# **News Release**



## Kamada Reports First Quarter Financial Results

**NESS ZIONA, Israel (May 8, 2014) – Kamada Ltd. (NASDAQ and TASE: KMDA),** a plasma-derived protein therapeutics company focused on orphan indications, announces financial results for the three months ended March 31, 2014.

Financial highlights of the first quarter of 2014 include:

- Total revenue increased 5% to \$13.2 million from \$12.6 million for the first guarter of 2013.
- Revenue from the Proprietary Products Segment decreased to \$7.4 million from \$8.1 million in the prior year in anticipation of U.S. Food and Drug Administration (FDA) approval for the significantly improved infusion rate for Glassia.
- Adjusted net loss was \$2.0 million compared with an adjusted net loss of \$1.8 million for the same period in 2013.

Clinical highlights of the first quarter of 2014 and recent weeks include:

- Received FDA approval for a significantly improved infusion rate for Glassia® (Alpha-1-Proteinase Inhibitor Human), the first and only ready-to-use liquid alpha-1-proteinase inhibitor indicated as a chronic augmentation and maintenance therapy in adults with Alpha-1 Antitrypsin Deficiency (AATD, or Inherited Emphysema), marketed in the U.S. by Baxter International Inc.
- Announced a proof-of-concept study with Glassia to treat graft-versus-host disease (GVHD) in cooperation with Baxter to be conducted at the Fred Hutchinson Cancer Research Center.
- Initiated a Phase 2 U.S. clinical trial of its proprietary inhaled Alpha-1 Antitrypsin (AAT-IH) therapy for the treatment of AATD.
- Initiated a Phase 2/3 clinical trial of Glassia to treat newly diagnosed pediatric patients with type 1 diabetes.
- Completed enrollment in a U.S. Phase 2/3 clinical trial of KamRAB® as a post-exposure prophylaxis for rabies; Kamada has a strategic agreement with Kedrion S.p.A for clinical development and marketing of KamRAB in the U.S.

#### **Management Commentary**

"These past months have been an exciting and busy time for Kamada as we continued to grow revenue and advanced multiple clinical programs," stated David Tsur, Co-Founder and Chief Executive Officer of Kamada. "During the quarter we initiated three important clinical trials that expand and enhance our proprietary plasma-derived protein therapeutics in areas of unmet medical need. We believe our robust product pipeline is broadly distributed across several important disease states, which diversifies our risk and offers multiple opportunities for partnerships and an expanded source of revenue. We look forward to advancing our studies with a goal of bringing safe and effective therapies to patients in need.

"We will report top-line results from our Phase 2/3 clinical trial in Europe of our inhaled Alpha-1 Antitrypsin for the treatment of AAT deficiency in the coming week. While we do not know what the results will be, pending a positive trial outcome, we remain on track to file for regulatory approval with the European Medicines Agency in the second half of 2014. Such an outcome would position Kamada as the leader in the fast-growing AATD market. We have been actively engaged with Chiesi, our European

marketing partner, to advance the strategic plans for commercial launch. Earlier clinical work suggests there are significant advantages to delivering the therapy directly to the lung instead of systemically via intravenous infusion. We look forward to the data from this trial and expect that further data from the open-label extension study will augment the long-term safety record we achieved thus far. This is an exciting opportunity for Kamada to bring the first inhaled therapy to patients suffering from this debilitating, life-threatening, orphan lung disease.

"We were pleased to initiate a U.S. clinical study of AAT-IH to treat AATD that will test pharmacokinetic parameters of different analytes in epithelial lining fluid and serum, as well as safety and tolerability. We intend to submit these data along with those from our European Phase 2/3 study in 2015 to the FDA to support U.S. approval of our AAT-IH product.

"We are excited about the opportunity for Kamada to bring a promising therapy to newly diagnosed pediatric patients with type 1 diabetes. Data from our earlier studies give us great optimism for continued positive outcomes with the pivotal study we recently initiated. We believe Glassia can be a groundbreaking treatment for these patients, and look for study data to demonstrate the ability to halt disease progression at its early stages and allow the pancreas to produce its own insulin.

