KAMADA LTD
Form 6-K
August 01, 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 August, 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.

Form 20-F T 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 T

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 August 1st, 2013, entitled “Second Quarter 2013 Financial Results”.

News Release

Kamada Reports Second Quarter 2013 Financial Results

Net Income of $1 million and Adjusted EBITDA of $4 million

Phase 3 clinical trial of Inhaled AAT for AATD in EU on track to complete this year

Conference Call Begins Today at 10:00 a.m. Eastern Time

NESS ZIONA, Israel (August 1, 2013) – Kamada Ltd. (Nasdaq and TASE: KMDA), a plasma-derived protein therapeutics company focused on orphan indications, announces financial results for the three and six months ended June 30, 2013.

"This year's second quarter was an exceptionally exciting time for Kamada, highlighted by our successful U.S. IPO and the expansion of our strategic distribution agreement with Baxter in the U.S. In addition, we made excellent progress growing proprietary product revenue, advancing our clinical development programs, fortifying our patent portfolio, maintaining Good Manufacturing Practice (GMP) compliance for Israel, and strengthening our balance sheet," said David Tsur, Chief Executive Officer of Kamada.

"We were particularly pleased to announce an extension to our strategic agreement with Baxter under which minimum revenues expected from 2010 through 2016 increased to $165 million from $110 million previously. The agreement also expanded our production of Glassia for Baxter's distribution through 2016, pushing out the transition to royalty payments for Glassia produced by Baxter until 2017. Until that time, we will continue to produce Glassia for distribution by Baxter, which we expect will result in higher profitability for Kamada in 2015 and 2016. During the quarter, we also achieved a milestone under the technology transfer agreement for which we received a $4.5 million payment.

"We remain on track to complete the European pivotal, multi-center Phase 2/3 clinical trial of our inhaled Alpha-1 Antitrypsin (AAT) for the treatment of AAT deficiency (AATD) and expect to report top-line results in early 2014. We have enrolled a high percentage of eligible patients from this study into the open-label extension (OLE) study. With 70 patients enrolled to date in the OLE, we believe participation underscores physician and patient preference for

an inhaled treatment for AATD.

“We expect to initiate a U.S. Phase 2 study of our inhaled AAT to treat AATD in the second half of 2013. In addition, we are making progress with plans for a Phase 2/3 clinical trial in Israel to treat newly diagnosed type 1 diabetes with D1-AAT, our intravenously administered AAT product. In a Phase 1/2 clinical trial D1-AAT was shown to be safe and well-tolerated and demonstrated potential to exert a protective effect on beta-cells, thereby slowing disease progression and re-modulation of the autoimmune attack. We expect to begin this study by the end of the year.

“In order to meet expected growth in product demand, we designed and implemented enhancements to our manufacturing processes to significantly improve capacity for our AAT products. We filed a request for approval of these enhancements with the U.S. Food and Drug Administration (FDA), and intend to provide requested additional data during the second half of 2013. We expect the FDA to approve these improvements in the first half of 2014. In the meantime we are distributing finished goods produced by the existing approved process as planned. Our 2013 revenue forecast does not assume U.S. approval of the improved manufacturing process.

“We recently announced the Israeli Ministry of Health (IMOH) completed a GMP audit of our manufacturing facility in Beit Kama, Israel. The audit was performed as part of their routine evaluation of our manufacturing process and concluded that we comply with the GMP requirements of the IMOH. This audit also qualifies as an audit by the European Union.

“We continue to build on our achievements and expect to report significant revenue growth while advancing our robust pipeline of plasma-derived protein therapeutics throughout the second half of 2013,” concluded Mr. Tsur.

Second Quarter Financial Results

Total revenue for the second quarter of 2013 increased 17% to $16.1 million from $13.7 million for the second quarter of 2012, with higher proprietary product revenue mainly attributed to the milestone achieved under the agreement with Baxter, partially offset by expected declines from distributed products.

