
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 January 2023

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 Announces Submission of Application to the U.S. FDA to Manufacture CYTOGAM® at the Company's Facility in Israel](#)

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: January 4, 2023

KAMADA LTD.

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

EXHIBIT INDEX

EXHIBIT NO. DESCRIPTION

99.1	Kamada Announces Submission of Application to the U.S. FDA to Manufacture CYTOGAM® at the Company's Facility in Israel
------	--

Kamada Announces Submission of Application to the U.S. FDA to Manufacture CYTOGAM® at the Company's Facility in Israel

- *FDA Approval Currently Expected by Mid-2023*
- *Sales of CYTOGAM® Highest Among Four IgG Products Acquired in November 2021, with Gross Margins Over 50%*
- *Ability to Manufacture CYTOGAM at Kamada's Facility to Positively Impact Plant Utilization and Efficiency*

Rehovot, Israel, and Hoboken, NJ – January 4, 2023 — Kamada Ltd. (NASDAQ: KMDA; TASE: KMDA.TA), a vertically integrated global biopharmaceutical company, focused on specialty plasma-derived therapeutics, today announced that it has submitted an application to the U.S. Food and Drug Administration (FDA) to manufacture CYTOGAM® (Cytomegalovirus Immune Globulin Intravenous [Human]) (CMV-IGIV) at its facility in Beit Kama, Israel. The application was submitted as a prior approval supplement (PAS) and FDA approval is currently expected by mid-2023.

The anticipated FDA approval will mark the successful conclusion of the technology transfer process for CYTOGAM from the previous manufacturer, CSL Behring. A similar application to the Canadian health authorities is expected to be submitted imminently.

Kamada's CYTOGAM technology transfer supplement includes an upstream protein solution manufacturing step performed by Prothya Biosolutions in its plant in Belgium, under a contract manufacturing agreement between the parties.

CYTOGAM is indicated for the prophylaxis of cytomegalovirus disease associated with the transplantation of the kidney, lung, liver, pancreas, and heart, and is the sole FDA-approved immunoglobulin (IgG) product for this indication. CYTOGAM is the highest selling of the four IgG products acquired from Saol Therapeutics in November 2021 and maintains gross margins of over 50%.

"The submission of this application to the U.S. FDA to manufacture CYTOGAM represents an important operational milestone for our company," said Amir London, Kamada's Chief Executive Officer. "Importantly, our business leveraged the significant benefits of the acquired portfolio of four FDA-approved IgGs throughout 2022, and we expect additional growth from these important products in 2023 and beyond. We plan to initiate commercial manufacturing of CYTOGAM at our Israeli facility in the second half of this year upon receipt of FDA approval, which will positively impact the facility's utilization and efficiency."

Kamada's currently available inventory of CYTOGAM is sufficient to meet market demand until the currently anticipated FDA approval timing of mid-2023.

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 InnovAAATe 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) FDA approval for manufacturing of CYTOGAM in Israel anticipated in mid-2023, 2) similar application to be submitted to the Canadian health authorities imminently, 3) additional growth expected for the IgG portfolio in 2023 and beyond, 4) commercial manufacturing of CYTOGAM in Israel in the second half of 2023, and 5) current supply of CYTOGAM sufficient until the manufacturing at the Israeli facilities. 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, availability of sufficient raw materials required to maintain manufacturing plans, disruption to the supply chain due to COVID-19 pandemic, continuation of inbound and outbound international delivery routes, continued demand for the IgG product portfolio, FDA and Canadian health authorities’ approval process, financial conditions of the Company’s customer, suppliers and services providers, Kamada’s ability to integrate the new product portfolio into its current product portfolio, Kamada’s ability to grow the revenues of its new product portfolio, and leverage and expand its international distribution network, Kamada’s ability to manage operating expenses, additional competition in the markets that Kamada competes, 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.

CONTACTS:

Chaime Orlev
Chief Financial Officer
IR@kamada.com

Brian Ritchie
LifeSci Advisors, LLC
212-915-2578
britchie@LifeSciAdvisors.com
