
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 August 2020

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, and the Registrant's Form F-3 Registration Statement, as amended, File No. 333-214816.

The following exhibit is attached:

99.1 Kamada and Kedrion Biopharma Announce Results of First and Only U.S. Post-Marketing Pediatric Trial of a Human Rabies Immune Globulin (HRIG); The Study Met Its Primary Objective

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: August 19, 2020

KAMADA LTD.

By: /s/ Orna Naveh
Orna Naveh
General Counsel and Corporate Secretary

EXHIBIT INDEX

EXHIBIT NO. DESCRIPTION

99.1	<u>Kamada and Kedrion Biopharma Announce Results of First and Only U.S. Post-Marketing Pediatric Trial of a Human Rabies Immune Globulin (HRIG); The Study Met Its Primary Objective</u>
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Kamada and Kedrion Biopharma Announce Results of First and Only U.S. Post-Marketing Pediatric Trial of a Human Rabies Immune Globulin (HRIG); The Study Met Its Primary Objective

- *The Study of KEDRAB® (Rabies Immune Globulin [Human]) Conducted in Children was the First and Only Pediatric Study for any HRIG Available in U.S.*
- *The Study Met its Primary Objective, Which Was to Confirm the Safety of KEDRAB in the Pediatric Population.*
- *Study Results Have Been Submitted to the U.S. FDA for Review and Potential Update to the KEDRAB Prescribing Information*
- *KEDRAB was Launched in the U.S. in 2018 and it Generated In-Market Sales of \$31 Million in 2019, Representing Approximately 20 Percent Share of the U.S. HRIG Market*

Rehovot, Israel and Fort Lee, New Jersey, August 19, 2020 – Kamada Ltd. (NASDAQ & TASE: KMDA) and Kedrion Biopharma, two leading biopharmaceutical companies specialized in plasma-derived protein therapeutics, today announced results from a U.S. post-marketing pediatric trial of KEDRAB® (Rabies Immune Globulin [Human]). The study represents the first and only trial of a currently available human *rabies* immune globulin (HRIG) conducted in children in the U.S. to date. The results have been submitted to the U.S. Food and Drug Administration for review and inclusion as pediatric data in the KEDRAB full prescribing information. KEDRAB is a human rabies immunoglobulin (HRIG) indicated for passive, transient post-exposure prophylaxis (PEP) treatment of rabies infection, when given promptly after contact with a rabid or possibly rabid animal.

The KEDRAB U.S. Pediatric Trial was conducted at two sites, one in Arkansas and another in Rhode Island. The study included 30 pediatric patients (ages 0-17 years old), each of whom received KEDRAB as part of PEP treatment following exposure or suspected exposure to an animal suspected or confirmed to be rabid, and safety follow-up was conducted for up to 84 days. The primary objective of the study was to confirm the safety of KEDRAB in the pediatric population. Secondary objectives included the evaluation of antibody levels and the efficacy of KEDRAB in the prevention of rabies disease when administered with a rabies vaccine according to the PEP recommended guidelines.

No serious adverse events were observed during the study. No incidence of rabies disease or deaths were recorded throughout the 84-day study period.

“These key study results represent the first clinical trial data in the U.S. pediatric population for any HRIG currently available in the US,” said Michal Stein, M.D., Vice President, Medical Director (Immunology) at Kamada “According to the World Health Organization, 40 percent of people bitten by suspected rabid animals are children under 15 years of age. Despite the large proportion of pediatric cases, limited safety and efficacy data from clinical trials currently exist for this population. Meeting the primary study objective of KEDRAB in children further strengthens our ongoing confidence in the product. We continue to believe that sales of KEDRAB has the potential to continue growing in the U.S., capturing a significant share of the estimated annual \$150 million U.S. HRIG market.”

“We know the incidence of kids being exposed to animals that may transmit rabies is high in the U.S. and abroad,” said Novinyo Amega, M.D., Head of U.S. Medical Affairs at Kedrion Biopharma. “However, little data exist that can help clinicians better understand the safety profiles of the various HRIG products currently available. Therefore, we are pleased to see that top-line results of this pediatric study support KEDRAB’s safety profile. Importantly, we believe that meeting the primary objective of this study could further differentiate KEDRAB from other currently available HRIGs in the U.S.”

KEDRAB was launched in the U.S. in April 2018 and generated in-market sales of \$31 million in 2019, representing approximately 20 percent of the U.S. HRIG market.

About KEDRAB®

KEDRAB [Rabies Immune Globulin (Human)] is a human rabies immunoglobulin (HRIG) indicated for passive, transient post-exposure prophylaxis (PEP) of rabies infection, when given promptly after contact with a rabid or possibly rabid animal. KEDRAB should be administered concurrently with a full course of rabies vaccine.