Revenue from the Proprietary Products Segment increased 70% to $11.9 million from $7.0 million in the year-ago quarter. Revenue from the Distribution Segment declined 37% to $4.2 million from $6.7 million in the second quarter of 2012.

Research and development (R&D) expenses in the second quarter of 2013 of $2.6 million were in line with $2.7 million in the second quarter of 2012 and down from the $3.7 million in the first quarter of this year, which was impacted by production facility costs that were allocated to R&D.

Selling, general and administrative (SG&A) expenses in the second quarter of 2013 of $3.2 million increased from $1.6 million in the second quarter of 2012, and included a one-time management compensation payment of $1.4 million associated with the successful U.S. IPO.

Gross profit for the second quarter of 2013 increased to $7.4 million from $3.3 million a year ago, while gross margin increased to 46% from 24% in the second quarter of 2012. Gross margin expansion is due to milestone revenues under the technology transfer agreement with Baxter.

For the second quarter of 2013 the Company reported operating income of $1.6 million compared with an operating loss of $1 million for the second quarter of 2012. Net income for the second quarter of 2013 was $0.90 million or $0.03 diluted income per share, compared with a net loss of $2.3 million or $0.08 loss per share for the same period in 2012.

Adjusted EBITDA for the second quarter of 2013 was $4.2 million compared with $0.1 million Adjusted EBITDA for the same quarter last year.

Six Months Financial Results

Total revenue for the first half of 2013 decreased 14% to $28.7 million from $33.4 million for the first half of 2012 due to expected declines in revenue in the Distribution Segment.

For the first half of 2013 revenue in the Proprietary Products Segment was $20.0 million, up slightly from $19.5 million for the same period in 2012. Revenue in the Distribution Segment declined 37% to $8.8 million from $13.9 million in the first half of 2012.

Gross profit for the first half of 2013 increased to $11.6 million from $8.9 million, while gross margin increased to 40% from 27% in the comparable prior-year period.

Operating income for the first six months of 2013 of $0.35 million compared with an operating loss of $0.71 million for the first six months of 2012. Net loss for the six months ended June 30, 2013 narrowed to $1.1 million or $0.04 per share, compared with a net loss of $2.7 million or $0.10 per share for the same period in 2012.

Adjusted EBITDA for the first six months of 2013 was $3.9 million, an increase of 165% compared with $1.5 million Adjusted EBITDA for the same period last year.

Balance Sheet Highlights

As of June 30, 2013, the Company had cash and cash equivalents and short term investments of $82.6 million, including net proceeds of $53.0 million raised in the U.S. IPO, compared with $33.8 million as of December 31, 2012.

Conference Call

Kamada management will host an investment community conference call today beginning at 10:00 a.m. Eastern time to discuss these results and answer questions. Shareholders and other interested parties may participate in the conference call by dialing (888) 803-5993 (from within the U.S.) or (706) 634-5454 (from outside the U.S.) and entering passcode 21054403. The call also will be broadcast live on the Internet at www.streetevents.com, www.earnings.com and www.kamada.com.

A replay of the conference call will be accessible two hours after its completion through August 6, 2013 by dialing (855) 859-2056 (from within the U.S.) or (404) 537-3406 (from outside the U.S.) and entering passcode 21054403. The call will also be archived for 90 days at www.streetevents.com, www.earnings.com and www.kamada.com.

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 immunomodulatory, 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 2/3 clinical trials in Europe and will be entering Phase 2 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 financial results forecast, commercial results, clinical trials, the EMA and US FDA authorizations 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, unexpected results of clinical trials, 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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CONSOLIDATED BALANCE SHEETS

