# 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 March 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>.

The following exhibit is attached:

# 99.1 99.2 <u>Kamada Issues 2023 CEO Letter to Shareholders</u> <u>Kamada 2022 Results Presentation</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: March 15, 2023 KAMADA LTD.

By: /s/ Yifat Philip

Yifat Philip Vice President General Counsel and Corporate Secretary

# EXHIBIT INDEX

EXHIBIT NO. DESCRIPTION

99.1 Kamada Issues 2

99.2 Kamada 2022 Re Kamada Issues 2023 CEO Letter to Shareholders Kamada 2022 Results Presentation

#### Kamada Issues 2023 CEO Letter to Shareholders

**Rehovot, Israel, and Hoboken, NJ** – **March 15, 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 issued a Letter to Shareholders from Amir London, Chief Executive Officer. Dear Shareholders, Colleagues and Business Partners:

The recently completed 2022 year was a transformational period for Kamada as we embarked on a new and exciting chapter in the Company's evolution. Most importantly, we have now completed our rapid transition from our historical dependence on GLASSIA® sales to Takeda to a diversified, fully integrated specialty plasma company with six U.S. Food and Drug Administration (FDA) approved proprietary products and strong commercial capabilities in the U.S. market, as well as a global sales footprint in over 30 countries.

Earlier today, we reported our full-year 2022 financial results, which met our annual guidance, with total revenues of \$129.3 million and EBITDA of \$17.8 million, representing margins of 14%. Our strong performance in 2022 represented year-over-year revenue growth of 25%, and a 3x increase in EBITDA.

Moreover, we generated a record operating cash flow of \$28.6 million during 2022, supporting the increase in our cash position to \$34.3 million as of December 31, 2022.

Looking ahead, we expect the momentum from 2022 to extend throughout 2023, with profitability to be further increased as compared to the past year. As such, we are introducing full-year 2023 revenue guidance of \$138 million to \$146 million and EBITDA of \$22 million to \$26 million; the mid-point expected EBITDA represents approximately 35% growth year-over-year.

Our impressive results in 2022, and positive outlook for this year, are the consequence of our ability to leverage multiple growth drivers, including the portfolio of four FDA approved IgGs, acquired in late 2021, KEDRAB® sales in the U.S., GLASSIA royalties from Takeda, other Proprietary products sales in the international markets, and our thriving Israeli distribution business.

#### These significant catalysts are driving our annual double-digit growth, with significant upside potential and limited downside risk.

The November 2021 acquisition of the four FDA approved IgGs, consisting of CYTOGAM®, HEPAGAMB®, VARIZIG® and WINRHO®SDF, following a thorough search for the ideal assets for Kamada, was a critical strategic and synergistic advancement for the Company. Full-year 2022 revenues of the acquired portfolio increased by 24% as compared to full-year 2021. This portfolio is generating over 50% gross margins. I am pleased to report that we anticipate continued growth in the portfolio's revenues in 2023 and beyond.

During 2022, as part of the establishment of our direct presence in the U.S. market, we deployed a team of U.S.-based experienced sales and medical affairs professionals who have rapidly established our operations in this key market. The U.S. sales team is making good progress in promoting our portfolio of specialty plasma-derived IgG products to physicians and other healthcare practitioners through direct engagement and opportunities at medical conventions. The Medical Affairs team is working to educate physicians, while addressing their scientific and clinical inquiries, including participating in major medical conferences in the U.S. We are also leveraging our existing strong international distribution network to grow product revenue in new territories, primarily in Asia, Latin America and the Middle East. Our achievements with these key products in 2022 included winning a new \$11.4 million procurement agreement for VARIZIG from an international organization operating principally in Latin America and securing a \$22 million extension of a Canadian supply tender.

CYTOGAM is the largest of the four acquired products. The product is indicated for the prophylaxis of cytomegalovirus disease associated with solid organs transplantation. This proprietary and unique therapy is the only FDA approved IgG product for its indication. We recently submitted an application to the FDA to manufacture CYTOGAM at our plant in Israel, and we expect to receive regulatory approval to do so by mid-2023. The anticipated FDA approval will mark the successful conclusion of the technology transfer process for the product from its previous manufacturer, CSL Behring. The ability to manufacture the product at our facility will positively impact our plant utilization and efficiency.

KEDRAB, marketed in the U.S. by Kedrion, continued to gain market share during 2022 in the U.S., a market which is estimated to be \$150 million annually. With Kamada's support, Kedrion's commercial team successfully leveraged the FDA approval obtained in 2021 for a label expansion for the product that helped differentiate it as the first and only human rabies immunoglobulin (HRIG) available in the U.S. to be clinically studied in children. We anticipate that sales of the product will continue to grow significantly over the next few years.

