

KAMADA LTD
Form 6-K
July 10, 2013

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 July, 2013_

Commission File Number 001-35948

Kamada Ltd.

(Translation of registrant's name into English)

7 Sapir St.
Kiryat Weizmann Science Park
P.O Box 4081
Ness Ziona 74140
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.

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Form 20-F x 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-_____

Attached hereto and incorporated herein by reference is a press release of the Company, dated July 10, 2013, entitled “STUDY DEMONSTRATING PANCREATIC ISLET XENOGRAFT SURVIVAL WITH KAMADA’S AAT PUBLISHED IN PEER-REVIEWED PUBLICATION”

News Release

STUDY DEMONSTRATING PANCREATIC ISLET XENOGRAFT SURVIVAL WITH KAMADA'S AAT PUBLISHED IN PEER-REVIEWED PUBLICATION

NESS ZIONA, Israel (July 10, 2013) – Kamada Ltd. (Nasdaq and TASE: KMDA) today announced that favorable results from a preclinical study analyzing the effects of the Company's human Alpha-1 Antitrypsin (AAT), Glassia, in inter-species islet graft transplantation were published in *PLOS One*, an open-access peer-reviewed publication. The article is entitled "Pancreatic Islet Xenograft Survival in Mice Is Extended by a Combination of Alpha-1-Antitrypsin and Single Dose Anti-CD4/CD8 Therapy."

The study was funded by the Juvenile Diabetes Research Foundation and performed by the team of Eli C. Lewis, Ph.D., Director of the Clinical Islet Laboratory, Ben-Gurion University, Negev, Israel.

This study examined transplant survival of pancreatic islets originating in other (xeno) species donors. Pancreatic islet transplantation from other species serves as a model for transplant survival and as a supporting model for type 1 diabetes (T1D) and the beneficial effects of AAT. Similar to the immune rejection of the new pancreatic beta cells, which are recognized as foreign by the host and, therefore, are destroyed by the host immune system, in T1D the immune system attacks and destroys the self pancreatic beta cells (autoimmune attack). The effect of AAT shown in this xenograft transplantation model demonstrates the potential role of AAT in the early stages of T1D.

Recent studies have demonstrated that AAT is an anti-inflammatory and tissue protective protein that also has islet autoimmune-tolerance capabilities. As such, it has the capability to control the immune response to foreign antigens, in this case, to the foreign islets.

Administration of the standard clinically-available treatment to decrease the extent of rejection using monoclonal antibodies alone (anti-CD4/CD8, the equivalent of the clinical regimen anti-thymocyte globulins) didn't achieve long term graft acceptance, yet, in combination with Glassia, there was a significant time extension in graft acceptance and a higher rate of graft acceptance compared with groups that did not receive Glassia. This synergism between these two approaches is unprecedented in the field of immune regulation, and could be highly attractive as a strategy for type 1 diabetes.

The investigators assume that temporary elimination of T-cells (achieved by anti-CD4/CD8), together with Glassia, enables a window of improved conditions for xenograft recovery and survival.

Dr. Lewis noted, “AAT is an important protein that is able to control unwanted immune responses and has very strong anti-inflammatory properties which modulate immune processes. This may have great benefit compared with current treatments, such as transplantation, which have issues due to the natural immune attack. In xenograft transplantation, where the rejection is even more potent and challenging, AAT can support the acceptance of a foreign graft and increase transplant prognosis. Improved performance of such unique xenograft transplantations offers the potential for additional safe treatment options for transplant recipients, where today we are limited to using organs from human donors.”

“The data are very encouraging and support the continued clinical development of our AAT therapeutic to treat type 1 diabetes,” said David Tsur, Chief Executive Officer of Kamada. “We look forward to advancing our AAT therapy in this area of great unmet medical need, and expect to initiate Phase II/III clinical studies in this patient population by year-end.”

Mr. Tsur added, “In a previous Phase I/II study in pediatric patients with newly diagnosed type-1 diabetes, our AAT therapeutic had a high safety and tolerability profile and encouraging signs of efficacy including improved metabolic control and beta-cell function 12 to 15 months from diagnosis. This indicated that AAT may have a protective effect on beta cells, leading to a possible halt in disease progression and re-modulation of the autoimmune attack.”

About Kamada

Kamada Ltd. is focused on plasma-derived protein therapeutics for orphan indications, and has a commercial product portfolio and a robust 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 proteins. AAT is a protein derived from human plasma with known and newly-discovered therapeutic roles given its immuno-modulatory, anti-inflammatory, tissue-protective and antimicrobial properties. The Company’s flagship product is Glassia®, the first and only liquid, ready-to-use, intravenous plasma-derived AAT product approved by the U.S. Food and Drug Administration. Kamada markets Glassia in the U.S. through a strategic partnership with Baxter International. In addition to Glassia, Kamada has a product line of nine other injectable pharmaceutical products that are marketed through distributors in more than 15 countries, including Israel, Russia, Brazil, India and other countries in Latin America, Eastern Europe and Asia. Kamada has five late stage plasma-derived protein products in development, including an inhaled formulation of AAT for the treatment of AAT deficiency that is in pivotal Phase II/III clinical trials in Europe and will be entering Phase II clinical trials in the U.S. Kamada also leverages its expertise and presence in the plasma-derived protein therapeutics market by distributing 10 complementary products in Israel that are manufactured by third parties.

Cautionary Note Regarding Forward-Looking Statements

This release contains forward-looking statements that involve risks, uncertainties and assumptions, such as statements regarding assumptions and results related to pre-clinical trials, the EMA and US FDA marketing authorization of our Inhaled AAT for AATD and timing of clinical trials. 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, delays or denial in the US FDA or the EMA approval process, additional competition in the AATD market or further regulatory delays. The forward-looking statements made herein speak only as of the date of this release and the Company 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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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: July 10 , 2013 **KAMADA LTD.**

By: /s/ Gil Efron
Gil Efron
Chief Financial
Officer