# **News Release**



## Kamada Reports 2014 Fourth Quarter and Full Year Financial Results

Posts Record Revenue for the Fourth Quarter and Generates Net Profit

Conference call begins today at 8:30 a.m. Eastern time

**NESS ZIONA, Israel (February 11, 2015) – Kamada Ltd. (NASDAQ and TASE: KMDA),** a plasma-derived protein therapeutics company focused on orphan indications, announces financial results for the three and 12 months ended December 31, 2014.

Financial highlights of the 2014 fourth quarter include:

- Record total revenues of \$25.8 million compared with \$24.4 million for the fourth quarter of 2013 and \$17.1 million for the third quarter of 2014;
- Gross profit of \$8.0 million compared with \$8.9 million in the year-ago fourth quarter and \$4.4 million for the third quarter of 2014; and
- Adjusted net income of \$2.4 million compared with \$2.0 in the year-ago fourth quarter and adjusted net loss of \$1.9 in the third quarter of 2014.

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

- Reported additional positive data from the Company's ongoing open-label Phase 1/2 clinical trial
  extension study with its intravenous Alpha1-Proteinase Inhibitor—Human (AAT) to treat recently
  diagnosed type 1 diabetes (T1D) pediatric patients;
- Reported encouraging discussions with the European co-rapporteurs regarding a European filing for the Company's inhaled AAT to treat alpha-1 antitrypsin deficiency (AATD);
- Reported that interim data from a Phase 1/2 clinical study of the Company's proprietary AAT for the treatment of graft-versus-host-disease (GvHD) conducted by the Fred Hutchinson Cancer Research Center were highlighted in a poster presentation at the 56<sup>th</sup> American Society of Hematology Annual Meeting; and
- Granted orphan drug designation by the U.S. Food and Drug Administration (FDA) for the Company's intravenous AAT to treat GvHD.

### **Management Commentary**

"We are very pleased with our progress in the fourth quarter of 2014. Record quarterly revenues underscore our ability to execute to plan and grow our core business, while generating significant cash flow supports our robust clinical development program," stated David Tsur, co-founder and Chief Executive Officer of Kamada.

"Our strong partnership with Baxter, including the committed orders for the coming years and the consistent increase in the number of patients treated by Glassia, up 25% in 2014, gives us good visibility into the growing number of patients treated with Glassia worldwide, which we expect will double within the next four to five years. This growth is expected to provide the platform from which we can achieve our mid-term revenue goal of \$100 million in 2017, including approximately 75% growth in the Proprietary Products Segment.

"Our clinical development programs continue to generate favorable data from studies with our intravenous AAT to treat newly diagnosed type 1 diabetes and to treat GvHD, both orphan indications with significant unmet medical need."

"In addition, we expect to report data from our anti-rabies immunoglobulin U.S. Phase 2/3 clinical trial for the post-exposure prophylactic treatment of rabies by mid-year, and subject to positive data, to file a Biologics License Application (BLA) with the FDA in the second half of 2015. We have a strategic partnership for the clinical development, sales and marketing of this product in the U.S. with Kedrion Biopharma. With favorable data and a high-quality product, we look forward to Kedrion's commercialization activities in an exciting market opportunity."

"We remain very encouraged by the constructive dialogue we've had with the European co-rapporteurs regarding our plans to file for approval with the European Medicines Agency (EMA) for our inhaled AAT as a treatment for AATD. They agreed that the application fulfills the requirements relating to unmet medical need and benefit to public health, and that it may meet the scope of Conditional Approval if the company convincingly proves the positive benefit-risk balance of the product by the time of Marketing Authorization Application (MAA) filing. The co-rapporteurs have requested the addition of supplemental data analyses that may address the benefit-risk balance and support the already available safety and efficacy data. We are in the process of conducting the additional analyses and plan to file the MAA with the EMA in this year's fourth quarter. In addition, we expect to present the complete data set from the Phase 2/3 clinical study in advance of the upcoming American Thoracic Society Annual Meeting in May 2015," concluded Mr. Tsur.

