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 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 Rul 101(b)(1):
Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rul 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

Nos. <u>333-192720</u>, <u>333-207933</u>, <u>333-215983</u>, <u>333-222891</u>, <u>333-233267</u> and <u>333-265866</u>.

This Form 6-K is being incorporated by reference into the Registrant's Form S-8 Registration Statements, File

The following exhibit is attached:

99.1 <u>Kamada Announces U.S. FDA Approval of its Application to Manufacture CYTOGAM® at the Company's Facility in Israel</u>

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 3, 2023 KAMADA LTD.

By: /s/ Nir Livneh

Nir Livneh Vice President General Counsel and Corporate Secretary

EXHIBIT INDEX

EXHIBIT NO. DESCRIPTION
99.1 Kamada Annour Kamada Announces U.S. FDA Approval of its Application to Manufacture CYTOGAM® at the Company's Facility in Israel

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

- Sales of CYTOGAM® Highest Among Four IgG Products Acquired in November 2021 with Approximately \$23 Million in Revenues in 2022, and Gross Margins Over 50%
- Approval to Manufacture CYTOGAM at Kamada's Facility to Positively Impact Plant Utilization and Efficiency

Rehovot, Israel, and Hoboken, NJ – May 3, 2023 -- Kamada Ltd. (NASDAQ: KMDA; TASE: KMDA.TA), a vertically integrated global biopharmaceutical company, focused on specialty plasma-derived therapeutics, today announced that the U.S. Food and Drug Administration (FDA) has approved its application to manufacture CYTOGAM® (Cytomegalovirus Immune Globulin Intravenous [Human]) (CMV-IGIV) at the Company's facility in Beit Kama, Israel. The FDA approval represents the successful conclusion of the technology transfer process for CYTOGAM from the previous manufacturer, CSL Behring.

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.

A similar technology transfer application was submitted to the Canadian health authorities in January 2023 and is currently under review.

CYTOGAM is indicated for the prophylaxis of cytomegalovirus disease (CMV) 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 by Kamada in November 2021, generating approximately \$23 million in sales in 2022, and maintains gross margins of over 50%.

"The U.S. FDA approval of this application to manufacture CYTOGAM, which was granted within our expected timeline, following a successful on-site inspection by the FDA, represents a significant accomplishment for Kamada. This is the third product, in addition to GLASSIA® and KEDRAB®, to be approved by the FDA for manufacturing at our Israeli site," said Amir London, Kamada's Chief Executive Officer. "Our business continues to leverage the substantial benefits of the acquired portfolio of four FDA-approved IgGs, and we expect additional growth from these important products in 2023 and beyond. We intend to initiate commercial manufacturing of CYTOGAM at our Israeli facility shortly, which will positively impact the facility's utilization and efficiency. Kamada's continued investment in the manufacturing and distribution of CYTOGAM is representative of the Company's commitment to ensuring the ongoing supply and availability of this important medicine to healthcare providers and solid organ transplant patients."

About Kamada

Kamada Ltd. (the "Company") is a commercial stage global biopharmaceutical company with a portfolio of marketed products indicated for rare and serious conditions and a leader in the specialty plasma-derived field, focused on diseases of limited treatment alternatives. The Company is also advancing an innovative development pipeline targeting areas of significant unmet medical need. The Company's strategy is focused on driving profitable growth from its significant commercial catalysts as well as its manufacturing and development expertise in the plasma-derived and biopharmaceutical fields. The Company's commercial products portfolio includes six FDA approved plasma-derived biopharmaceutical products: CYTOGAM®, KEDRAB®, WINRHO SDF®, VARIZIG®, HEPAGAM B® and GLASSIA®, as well as KAMRAB®, KAMRHO (D)® and two types of equine-based anti-snake venom (ASV) products. 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, Argentina, Brazil, India,

Australia and other countries in Latin America, Europe, Middle East, and Asia. The Company leverages its expertise and presence in the Israeli market to distribute, for use in Israel, more than 25 pharmaceutical products that are supplied by international manufacturers and during recent years added eleven biosimilar products to its Israeli distribution portfolio, which, subject to the European Medicines Agency (EMA) and the Israeli Ministry of Health approvals, are expected to be launched in Israel through 2028. The Company owns an FDA registered plasma collection center in Beaumont, Texas, which currently specializes in the collection of hyper-immune plasma used in the manufacture of KAMRHO (D). In addition to the Company's commercial operation, it invests in research and development of new product candidates. The Company's leading investigational product is an inhaled AAT for the treatment of AAT deficiency, for which it is continuing to progress the InnovAATe clinical trial, a randomized, double-blind, placebocontrolled, pivotal Phase 3 trial. 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 business continuing to leverage the substantial benefits of the acquired portfolio of four FDA-approved IgGs, 2) additional growth expected for the IgG portfolio in 2023 and beyond, and 3) commercial manufacturing of CYTOGAM in Israel shortly, which will positively impact the facility's utilization and efficiency. 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, availability of sufficient raw materials required to maintain manufacturing plans, approval by the Canadian health authorities of the CYTOGAM technology transfer application, continued utilization of Kamada's Israeli manufacturing site, 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 customers, 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:

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