
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 November 2022

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](#), [333-233267](#) and [333-265866](#).

The following exhibit is attached:

99.1 [Kamada Provides Update on Recent Progress Achieved in Ongoing Pivotal Phase 3 Clinical Trial of Inhaled AAT](#)

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: November 7, 2022

KAMADA LTD.

By: /s/ Yifat Philip
Yifat Philip
Vice President General Counsel and
Corporate Secretary

EXHIBIT INDEX

EXHIBIT NO. DESCRIPTION

99.1 [Kamada Provides Update on Recent Progress Achieved in Ongoing Pivotal Phase 3 Clinical Trial of Inhaled AAT](#)

Kamada Provides Update on Recent Progress Achieved in Ongoing Pivotal Phase 3 Clinical Trial of Inhaled AAT

- *Trial Recruitment Beginning to Accelerate; 30 Patients Enrolled and Treated to Date*
- *Independent Data Safety Monitoring Board (DSMB) Recommends Study Continuation Without Modification for Fourth Time Since Study Initiation*
- *Based on Encouraging Safety Observed to Date, Trial Inclusion Criteria Revised to Also Include Patients with Severe Airflow Limitation, Thereby Expanding Potential Patient Treatment Population*
- *Company Intends to Meet with U.S. Food and Drug Administration and European Medicines Agency During First Half of 2023 to Discuss Study Progress and Potential Opportunities to Shorten the Regulatory Pathway*

Rehovot, Israel, and Hoboken, NJ, November 7, 2022 – Kamada Ltd. (NASDAQ: KMDA; TASE: KMDA.TA), a vertically integrated global biopharmaceutical company focused on specialty plasma-derived therapeutics, today provided an update on recent progress achieved in its ongoing pivotal Phase 3 InnovAAATe 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).

Earlier this year, following the moderation of the COVID-19 pandemic, the study was expanded to additional sites across Europe and enrollment has recently begun to accelerate. To date, 30 patients have been enrolled for treatment, including 14 patients who have already completed the two-year study treatment period at the initial trial site in Leiden, the Netherlands. Importantly, none of these patients discontinued treatment prematurely and no drug-related serious adverse events were reported. Additionally, as part of routine and planned monitoring processes, and for the fourth time since study initiation, the independent Data Safety Monitoring Board (DSMB) recently recommended that the trial continue without modification. Moreover, based on the encouraging safety observed to date, the DSMB supported an expansion to the inclusion criteria to also include subjects with severe airflow limitation (40%<FEV1<80% of predicted; previously inclusion criteria were 50%<FEV1<80%), which is expected to further expedite patient enrolment.

“The strong association between AATD and Chronic Obstructive Pulmonary Disease (COPD) or emphysema suggests that inhaled administration of AAT directly to the lungs may benefit AATD patients,” said Jan Stolk, M.D., Department of Pulmonology, Member of European Reference Network LUNG, Leiden University Medical Center, The Netherlands. “Based on results published in the *European Respiratory Journal* in 2019, Kamada’s previously completed randomized placebo-controlled clinical trial suggested that a decline in lung function as measured by FEV1, the most important parameter associated with shortness of breath, could be attenuated by daily AAT inhalation. Importantly, we have treated 19 patients to date at our site in Kamada’s pivotal Phase 3 InnovAAATe clinical trial, none of whom dropped out, indicating high patient adherence to the treatment. I am highly encouraged by the recent expansion of the trial to additional sites across Europe, and hope that the study results, once available, will validate that daily AAT inhalation is an effective and safe treatment for AATD patients suffering from emphysema. If so, I look forward to supporting regulatory approval of Kamada’s inhaled AAT for the benefit of the AATD community.”

“As the most advanced investigational product for AATD, a substantial commercial opportunity exists for Inhaled AAT to be a transformational next-generation augmentation therapy in the AAT market, which is already over \$1 billion in annual sales in the U.S. and EU,” said Amir London, Kamada’s Chief Executive Officer. “We are pleased with the continued progress of the InnovAAATe trial, the preliminary safety profile demonstrated to date, and support from AATD patients and physicians, which is reflected in the adherence to the treatment. We intend to meet with the FDA and EMA during the first half of 2023 to discuss trial progress and potential opportunities to shorten the regulatory pathway.”

About Kamada

Kamada Ltd. (the “Company”) is a vertically integrated global biopharmaceutical company, focused on specialty plasma-derived therapeutics, with a diverse portfolio of marketed products, a robust development pipeline and industry-leading manufacturing capabilities. The Company’s strategy is focused on driving profitable growth from our current commercial activities as well as our manufacturing and development expertise in the plasma-derived biopharmaceutical market. The Company’s commercial products portfolio includes its developed and FDA approved products GLASSIA® and KEDRAB® as well as its recently acquired FDA approved plasma-derived hyperimmune products CYTOGAM®, HEPAGAM B®, VARIZIG® and WINRHO®SDF. The Company has additional four plasma-derived products which are registered in markets outside the U.S. The Company distributes its commercial products portfolio directly, and through strategic partners or third-party distributors in more than 30 countries, including the U.S., Canada, Israel, Russia, Brazil, Argentina, India and other countries in Latin America and Asia. The Company has a diverse portfolio of development pipeline products including an inhaled AAT for the treatment of AAT deficiency for which the Company is currently conducting the InnovAAte clinical trial, a randomized, double-blind, placebo-controlled, pivotal Phase 3 trial. The Company leverages its expertise and presence in the Israeli pharmaceutical market to distribute in Israel more than 20 products that are manufactured by third parties and have recently added eleven biosimilar products to its Israeli distribution portfolio, which, subject to EMA and the Israeli MOH approvals, are expected to be launched in Israel through 2028. FIMI Opportunity Fund, the leading private equity investor in Israel, is the Company’s lead shareholder, beneficially owning approximately 21% of the outstanding ordinary shares.

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: 1) the potential expansion of the study which may accelerate enrollment, 2) potential successful results from the Phase 3 clinical study, 3) potential benefits of Inhaled AAT, including treatment for AATD patients suffering from emphysema and inhaled administration of AAT directly to the lungs being beneficial to AATD patients, and 4) Inhaled AAT being a transformational next-generation augmentation therapy in the AAT 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, the continued evolution of the COVID-19 pandemic, its scope, effect and duration, unexpected results of the Phase 3 clinical study, delays with the studies, additional competition in the AAT market, regulatory delays, changes with FDA and other regulatory agencies’ rules and regulations, prevailing market conditions and the impact of general economic, industry or political conditions in the U.S., Israel or otherwise, and other risks detailed in Kamada’s filings with the U.S. Securities and Exchange Commission (the “SEC”) including those discussed in its most recent Annual Report on Form 20-F and in any subsequent reports on Form 6-K, each of which is on file or furnished with the SEC and available at the SEC’s website at www.sec.gov. 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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