"We announced our support of another important clinical program with the launch of the proof-of-concept study of Glassia to treat GVHD. This study is being undertaken in cooperation with Baxter, our U.S. marketing partner for Glassia, and is being conducted at the Fred Hutchinson Cancer Research Center, a prestigious National Cancer Institute Comprehensive Cancer Center. We are pleased to be advancing Glassia to treat GVHD. Glassia is expected to decrease GVHD-related symptoms including progressive tissue damage, and thereby potentially increase the survival rates of patients suffering from this complication and possibly reduce or eliminate the need for steroid therapy.

"In summary, 2014 has gotten off to a strong start with significant advances to our clinical pipeline. We look forward to making continued progress with these important programs, while growing proprietary product revenue throughout the remainder of the year," added Mr. Tsur.

#### **First Quarter Financial Results**

Total revenue for the first quarter of 2014 increased 5% to \$13.2 million from \$12.6 million for the first quarter of 2013, reflecting higher revenue in the Distribution Segment.

Revenue from the Proprietary Products Segment decreased to \$7.4 million from \$8.1 million in the year-ago quarter due to the timing of orders from a partner as the Company awaited FDA approval for the significantly improved infusion rate for Glassia. Such timing of orders will not affect full-year 2014 total revenue from this partner. Revenue from the Distribution Segment of \$5.8 million increased from \$4.5 million in the first quarter of 2013.

Research and development (R&D) expenses in the first quarter of 2014 of \$3.4 million decreased from \$3.7 million in the first quarter of 2013, with increased activity in support of various clinical studies including the launch of three important clinical trials offset by a decrease in facility costs allocated to research and development use.

Selling, general and administrative (SG&A) expenses in the first quarter of 2014 of \$2.6 million increased from \$1.8 million in the first quarter of 2013, largely due to the costs of being a U.S. publicly traded company and stock-based compensation.

Gross profit for the first quarter of 2014 decreased to \$3.3 million from \$4.2 million in the first quarter of 2013 reflecting lower product sales, while gross margin decreased to 25% from 33% in the first quarter of 2013 due to product mix as the Distribution Segment revenues increased during this quarter.

For the first quarter of 2014, the Company reported an operating loss of \$2.5 million compared with an operating loss of \$1.3 million for the first quarter of 2013. Net loss for the first quarter of 2014 was \$3.1 million or \$0.09 per share, compared with a net loss of \$2.0 million or \$0.07 per share for the same period in 2013. Adjusted net loss for the first quarter of 2014 was \$2.0 million compared with an adjusted net loss of \$1.8 million for the same period in 2013.

Adjusted EBITDA for the first quarter of 2014 was a negative \$1.0 million compared with a negative \$0.3 million for the first quarter of 2013.

### **Balance Sheet Highlights**

As of March 31, 2014, Kamada had cash, cash equivalents and short-term investments of \$72.1 million, compared with \$74.2 million as of December 31, 2013. During the first quarter of 2014, the Company used \$1.5 million in cash to fund operations and \$0.6 million for capital expenditures.

### **Financial Guidance**

The Company expects to provide financial guidance for 2014 following the release of top-line results from the Phase 2/3 clinical trial in Europe of its AAT-IH for the treatment of AATD.

#### **Conference Call**

The Company will not hold a quarterly conference call to discuss these results given the proximity to the announcement in the coming week of top-line results from the Phase 2/3 clinical trial in Europe of its AAT-IH for the treatment of AATD. The Company plans to hold a conference in conjunction with releasing those results.

#### **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 newlydiscovered therapeutic roles given its immunomodulatory, anti-inflammatory, tissue-protective and antimicrobial properties. The Company's flagship product is Glassia<sup>®</sup>, 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 completed pivotal Phase 2/3 clinical trials in Europe and entered 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 includes forward-looking statements within the meaning of Section 27A of the U.S. Securities Act of 1933, as amended, 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, such as statements

regarding assumptions and results related to financial results forecast, commercial results, timing and results of clinical trials and EMA and U.S. FDA authorizations. 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, unexpected results of clinical trials, delays or denial in the U.S. 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 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.

