, such as additional pulmonary functions, exacerbation rate and six minute walk test. The safety profile will be monitored continuously by a Data Monitoring Committee with predefined rules to be applied after the first 60 subjects have completed six months of treatment.

Based on recent feedback received from the U.S. Food and Drug Administration (FDA) regarding anti-drug antibodies (ADA) to inhaled AAT, the Company intends to concurrently conduct a sub-study in North America in which approximately 30 patients will be evaluated for the effect of ADA on AAT levels in plasma with inhaled AAT and IV AAT treatments.

Kamada expects to receive further feedback from the FDA related to its Human Factor Study (HFS), which the Company completed in the third quarter of 2019. The HFS was required to support the combination product, consisting of Kamada's inhaled AAT and the investigational eFlow nebulizer system of PARI Pharma GmbH.

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, including statements regarding the current AAT market being valued at approximately \$1 billion and growing 6% to 8% annually, the design and initiation of the FDA required sub-study and the prospects of completing the HFS and the FDA's feedback of the study. 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, further feedback from the FDA and other regulatory bodies with respect to the results of the HFS or the design of the Inhaled AAT phase 3 clinical study or the required sub-study, unexpected results of the Phase 3 clinical study, unexpected results of other ongoing clinical studies, delays of clinical studies including the Phase 3 study as a result of inability to recruit patients, additional competition in the markets that Kamada competes, including AAT, regulatory delays, prevailing market conditions, corporate events associated with our partners, including Takeda, 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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