During 2022, as planned, we began receiving royalties from Takeda based on sales of GLASSIA. We expect royalties in the range of \$10 million to \$20 million per year through 2040, which will support our profitability and cash position. In addition, we continue to grow sales of GLASSIA in international markets through our local partners.

Another major strategic step we are taking is the advancement of our plasma collection business through our wholly owned subsidiary, Kamada Plasma, based in Texas. Last year, we expanded the hyperimmune plasma collection capacity at our first center and are currently advancing our plan to open additional centers in the U.S. to further enhance our supply of specialty and regular plasma.

We are also very excited about our innovative investigational Inhaled AAT product candidate for the treatment of AAT Deficiency, a technology which has shown to be highly effective in delivering AAT directly into a patient's lungs. A substantial opportunity exists for Inhaled AAT to be a transformational product in a market that is already over \$1 billion in annual sales in the U.S. and EU. We are currently conducting the InnovAATe clinical trial, a randomized, double-blind, placebo-controlled, pivotal Phase 3 study. During 2022, we began to accelerate trial recruitment with seven clinical sites now open and enrolling patients. In November 2022, the independent Data Safety Monitoring Board (DSMB) recommended that the study continue without modification for the fourth time since study initiation. Moreover, based on encouraging safety observed to date, the study inclusion criteria were revised to also include patients with severe airflow limitation. During 2023, we intend to continue expediting trial recruitment, as well as meet with the FDA and the European Medicines Agency to discuss study progress and potential opportunities to shorten the regulatory pathways.

In our distribution segment, we are leveraging our expertise and strong presence in the Israeli market to register, market and distribute more than 25 products that are developed and manufactured by our international partners. In recent years, we have significantly grown our pipeline of distributed products and, in 2023, we anticipate continuing to launch new therapies across multiple medical specialties. An area of key strategic focus in this business is the planned distribution of a portfolio of 11 biosimilar products, expected to be launched upon receipt of Israeli regulatory approval, through 2028, with overall annual anticipated peak sales, within several years of launch, of more than \$40 million. Included in this portfolio are 8 products through a distribution agreement with Alvotech, a global leader in the development and manufacturing of biosimilar drugs.

In closing, 2022 was a year of significant progress for Kamada during which we executed on a rapid financial turnaround of the Company by leveraging multiple robust value-creating catalysts, and we are well-positioned for further substantial revenue and profitability growth in 2023 and the years beyond with substantial upside potential and limited downside risk as a global leader in the specialty plasma industry. Importantly, looking past 2023, based on our multiple catalysts, we continue to project annual double-digit growth in revenues and profits in the foreseeable years ahead.

On behalf of the entire Kamada team, we look forward to continuing to support patients and clinicians with the important lifesaving products that we develop, manufacture, and commercialize. We thank all of our investors for their support and remain committed to creating long-term shareholder value.

Sincerely,

Amir London Chief Executive Officer Kamada Ltd.

#### **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, 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.

#### **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: 2023 revenue guidance in the range of \$138 million to \$146 million, 2) 2023 EBITDA guidance in the range of \$22 million to \$26 million, 3) expected mid-point EBITDA representing approximately 35% growth year over year, 4) expectation that there will be continued growth in the IgGs portfolio in 2023, 5) expectation to receive FDA approval to manufacture CYTOGAM at Kamada's plant in Israel by mid-2023, which will positively impact Kamada's plant utilization and efficiency, 6) anticipation that KEDRAB's sales will continue to grow significantly over the next few years, 7) expectation of receiving GLASSIA royalties in the range of \$10 million to \$20 million per year through 2040, 8) plans to open additional plasma centers in the U.S., 9) 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, 10) anticipation that in 2023 we will continue to launch new therapies across multiple medical specialties, 11) planned distribution of a portfolio of 11 biosimilar products, expected to be launched upon receipt of Israeli regulatory approval, through 2028, with an overall annual anticipated peak sales, within several years of launch, of more than \$40 million, 12) belief that by leveraging multiple robust valuecreating catalysts Kamada is well positioned for further substantial revenue and profitability growth in 2023 and the years beyond with limited downside risk and substantial upside potential and 13) belief that based on multiple catalysts, Kamada will experience annual double-digit growth in revenues and profits in the foreseeable years ahead. 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, 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, impact of the workforce downsizing plan, continued demand for Kamada's products, including GLASSIA and KEDRAB and its Distribution segment related products in Israel, 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 this new product portfolio, and leverage and expand its international distribution network, ability to reap the benefits of the recent acquisition of the plasma collection center, including the ability to open additional U.S. plasma centers, and acquisition of the FDA-approved plasmaderived hyperimmune commercial products, the ability to continue enrollment of the pivotal Phase 3 InnovAATe clinical trial, unexpected results of clinical studies, Kamada's ability to manage operating expenses, additional competition in the markets that Kamada competes, regulatory delays, the impacts of the failure of Silicon Valley Bank and recent turmoil in the banking industry, 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



#### FORWARD LOOKING STATEMENT



This presentation is not intended to provide investment or medical advice. It should be noted that some products under development described herein have not been found safe or effective by any regulatory agency and are not approved for any use outside of clinical trials.