	As of June 30, 2013	As of June 30, 2012	As of December 31, 2012
	In thousands		
Current Assets			
Cash and cash equivalents	$73,403	$18,278	$ 16,866
Short-term investments	9,152	14,353	16,929
Trade receivables	12,340	11,053	13,861
Other accounts receivables	1,400	1,062	1,661
Inventories	23,901	17,066	20,513
	120,196	61,812	69,830
Non-Current Assets			
Long-term inventories	165	394	238
Property, plant and equipment, net	19,993	17,859	18,827
Other long-term assets	193	166	219
	20,351	18,419	19,284
	140,547	80,231	89,114
Current Liabilities			
Short term credit and Current maturities of convertible debentures	5,534	12	5,370
Trade payables	9,098	12,593	12,220
Other accounts payables	5,481	3,026	3,413
Deferred revenues	8,596	5,601	8,176
	28,709	21,232	29,179
Non-Current Liabilities			
Loans from others	-	6	-
Warrants	-	19	23
Convertible debentures	19,930	22,367	18,747
Employee benefit liabilities, net	770	715	718
Deferred revenues	10,149	13,700	12,054
	30,849	36,807	31,542
Equity			
Share capital	8,983	7,015	7,204
Share premium	148,655	93,706	96,874
Warrants	-	325	-
Conversion option in convertible debentures	3,794	3,794	3,794
Capital reserve due to translation to presentation currency	(3,490)	(3,490)	(3,490)

Capital reserve from hedges	121	-	229
Other capital reserves	4,762	4,494	4,473
Accumulated deficit	(81,836)	(83,652)	(80,691)
	80,989	22,192	28,393
	$140,547	$80,231	$89,114

Consolidated Statements of Comprehensive Income (loss)

	Six months period Ended June 30		Three months period Ended June 30		Year ended December 31
	2013	2012	2013	2012	2012
	Thousands of US dollar (Except for per-share loss data)				
Revenues from proprietary products	$19,957	$19,502	$11,897	$7,024	$ 46,445
Revenues from distribution	8,754	13,852	4,218	6,728	26,230
Total revenues	28,711	33,354	16,115	13,752	72,675
Cost of revenues from proprietary products	9,682	12,137	5,121	4,544	26,911
Cost of revenues from distribution	7,412	12,314	3,573	5,928	23,071
Total cost of revenues	17,094	24,451	8,694	10,472	49,982
Gross profit	11,617	8,903	7,421	3,280	22,693
Research and development expenses	6,334	6,210	2,604	2,744	11,821
Selling and marketing expenses	963	966	450	494	1,853
General and administrative expenses	3,975	2,433	2,719	1,085	4,781
Operating income (loss)	345	(706)	1,648	(1,043)	4,238
Financial income	165	336	79	153	578
Income (expense) in respect of currency exchange and translation differences and derivatives instruments, net	(70)	(49)	(132)	15	(100)
Expense in respect of revaluation of warrants to fair value		(573)		(518)	(576)
Financial expense	(1,549)	(1,709)	(693)	(836)	(3,357)
Income (loss) before taxes on income	(1,109)	(2,701)	902	(2,229)	783
Taxes on income	36	-	12	-	523
Net Income (loss)	(1,145)	(2,701)	890	(2,229)	260
Other Comprehensive Income (loss):					
Items that may be reclassified to profit or loss in subsequent periods:					
Net gain (loss) on cash flow hedge	(108)	-	(67)	-	229
Items that will not be reclassified to profit or loss in subsequent periods:					
Actuarial net gain of defined benefit plans	-	-	-	-	46
Total comprehensive income (loss)	$(1,253)	$(2,701)	$823	$(2,229)	$ 535

Income (loss) per share attributable to equity holders of the Company:				
Basic loss per share	$(0.04)	$(0.10)	$0.03	$(0.08)	$ 0.01
Diluted loss per share	$(0.04)	$(0.10)	$0.03	$(0.08)	$ 0.01