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-Tables to Follow-

	As of M	As of December 31,	
	2014	2013	
	Unat	udited In thousands	Audited
Current Assets		III tiiousaiius	-
Cash and cash equivalents	\$ 33,314	\$ 22,641	\$ 59,110
Short-term investments	38,811	10,395	
Trade receivables	12,592	9,177	
Other accounts receivables	3,284	2,860	
Inventories	28,614	23,743	21,933
	116,615	68,816	117,686
Non-Current Assets			
Long-term inventories	-	238	_
Property, plant and equipment, net	21,384	19,289	
Other long-term assets	262	208	250
	21,646	19,735	21,693
	138,261	88,551	139,379
Current Liabilities		33,232	
Short term credit and Current maturities of convertible debentures	8,678	5,494	8,718
Trade payables	16,321	12,693	
Other accounts payables	3,750	3,301	
Deferred revenues	5,431	9,603	
	34,180	31,091	32,578
Niew Channel I inhilities			
Non-Current Liabilities Convertible debentures	7,686	19,503	7,498
Employee benefit liabilities, net	801	738	
Deferred revenues	7,683	10,493	
	16,170	30,734	16,831
Equity	0.201	7.220	0.201
Share capital	9,201	7,220 97,185	
Share premium Conversion option in convertible debentures	157,117 2,217	3,794	
Capital reserve due to translation to presentation currency	(3,490)	(3,490)	
Capital reserve from hedges	87	188	
Capital reserve from available for sale financial assets	12	-	(27)
Capital reserve from share-based payments	6,266	4,696	
Capital reserve from employee benefits	(129)	(141)	(129)
Accumulated deficit	(83,370)	(82,726)	
	87,911	26,726	89,970
	\$ 138,261	\$ 88,551	\$ 139,379

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

•		For the Year Ended March 31		
	2014	December 31 2013		
		Unaudited		
	]	In thousands		
Revenues from proprietary products Revenues from distribution	\$ 7,421 5,766	\$ 8,060 4,536		
Total revenues	13,187	12,596	70,623	
Cost of revenues from proprietary products	5,003	4,562	27,104	
Cost of revenues from distribution	4,922	3,839	17,112	
Total cost of revenues	9,925	8,401	44,216	
Gross profit	3,262	4,195	26,407	
Research and development expenses	3,365	3,730	12,745	
Selling and marketing expenses	647	513	2,100	
General and administrative expenses	1,957	1,256		
Operating income (loss)	(2,707)	(1,304)		
Financial income Income (expense) in respect of currency exchange and	243	86	289	
translation differences and derivatives instruments, net	39	62	(369)	
Financial expense	(674)	(855)	(3,153)	
Income (loss) before taxes on income Taxes on income	(3,099)	(2,011) 24	467	
Taxes on income	23	24	24	
Net Income (loss)	(3,122)	(2,035)	443	
Other Comprehensive Income (loss): Items that may be reclassified to profit or loss in subsequent periods:				
Net gain (loss) on available for sale financial assets Net gain (loss) on cash flow hedge Items that will not be reclassified to profit or loss in	39 (69)	(41)	(27) 12	
subsequent periods: Actuarial net gain of defined benefit plans			(73)	
Total comprehensive income (loss)	\$ (3,152)	\$ (2,076)	\$ 355	
Income (loss) per share attributable to equity holders of the Company:				
Basic income (loss) per share	\$ (0.09)	\$ (0.07)	\$ 0.01	
Diluted income (loss) per share	\$ (0.09)	\$ (0.07)	\$ 0.01	