#### **Fourth Quarter Financial Results**

Total revenues for the fourth quarter of 2014 of \$25.8 million compare with \$24.4 million for the fourth quarter of 2013. Revenue from the Proprietary Products Segment was \$20.0 million compared with \$9.1 million in the third quarter of this year and \$18.6 million in the year-ago quarter, with the changes being primarily due to ordering patterns of Glassia from Baxter. Revenue from the Distributed Product Segment remained steady at \$5.8 million during the fourth quarter of both 2014 and 2013.

Research and development (R&D) expenses in the fourth quarter of 2014 of \$3.4 million decreased from \$3.6 million in the fourth quarter of 2013 and from \$4.2 million in the third quarter of 2014, due to changes in activity in support of various clinical studies including three key clinical trials, the closing and analysis of the European Phase 2/3 study of inhaled AAT, as well as a decrease in the fourth quarter of facility costs allocated to R&D use compared with prior quarters.

Selling, general and administrative (SG&A) expenses in the fourth quarter of 2014 of \$2.4 million decreased from \$2.9 million in the fourth quarter of 2013, largely due to a decrease in expenses for doubtful debt.

Gross profit for the fourth quarter of 2014 was \$8.0 million compared with \$8.9 million in the fourth quarter of 2013 and \$4.4 million in the third quarter of 2014. The decline versus the prior year was a result of lower revenue and product mix within the Distributed Product Segment, as well as excess capacity in the Proprietary Products Segment during the year leading to lower profitability in the short term and one time sales efforts in certain markets.

Gross margin declined to 31% from 36% in the fourth quarter of 2013 and increased from 26% in the third quarter of 2014.

For the fourth quarter of 2014, the Company reported operating income of \$2.2 million compared with operating income of \$2.4 million for the fourth quarter of 2013 and an operating loss of \$2.5 million in the third quarter of 2014. Net income for the fourth quarter of 2014 was \$1.7 million or \$0.05 per diluted share, compared with net income of \$1.6 million or \$0.04 per diluted share for the same period

in 2013 and a net loss of \$2.9 million or \$0.09 per share in the third quarter of 2014. Adjusted net income for the fourth quarter of 2014 was \$2.4 million compared with adjusted net income of \$2.0 million for the same period in 2013 and an adjusted net loss of \$1.9 million in the third quarter of 2014.

Adjusted EBITDA for the fourth quarter of 2014 was \$3.6 million compared with \$3.5 million for the fourth quarter of 2013 and negative \$0.8 million in the third quarter of 2014.

#### **2014 Financial Results**

Total revenues for 2014 were \$71.9 million, compared with \$70.6 million for 2013. Revenue in the Proprietary Products Segment was \$45.2 million for the year, compared with \$50.7 million for 2013, which included a \$4.5 million milestone payment. 2014 revenue in the Distributed Product Segment increased 34% to \$26.7 million from \$20.0 million in 2013.

Gross profit for 2014 decreased to \$15.6 million from \$26.4 million in 2013, with gross margin declining to 22% from 37%. Excluding the \$3.0 million inventory write-off in the second quarter of 2014 and the \$4.5 million milestone payment in the second quarter of 2013, gross profit for 2014 decreased to \$18.6 million from \$21.9 million in the prior year.

Operating loss for 2014 of \$10.9 million compares with operating income of \$3.7 million for 2013. Net loss for the 2014 year was \$12.6 million or \$0.35 per share, compared with net income of \$0.5 million or \$0.01 per diluted share for the prior year.

Adjusted EBITDA for 2014 was negative \$4.4 million, compared with positive \$9.4 million for 2013.