Important Safety Information

- Patients who can document previous complete rabies pre-exposure prophylaxis or complete post-exposure prophylaxis should only receive a booster rabies vaccine without KEDRAB, because KEDRAB may interfere with the anamnestic response to the vaccine.
- KEDRAB should not be injected into a blood vessel because of the risk of severe allergic or hypersensitivity reactions, including anaphylactic shock.
- Patients with a history of prior systemic allergic reactions following administration of human immune globulin preparations should be monitored for hypersensitivity.
- KEDRAB contains a small quantity of IgA. Patients who are deficient in IgA have the potential to develop IgA antibodies and may have anaphylactic reactions following administration of blood components containing IgA.
- KEDRAB administration may interfere with the development of an immune response to live attenuated virus vaccines.
- KEDRAB is derived from human plasma; therefore, the potential exists that KEDRAB administration may transmit infectious agents.
- In clinical trials, the most common adverse reactions in subjects treated with KEDRAB were injection site pain, headache, muscle pain, and upper respiratory tract infection.
- Please see KEDRAB Full Prescribing Information for complete prescribing details.

About Rabies

Rabies is a preventable viral disease of mammals most often transmitted through the bite of a rabid animal. It is a serious, and nearly always fatal, infection. In the U.S., rabies in wild animals, especially raccoons, skunks, foxes and bats, accounts for most cases of rabies passed on to humans, pets, and other domestic animals. An acute, progressive viral encephalomyelitis, rabies carries the highest case fatality rate of any conventional etiological agent. Rabies is one of the oldest described infectious diseases, known for over 5,000 years.

About Kamada

Kamada Ltd. (“the Company”) is a commercial stage plasma-derived biopharmaceutical company focused on orphan indications, with an existing marketed product portfolio and a late-stage product pipeline. The Company uses its proprietary platform technology and know-how for the extraction and purification of proteins from human plasma to produce Alpha-1 Antitrypsin (AAT) in a highly-purified, liquid form, as well as other plasma-derived immune globulins. The Company’s flagship product is GLASSIA®, the first liquid, ready-to-use, intravenous plasma-derived AAT product approved by the U.S. FDA. The Company markets GLASSIA in the U.S. through a strategic partnership with Takeda Pharmaceuticals Company Limited and in other countries through local distributors. The Company’s second leading product is KamRab®, a rabies immune globulin (Human) for post-exposure prophylaxis against rabies infection. KamRab is FDA approved and is being marketed in the U.S. under the brand name KEDRAB® through a strategic partnership with Kedrion S.p.A. In addition to Glassia and KEDRAB, the Company has a product line of four other plasma-derived pharmaceutical products administered by injection or infusion, that are marketed through distributors in more than 15 countries, including Israel, Russia, Brazil, India and other countries in Latin America and Asia. The Company has late-stage products in development, including an inhaled formulation of AAT for the treatment of AAT deficiency. In addition, the Company’s intravenous AAT is in development for other indications, such as GvHD and prevention of lung transplant rejection, and during 2020, the Company initiated the development of a plasma derived immunoglobulin (IgG) product as a potential treatment for coronavirus disease (COVID-19). The Company leverages its expertise and presence in the plasma-derived protein therapeutics market by distributing more than 20 complementary products in Israel that are manufactured by third parties. 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 Kedrion Biopharma

Kedrion Biopharma is a leading international biopharmaceutical company that specializes in the development, production and distribution of plasma-derived therapeutic products for use in treating serious diseases, disorders and conditions such as immune system deficiencies and coagulation disorders. Kedrion has special expertise in the treatment of rare diseases and in the manufacture of hyper-immune products such as anti-hepatitis B, anti-tetanus and RhoGAM for prophylaxis against Rh sensitization and subsequent hemolytic disease of the fetus and newborn. The company operates through a fully integrated business model from the collection of plasma in its own centers in the United States and Hungary to fractionation and production in its manufacturing facilities located in Italy, Hungary and the United States. Headquartered in Castelvechio Pascoli (Italy), Kedrion has over 2,500 employees and a commercial presence in approximately 100 countries worldwide. Kedrion places a high value on the welfare of those who benefit from its products, as well as on the people and the communities it serves. Additional information about Kedrion Biopharma can be found at www.kedrion.com and www.kedrion.us.

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 (i) the expectation that based on the results submitted to the U.S. Food and Drug Administration, it will approve the inclusion of pediatric data in the KEDRAB full prescribing information; (ii) the belief that sales of KEDRAB has the potential to continue growing in the U.S. by capturing a significant share of the estimated annual \$150 million U.S. HRIG market, and (iii) the belief that meeting the primary objective of this study could further differentiate KEDRAB from other currently available HRIGs in the U.S. Forward-looking statements are based on Kamada's and Kedrion'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, if and when the U.S. FDA would include pediatric data in KEDRAB's label, competition within, and entry of new treatments for, the U.S. HRIG market, corporate events associated with Kamada, Kedrion and their respective partners in relation to KEDRAB and the impact of general economic, industry or political conditions in the U.S., Israel or otherwise. The forward-looking statements made herein speak only as of the date of this announcement, Kamada and Kedrion 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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