## **Adjusted EBITDA**

	Three months period Ended March 31		For the year Ended December 31	
	2014	2013	2013	
	Thousands of US dollar			
Net income (loss)	\$ (3,122)	\$ (2,035)	\$ 443	
Income tax expense	23	24	24	
Financial expense, net	431	769	2,864	
Depreciation and amortization expense	663	823	3,001	
Share-based compensation charges	1,086	213	1,327	
Expense (Income) in respect of translation differences and derivatives instruments, net	(39)	(62)	369	
One time management compensation	\$ (958)	\$ (268)	1,386 \$ 9.414	
Depreciation and amortization expense  Share-based compensation charges  Expense (Income) in respect of translation differences and derivatives instruments, net	663 1,086	823 213	3,001 1,327 369	

## Adjusted net income

	Three months p Ended March		For the year ded December 31			
	2014	2013	2013			
	Thousands of US dollar					
Net income (loss)	\$ (3,122)	\$ (2,035)	\$ 443			
Share-based compensation charges	1,086	213	1,327			
One time management compensation Adjusted EBITDA	\$ (2,036)	\$ (1,822)	1,386 \$ 3,156			

	Three months period Ended March, 31			Year Ended December 31,		
		2014		2013	20	13
		Una	audite	ed	Aud	ited
			]	In thousands		
Cash Flows from Operating Activities						
Net income (loss)	\$	(3,122)	\$	(2,035)	\$	443
Adjustments to reconcile loss to net cash used in operating activities:						
Adjustments to the profit or loss items:						
Depreciation and amortization		663		823		3,001
Finance expenses, net		392		707		3,233
Cost of share-based payment		1,086		213		1,327
Taxes on income		23		24		24
Loss from sale of property and equipment		-		-		73
Change in employee benefit liabilities, net		(26)		20		121
		2,138		1,787		7,779
Changes in asset and liability items:						
Decrease (increase) in trade receivables		5,236		4,840		(3,445)
Increase in other accounts receivables		(240)		(442)		(444)
Increase in inventories and long-term		(2.0)		(112)		( )
inventories		(6,681)		(3,230)		(1,182)
Decrease (increase) in deferred expenses		559		(111)		(1,231)
Increase in trade payables		2,241		538		1,579
Increase (decrease) in other accounts payables		(563)		(230)		264
Decrease in deferred revenues		(846)		(134)		(6,270)
		(294)		1,231		(10,729)
		(2)4)		1,231		(10,727)
Cash paid and received during the period for						
Cash paid and received during the period for: Interest paid		(301)		(535)		(1,968)
Interest received		94		83		663
Taxes paid		(60)		(31)		(42)
r		(00)		(01)		( .=)
		(267)		(483)		(1,347)
Net cash provided by (used in) operating						
activities	\$	(1,545)		\$ 500	\$	(3,854)

	Three months Mar	Year Ended December 31,		
	2014	2013	2013	
	Una	udited	Audited	
		In thousands		
Cash Flows from Investing Activities Short-term investments Purchase of property and equipment Proceeds from sale of property and equipment Net cash provided by (used in) investing activities Cash Flows from Financing Activities	\$ (23,432) (616) - (24,048)	\$ 6,569 (1,274) - - 5,295	\$ 1,732 (5,643) 8 (3,903)	
Exercise of warrants and options into shares	_	173	562	
Issuance expenses	-	(521)	-	
Short term credit from bank and others, net	-	-	(12)	
Proceeds from issuance of ordinary shares, net	-	-	52,953	
Repayment of convertible debentures	-		(4,295)	
Net cash provided by (used in) financing activities	-	(348)	49,208	
Exchange differences on balances of cash and cash equivalent	(203)	328	793	
Increase (decrease) in cash and cash equivalents	(25,796)	5,775	42,244	
Cash and cash equivalents at the beginning of the year	59,110	16,866	16,866	
Cash and cash equivalents at the end of the period	\$ 33,314	\$ 22,641	\$ 59,110	
Significant non-cash transactions				
Issuance expenses accrued in other accounts payable	\$ -	\$ 100	\$ 151	
Exercise of options presented as liability	\$ -	\$ 23	\$ 23	
Exercise of convertible debentures into shares	\$ 7	\$ -	\$ 6,508	