This presentation contains forward-looking statements, which express the current beliefs and expectations of Kamada's management. Such statements include the 2023 financial guidance, the information on the slide titled: "Financial Growth Trajectory," and "5 Significant Catalysts Driving Double Digit Growth" projected future royalties from Takeda for Glassia, success of the inhaled AAT clinical study, its benefits and potential market size, success of the U.S. plasma collection expansion and revenue potential, and success in launching new products in the Israel distribution business segment. These statement involve a number of known and unknown risks and uncertainties that could cause Kamada's future results, performances or achievements to differ significantly from the prospected results, performances or achievements expressed or implied by such forward-looking statements. Important factors that could cause or contribute to such differences include, but are not limited to, risks relating to Kamada's ability to successfully develop and commercialize its products and product candidates, the progress and results of any clinical trials, the introduction of competing products, the continued market acceptance of Kamada's commercial products portfolio, the impact of any changes in regulation and legislation that could affect the pharmaceutical industry, the difficulty of predicting, obtaining or maintaining U.S. Food and Drug Administration, European Medicines Agency and other regulatory authority approvals, the regulatory environment, restrains related to third parties? I'p rights and changes in the worldwide pharmaceutical industry and other factors that are discussed under the heading "Risk Factors" of Kamada's 2022 Annual Report on Form 20-F (filed on March 15, 2023) as well as in Kamada's recent Forms 6-K filed with the U.S. Securities and Exchange Commission.

This presentation includes certain non-IFRS financial information, which is not intended to be considered in isolation or as a substitute for, or superior to, the financial information prepared and presented in accordance with IFRS. The non-IFRS financial measures may be calculated differently from, and therefore may not be comparable to, similarly titled measures used by other companies. In accordance with the requirement of the SEC regulations a reconciliation of these non-IFRS financial measures to the comparable IFRS measures is included in an appendix to this presentation. Management uses these non-IFRS financial measures for financial and operational decision-making and as a means to evaluate period-to-period comparisons. Management believes that these non-IFRS financial measures provide meaningful supplemental information regarding Kamada's performance and liquidity.

Forward-looking statements speak only as of the date they are made, and Kamada undertakes no obligation to update any forward-looking statement to reflect the impact of circumstances or events that arise after the date the forward-looking statement was made, except as required by applicable securities laws. You should not place undue reliance on any forward-looking statement and should consider the uncertainties and risks noted above, as well as the risks and uncertainties more fully discussed under the heading "Risk Factors" of Kamada's 2022 Annual Report on Form 20-F (filed on March 15, 2023) as well as in Kamada's recent Forms 6-K filed with the U.S. Securities and Exchange Commission.

2

#### **KAMADA HIGHLIGHTS**



Kamada is a commercial stage global biopharmaceutical company with a portfolio of marketed products indicated for rare and serious conditions. The company is a leader in the specialty plasma-derived field focused on diseases of limited treatment alternatives.

Kamada is advancing an innovative development pipeline targeting areas of significant unmet medical need



6 FDA approved products; global commercial network selling in over 30 countries



Multiple growth drivers with significant upside potential and limited downside risk



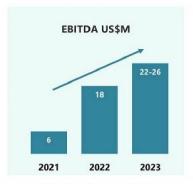
2023 revenue guidance of \$138M-\$146M; EBITDA of \$22M-\$26M; rapidly growing; positive cash 3 flow; compelling financial profile Kamada / March 2023

# FINANCIAL GROWTH TRAJECTORY



# Strategic acquisition & multiple catalysts drove 2022 financial turnaround & expected 2023 growth





2023 represents annual guidance

### Record Annual Operating Cash Flow - \$28.6 Million in Fiscal Year 2022

Adjusted EBITDA is defined as net income, plus (i) tax expense, (i) financial income (expense), net, (iii) depreciation and amortization; and (v) non-cash share-based compensation expenses

