
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 May 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](#) and [333-233267](#).

The following exhibit is attached:

99.1 [Kamada Announces Expansion of Pivotal Phase 3 Clinical Trial of Inhaled AAT to Additional Six Clinical Sites Across Europe; and Positive Recommendation by DSMB to Continue the Trial Without Modification](#)

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: May 17, 2022

KAMADA LTD.

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

EXHIBIT INDEX

EXHIBIT NO. DESCRIPTION

99.1	<u>Kamada Announces Expansion of Pivotal Phase 3 Clinical Trial of Inhaled AAT to Additional Six Clinical Sites Across Europe; and Positive Recommendation by DSMB to Continue the Trial Without Modification</u>
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Kamada Announces Expansion of Pivotal Phase 3 Clinical Trial of Inhaled AAT to Additional Six Clinical Sites Across Europe; and Positive Recommendation by DSMB to Continue the Trial Without Modification

REHOVOT, Israel – May 17, 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 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).

Following the recent moderation of the global COVID-19 pandemic, the Company is expanding the study to new European sites. Clinical sites were recently opened in Belgium, Finland and Sweden, and patient enrollment has started. In the coming weeks, three additional sites in the UK, Ireland and the Netherlands are expected to open for patients' enrollment. These six sites are in addition to the existing site in Leiden, the Netherlands, which has been active and recruited patients since study initiation in November 2019.

Moreover, as part of routine and planned monitoring processes, the Independent Data Safety Monitoring Board (DSMB) recently recommended that the trial continue without modification. To date, no patients have discontinued treatment prematurely and no drug-related serious adverse events have been reported. Additionally, nine patients, treated at the Leiden site, have already completed the full two-year treatment period and are now under follow up.

"With the global COVID-19 pandemic now moderating, we are excited to be in a position to expand this promising pivotal study, open new sites and expedite enrollment," said Amir London, Kamada's Chief Executive Officer. "Importantly, this is a unified trial, as the study's data are expected to qualify for regulatory submissions with both the FDA and the EMA. A substantial opportunity exists for inhaled AAT to be a transformational next-generation augmentation therapy with the potential to improve patients' convenience and quality of life compared to existing available IV treatments. The AAT market is already over \$1 billion in annual sales in the U.S. and EU and growing steadily. We look forward to further expanding this trial, which is the most advanced investigational product for AAT deficiency."

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.

More information about the study and the clinical sites can be found at www.innovaate-study.com

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 11 biosimilar products to its Israeli distribution portfolio, which, subject to EMA and the Israeli MOH approvals, are expected to be launched in Israel between the years 2022 and 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: moderation of COVID-19 pandemic and its positive effect on patient enrollment, positive developments for the clinical trial, the ability to submit the clinical study results with the FDA and EMA, and market opportunities for inhaled AAT and its perceived advantages to comparable products. 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 evolvement of the COVID-19 pandemic, its scope, effect and duration, disruption to the supply chain due to COVID-19 pandemic, ability to continue to recruiting patients into the pivotal Phase 3 InnovAATe clinical trial, unexpected results of clinical studies, regulatory delays, 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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