# **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 <a href="https://www.streetevents.com">www.streetevents.com</a>, <a

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 <a href="www.streetevents.com">www.streetevents.com</a>, <a hr

#### **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 AAT is a protein derived from human plasma with known and newlyplasma-derived proteins. 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-touse, 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 Short-term investments Trade receivables Other accounts receivables Inventories	\$ 73,403 9,152 12,340 1,400 23,901	\$ 18,278 14,353 11,053 1,062 17,066	\$ 16,866 16,929 13,861 1,661 20,513	
Non-Current Assets Long-term inventories Property, plant and equipment, net Other long-term assets	165 19,993 193 20,351	394 17,859 166 18,419	238 18,827 219	
Current Liabilities Short term credit and Current maturities of convertible debentures Trade payables Other accounts payables Deferred revenues	5,534 9,098 5,481 8,596	80,231 12 12,593 3,026 5,601 - 21,232	5,370 12,220 3,413 8,176 29,179	
Non-Current Liabilities Loans from others Warrants Convertible debentures Employee benefit liabilities, net Deferred revenues	19,930 770 10,149	6 19 22,367 715 13,700	23 18,747 718 12,054	
Equity Share capital Share premium Warrants Conversion option in convertible debentures Capital reserve due to translation to presentation currency Capital reserve from hedges Other capital reserves Accumulated deficit	30,849 8,983 148,655 3,794 (3,490) 121 4,762 (81,836)	36,807 7,015 93,706 325 3,794 (3,490) - 4,494 (83,652)	31,542 7,204 96,874 3,794 (3,490) 229 4,473 (80,691)	
	\$ 140,547	\$ 80,231	\$ 89,114	

## **Consolidated Statements of Comprehensive Income (loss)**

	Six months period Ended June 30		Three mon Ended J	Year ended December 31			
	2013	2012	2013	2012	2012		
		Thousands of	of US dollar (E	xcept for per-	share loss data)		
Revenues from proprietary products Revenues from distribution	\$ 19,957 8,754	\$ 19,502 13,852	\$ 11,897 4,218	\$ 7,024 6,728	\$ 46,445 26,230		
Total revenues	28,711	33,354	16,115	13,752	72,675		
Cost of revenues from proprietary products Cost of revenues from distribution	9,682 7,412	12,137 12,314	5,121 3,573	4,544 5,928	26,911 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 Selling and marketing expenses General and administrative expenses	6,334 963 3,975	6,210 966 2,433	2,604 450 2,719	2,744 494 1,085	11,821 1,853 4,781		
Operating income (loss)	345	(706)	1,648	(1,043)	4,238		
Financial income Income (expense) in respect of currency exchange and translation differences and	165	336	79	153	578		
derivatives instruments, net Expense in respect of revaluation of	(70)	(49)	(132)	15	(100)		
warrants to fair value Financial expense	(1,549)	(573) (1,709)	(693)	(518) (836)	(576) (3,357)		
Income (loss) before taxes on income Taxes on income	(1,109)	(2,701)	902	(2,229)	783 523		
Net Income (loss) Other Comprehensive Income (loss): Items that may be reclassified to profit or	(1,145)	(2,701)	890	(2,229)	260		
loss in subsequent periods: Net gain (loss) on cash flow hedge Items that will not be reclassified to profit or loss in subsequent periods:	(108)	-	(67)	-	229		
Actuarial net gain of defined benefit plans 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 FL	Six month Ended J		Three months	Year Ended December 31,		
<del>-</del>	2013 2012		2013	2012	2012	
<u> </u>		Thous	ands of US dolla	nr		
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 Finance expenses, net Cost of share-based payment Loss from sale of fixed assets Taxes on income Change in employee benefit liabilities,	1,515 1,454 649 67 36	1,507 1,994 686 14	692 747 436 67 12	755 1,186 338 14	3,044 3,455 1,267 523	
net	52	(11)	32	(134)	38	
Changes in asset and liability items:	3,773	4,190	1,986	2,159	8,327	
Decrease (increase) in trade receivables Decrease (increase) in other accounts	1,743	(4,343)	(3,097)	197	(6,662)	
receivables Increase in inventories and long-term	207	831	649	933	451	
inventories Decrease (increase) in deferred	(3,315)	(1,571)	(85)	(1,135)	(4,861)	
expenses Increase (decrease) in trade payables Increase (decrease) in other accounts	28 (3,178)	39 347	139 (3,716)	(4) 1,561	89 (157)	
payables decrease in deferred revenues	960 (1,485)	(14) (4,035)	1,190 (1,351)	(378) (1,658)	322 (3,438)	
_	(5,040)	(8,746)	(6,271)	(484)	(14,256)	
Cash paid and received during the period for:						
Interest paid Interest received Taxes paid	(1,062) 195 (54)	(1,140) 430 (36)	(527) 112 (23)	(555) 272 (33)	(2,200) 249 (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		2	013	2012			20	12		
				Th	ousa	nds of l	JS do	ollar			
Cash Flows from Investing Activities Short-term investments Purchase of property and equipment Proceeds from sale of equipment Restricted cash	\$	7,848 (2,747) 3		1,912 (1,982) - 1,512		1,279 1,473) 3	\$	6,247 (1,422) - -		\$	665 (4,609) - 1,512
Net cash provided by (used in) investing activities		5,104		1,442		<u>(191)</u>		4,825			(2,432)
Cash Flows from Financing Activities Exercise of warrants and options into shares Proceeds from issuance of ordinary shares, net Short term credit from bank and others, net		309 53,958 (6)		582 (6)	5	136 4,479 (6)		476 (3)			2,978 (12)
Net cash provided by financing activities		54,261		576	5	<u>4,609</u>		473			2,966
Exchange differences on balances of cash and cash equivalent		<u>505</u>		(111)		177		61			220
Increase (decrease) in cash and cash equivalents		56,537	(	(6,096)	5	0,762		4,489			(7,508)
Cash and cash equivalents at the beginning of the year		16,866		24,374	2	<u>2,641</u>		13,789			24,374
Cash and cash equivalents at the end of the period	\$	73,403	\$	18,278	\$ 7	3,403	\$	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	\$	<u>-</u>	\$	994	\$		\$		

## **ADJUSTED EBITDA**

	Six months period Ended June 30		Three mon Ended J	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				