CONSOLIDATED STATEMENTS OF CASH FLOWS

	Six months period Ended June 30,		Three months period Ended June 30,		Year Ended December 31,
	2013	2012	2013	2012	2012
	Thousands of US dollar				
Cash Flows from Operating Activities					
Net income (loss)	$(1,145)	$(2,701)	$890	$(2,229)	$260
Adjustments to reconcile loss to net cash provided by (used in) operating activities:					
Adjustments to the profit or loss items:					
Depreciation and amortization	1,515	1,507	692	755	3,044
Finance expenses, net	1,454	1,994	747	1,186	3,455
Cost of share-based payment	649	686	436	338	1,267
Loss from sale of fixed assets	67	14	67	14	523
Taxes on income	36	-	12	-	-
Change in employee benefit liabilities, net	52	(11)	32	(134)	38
	3,773	4,190	1,986	2,159	8,327
Changes in asset and liability items:					
Decrease (increase) in trade receivables	1,743	(4,343)	(3,097)	197	(6,662)
Decrease (increase) in other accounts receivables	207	831	649	933	451
Increase in inventories and long-term inventories	(3,315)	(1,571)	(85)	(1,135)	(4,861)
Decrease (increase) in deferred expenses	28	39	139	(4)	89
Increase (decrease) in trade payables	(3,178)	347	(3,716)	1,561	(157)
Increase (decrease) in other accounts payables	960	(14)	1,190	(378)	322
Decrease in deferred revenues	(1,485)	(4,035)	(1,351)	(1,658)	(3,438)
	(5,040)	(8,746)	(6,271)	(484)	(14,256)
Cash paid and received during the period for:					
Interest paid	(1,062)	(1,140)	(527)	(555)	(2,200)
Interest received	195	430	112	272	249
Taxes paid	(54)	(36)	(23)	(33)	(642)
	(921)	(746)	(438)	(316)	(2,593)
Net cash used in operating activities	$(3,333)	$(8,003)	$(3,833)	$(870)	$(8,262)

CONSOLIDATED STATEMENTS OF CASH FLOWS

	Six months period Ended June 30,		Three months period Ended June 30,		Year Ended December 31,
	2013	2012	2013	2012	2012
	Thousands of US dollar				
Cash Flows from Investing Activities					
Short-term investments	$7,848	$1,912	$1,279	$6,247	$ 665
Purchase of property and equipment	(2,747)	(1,982)	(1,473)	(1,422)	(4,609)
Proceeds from sale of equipment	3	-	3	-	-
Restricted cash	-	1,512	-	-	1,512
Net cash provided by (used in) investing activities	5,104	1,442	(191)	4,825	(2,432)
Cash Flows from Financing Activities					
Exercise of warrants and options into shares	309	582	136	476	2,978
Proceeds from issuance of ordinary shares, net	53,958		54,479		
Short term credit from bank and others, net	(6)	(6)	(6)	(3)	(12)
Net cash provided by financing activities	54,261	576	54,609	473	2,966
Exchange differences on balances of cash and cash equivalent	505	(111)	177	61	220
Increase (decrease) in cash and cash equivalents	56,537	(6,096)	50,762	4,489	(7,508)
Cash and cash equivalents at the beginning of the year	16,866	24,374	22,641	13,789	24,374
Cash and cash equivalents at the end of the period	$73,403	$18,278	$73,403	$18,278	$ 16,866
Significant non-cash transactions					
Purchase of property, equipment and intangible assets on credit	$-	$488	$-	$88	$ -
Exercise of options presented as liability	$23	$1,215	$-	$1,215	$ 1,215
Issuance expenses accrued in other accounts payables	$1,094	$-	$994	$-	$ -

ADJUSTED EBITDA

	Six months period Ended June 30		Three months period Ended June 30		Year ended December 31
	2013	2012	2013	2012	2012
	Thousands of US dollar				
Net Income (loss)	$(1,145)	$(2,701)	$890	$(2,229)	$ 260
Income tax expense	36		12		523
Financial expense, net	1,384	1,373	614	683	2,779
Depreciation and amortization expense	1,515	1,507	692	755	3,044
Share-based compensation charges	649	686	436	338	1,267
Expense (income) in respect of translation differences and derivatives instruments, net	70	49	132	(15)	100
Expense (income) in respect of revaluation of warrants fair value	-	573		518	576
One-time management compensation	1,386		1,386		
Adjusted EBITDA	$3,895	$1,487	$4,162	$50	$ 8,549

# # #

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.

KAMADA LTD.

Date: August 1st, 2013

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