# 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 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. <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> .

# 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 16, 2023 KAMADA LTD.

By: /s/ Nir Livneh

Nir Livneh

Vice President General Counsel and

Corporate Secretary

# EXHIBIT INDEX

EXHIBIT NO. 99.1 DESCRIPTION Kamada Announ Kamada Announces Receipt of Marketing Authorization for Glassia® for Treatment of Alpha-1 Antitrypsin Deficiency in Switzerland

#### Kamada Announces Receipt of Marketing Authorization for Glassia® for Treatment of Alpha-1 Antitrypsin Deficiency in Switzerland

- Switzerland is the first European country to approve Glassia®, which received U.S. FDA approval in 2010
- Glassia will be commercialized by IDEOGEN AG in Switzerland and the therapy is expected to be available to patients and providers during the second half of 2023
- The current Alpha-1 Antitrypsin Deficiency (AATD) market in Switzerland is estimated to be over \$15 million annually

REHOVOT, Israel, and Hoboken, NJ – May 16, 2023 -- Kamada Ltd. (NASDAQ: KMDA; TASE: KMDA.TA), 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, today announced that Swissmedic has granted marketing authorization for Glassia® [Alpha-1 Proteinase Inhibitor (Human)] in Switzerland for chronic augmentation and maintenance therapy in adults with clinically evident emphysema due to severe hereditary Alpha-1 antitrypsin deficiency (AATD).

"Switzerland is the first European country to approve Glassia for AATD, representing a significant milestone for Kamada, in a market which is currently estimated to be over \$15 million annually," said Amir London, Kamada's Chief Executive Officer. "The commercial launch of the product in Switzerland is expected to occur during the second half of this year, upon obtaining the required reimbursement coverage. To ensure wide access to eligible patients, we are excited to partner with the IDEOGEN Group, a company focused on the commercialization of specialty medicines for rare diseases across Europe."

"We are delighted to announce our partnership with Kamada for the commercialization of Glassia in Switzerland. IDEOGEN is focused on rapidly introducing essential U.S. Food and Drug Administration (FDA)-approved therapies that enhance patients' quality of life into the European markets and serving as a reliable partner for leading international biopharmaceutical companies," stated H. Tuygan Göker, Founder, Chairman, and CEO of IDEOGEN Group. "With Glassia's expanded label and the advantage of a ready-to-infuse liquid form, the product represents a compelling treatment alternative for AATD patients in Switzerland. Currently, according to the official Swiss Alpha-1 Patient Registry, approximately 200 patients are undergoing treatment for this devastating medical condition. Furthermore, it is estimated that approximately 1,400 patients remain undiagnosed and unaware of their developing AATD. Our specialized medical and clinical expertise, as well as our operational agility and expertise, in combination with Glassia's product profile, have the potential to positively impact the current AATD treatment landscape in Switzerland."

Glassia previously received FDA approval in 2010, and the product is approved for use in multiple other international markets, including Argentina, Russia, Israel, and Brazil. In the U.S., Kamada currently receives royalties, anticipated to be in the range of \$10 million to \$20 million per year through 2040, for Glassia from Takeda. Ex-U.S. sales of Glassia were approximately \$6 million in 2022.

In addition to its focus on expanding the commercialization of Glassia in the international markets, Kamada is also committed to advancing the development of an Inhaled AAT treatment, conducting the InnovAATe study, an ongoing pivotal Phase 3 clinical trial of Inhaled AAT for patients with AATD. The Company intends to meet with the FDA and the European Medicines Agency to discuss study progress and potential opportunities to shorten regulatory pathways in the first half of 2023.

#### About Glassia®

GLASSIA is an Alpha1 -Proteinase Inhibitor (Human), indicated for chronic augmentation and maintenance therapy in individuals with clinically evident emphysema due to severe hereditary deficiency of Alpha1, also known as alpha1-antitrypsin (AAT) deficiency. GLASSIA increases antigenic and functional (anti-neutrophil elastase capacity, ANEC) serum levels and antigenic lung epithelial lining fluid levels of Alpha1.

#### 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 licensed 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, placebo-controlled, 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.

#### About Ideogen

Ideogen Group GmbH is a Swiss, privately-owned, specialty pharmaceutical and disease management company addressing unmet medical needs in Oncology, Hematology, and Rare/Orphan diseases, along with a diverse range of other therapeutic areas. With a strong track record in navigating the commercialization process, Ideogen guides unlicensed products through Managed Access Programs (MAP) to achieve licensed sales of registered assets. Ideogen's comprehensive approach encompasses all aspects of the value chain, including regulatory, market access, pricing, and reimbursement strategies, as well as product commercialization in Europe, MENA, Russia/CIS. Ideogen's accomplishments to date are driven by a robust in-house medical and clinical team, experienced key account management professionals, and established partner relationships in specialized settings that demand geography-specific solutions. This unique combination of expertise enables Ideogen to excel in delivering life-changing therapies to patients at the speed of life. With its headquarters in Switzerland, sub-regional hubs in Austria, Netherlands, and Spain supported by field presence in Germany, France, Italy, UK and a regional hub in Turkey catering to Turkish, Middle East, and Russia/CIS markets, Ideogen boasts a wide-reaching presence that covers Europe and Eurasia effectively. Continuously striving to transform into a pioneer, Ideogen is actively expanding its capabilities by entering the high-value injectables Gene Therapy manufacturing space in the EU. This strategic move will position Ideogen as a vertically integrated, specialty pharmaceutical organization with comprehensive CDMO capabilities, ready to meet the emerging needs of the next generation of personalized medicine.

#### **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 expected date of the commercial launch of the product in Switzerland in the second half of 2023, 2) obtaining the required reimbursement coverage for the product in Switzerland, 3) the impact of the partnership between Kamada and Ideogen on the current AATD treatment landscape in Switzerland, 3) expectation of receiving GLASSIA royalties in the range of \$10 million to \$20 million per year through 2040, 4) intention to meet with the FDA and European Medicines Agency during the first half of 2023 to discuss study progress and potential opportunities to shorten the regulatory pathway, 5) planned distribution of a portfolio of 11 biosimilar products, expected to be launched upon receipt of Israeli regulatory approval, through 2028, 6) the estimates AATD market in Switzerland of \$15 million annually, and 7) the estimated unaware and undiagnosed 1,400 AATD patients in Switzerland. 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, 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 international 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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