# **5 SIGNIFICANT CATALYSTS DRIVING DOUBLE DIGIT GROWTH**



Contribution to overall revenue (by estimated proportion of each catalyst)



CYTOGAM (~\$23M FY22) & KEDRAB (~\$16M FY22) significant growth in the U.S. @ over 50% GM



6 IgG products marketed in over 30 countries, including WHO (~\$44M FY22)



Israeli distribution growth, including launch of Biosimilar products (~\$27M FY22)



Glassia royalties \$10M-\$20M/year through 2040 (~\$12M FY22)



Glassia ex-U.S. (~\$6M FY22) @ 40% GM

5

# 6 FDA-APPROVED SPECIALITY PLASMA PRODUCTS; KEY FOCUS ON TRANSPLANTATION & RARE CONDITIONS





#### **CYTOGAM**®

[Cytomegalovirus Immune Globulin Intravenous (Human)] Prophylaxis of cytomegalovirus disease associated with transplantation



### **KEDRAB/KAMRAB®**

[Rabies Immune Globulin (Human)] Post exposure prophylaxis of rabies infection



#### WINRHO®

[Rho(D) Immune Globulin (Human)] Treatment of immune thermobocytopunic purpura (ITP) & suppression of Rh isoimmunization (HDN)



### **HEPGAM B®**

[Hepatitis B Immune Globulin (Human)] Prevention of HBV recurrence following liver transplantation



#### **VARIZIG®**

[Varicella Zoster Immune Globulin (Human)] Post-exposure prophylaxis of varicella in high- risk patient groups



#### **GLASSIA®**

[Alpha1-Proteinase Inhibitor (Human)] Augmentation therapy for Alpha-1 Antitrypsin Deficiency (AATD)

. 6

# STRATEGIC ENTRY INTO THE U.S. PLASMA COLLECTION MARKET



Kamada Plasma was established in Q1 2021 through the acquisition of an FDA-licensed plasma collection center in Texas; focused on collecting hyper-immune plasma for specialty IgG's

- Strategic transaction which advances Kamada's objective to evolve into a fully integrated specialty plasma company, enhancing selfsupply for our hyperimmune products
- Planning to open additional centers in the U.S., collecting hyper-immune plasma, as well as normal source plasma (NSP)
- Average annual revenues of a mature collection center ranges between \$8M-\$10M



#### **INHALED AAT ANTICIPATED BENEFITS**





Global, double-blind, randomized, placebo-controlled pivotal Phase 3 clinical trial to test the safety and efficacy of inhaled AAT in patients with AATD. Study design meets FDA and EMA's requirements

- Non-invasive, at-home treatment. Expected better ease of use and quality of life for AATD patients than current IV standard of care
- Most effective mode of treatment for delivering therapeutic amounts of AAT directly into the airways
- Studied in more than 200 individuals to date, with an established safety profile
- Demonstrated positive effect on lung function (FEV1) decline in a previous placebo-controlled study
- Only 1/8th of the IV AAT dosing, more cost-effective; favorable market access landscape
- The leading new innovative AATD treatment in advanced clinical stage (Ph-3)

9

### KAMADA INVESTMENT HIGHLIGHTS



A global leader; focused on areas of limited treatment alternatives

Financially attractive; profitable; cash-generating; continued double digit

growth

6 FDA approved products with significant worldwide growth potential

Leading innovative product for AAT Deficiency in late stage development;

targeting a market of over \$1B

Significant upside potential with limited downside













9

# **SUMMARY FINANCIAL DATA**



# Strong 2022 performance demonstrates successful strategic transition

US \$ M	2021	2022	Details
PROPRIETARY	76	103	36% YoY increase
DISTRIBUTION	28	27	
TOTAL REVENUES	104	129	25% YoY increase
GROSS PROFIT	31	47	54% YoY increase
GROSS MARGIN	30%	36%	
OPEX	(31)	(42)	
NET PROFIT	(0)	(2)	Amortization (\$7.1M) & finance costs on LT liabilities (\$6.8)
ADJ. EBITDA	6	18	2022 EBITDA @ 14%, within annual guidance
CASH	19	34	\$15M positive cash flow; \$29 positive cash flow from operations
ASSETS	319	322	Including acquisition related intangible assets (\$143M)
LIABILITIES	(38)	(45)	Including, current, lease and LT employe benefits
BANK LOAN	(20)	(17)	5-year term loan
CONTINGENT LIABILITIES	(84)	(85)	Acquisition related contingent liabilities
EQUITY	(177)	(176)	

Adjusted EBITDA is defined as net income, plus (i) tax expense, (ii) financial income (expense), net, (iii) depreciation and amortization; and (v) non-cash share-based compensation expenses

10