### **Balance Sheet Highlights**

As of December 31, 2014, Kamada had cash, cash equivalents and short-term investments of \$51.9 million, compared with \$74.2 million as of December 31, 2013. During 2014, the Company used \$9.9 million in cash to fund operations, \$3.1 million for capital expenditures and \$7.7 million for repayment of convertible debt.

## **Conference Call**

Kamada management will host an investment community conference call today at 8:30 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.), 706-634-5454 (from outside the U.S.) or 1-809-457-877 (toll-free from Israel) and entering the conference identification number: 72411145.

A replay of the call will be accessible beginning two hours after its completion through February 17, 2015 by dialing 855-859-2056 (from within the U.S.) or 404-537-3406 (from outside the U.S.) and entering the conference identification number: 72411145. The call will also be archived for 90 days at <a href="https://www.streetevents.com">www.streetevents.com</a> and <a href="https://www.kamada.com">www.kamada.com</a>.

#### **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 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.

### **Contacts:**

Gil Efron CFO ir@kamada.com Anne Marie Fields LHA 212-838-3777 afields@lhai.com

**Tables to Follow** 

	As of Dec	ember 31,	
	2014	2013	
	In the	ousands	
Current Assets Cash and cash equivalents Short-term investments Trade receivables Other accounts receivables Inventories	\$ 14,546 37,350 17,993 2,359 25,423	\$ 59,110 15,067 17,882 3,694 21,933	
	97,671	117,686	
Non-Current Assets Long-term inventories Property, plant and equipment, net Long term assets	21,769 179 21,948 119,619	85 21,443 165 21,693 139,379	
Current Liabilities Short term credit and Current maturities of convertible debentures Trade payables Other accounts payables Deferred revenues	7,492 16,530 4,045 2,821	8,718 14,093 4,313 5,454	
	30,888	32,578	
Non-Current Liabilities Convertible debentures Employee benefit liabilities, net Deferred revenues	722 7,015 7,737	7,498 827 8,506 16,831	
Shareholder's Equity Kamada Ltd.'s shareholders' equity: Ordinary shares of NIS 1 par value: Authorized - 60,000,000 ordinary shares; Issued and outstanding - 35,988,563 and 35,959,939 shares at December 31, 2014 and 2013, respectively Additional paid in capital Conversion option in convertible debentures Capital reserve due to translation to presentation currency Capital reserve from hedges Available for sale reserve Capital reserve from share-based payments Capital reserve from employee benefits Accumulated deficit	9,208 158,417 1,147 (3,490) (116) 10 8,783 (81) (92,884) 80,994	9,201 157,100 2,218 (3,490) 156 (27) 5,189 (129) (80,248) 89,970	

Consolidated	Statements	of					
Comprehensive Income							

Comprehensive Income	For the ye		For the 3 months ended December 31,			
	2014	2013	2014	2013		
		In thous				
Revenues from proprietary products Revenues from distribution	\$45,249 26,676	\$ 50,658 19,965	\$ 19,964 5,827	\$ 18,635 5,797		
Total revenues	71,925	70,623	25,791	24,432		
Cost of revenues from proprietary products Cost of revenues from distribution	32,900 23,406	27,104 17,112	12,455 5,288	10,587 4,979		
Total cost of revenues	56,306	44,216	17,743	15,566		
Gross profit	15,619	26,407	8,048	8,866		
Research and development expenses Selling and marketing expenses General and administrative expenses Operating income (loss)	16,030 2,898 7,593 (10,902)	12,745 2,100 7,862 3,700	3,417 857 1,582 2,192	3,578 546 2,344 2,398		
Financial income Expense in respect of currency exchange and translation differences and	1,611	289	572	44		
derivatives instruments, net Financial expense	(199) (3,094)	(369) (3,153)	(293) (744)	(203) (679)		
Income before taxes on income Taxes on income	(12,583) 52	467 24	1,727 (18)	1,560 9		
Net Income (loss)	(12,636)	443	1,745	1,551		
Other Comprehensive Income: Net gain on available for sale Actuarial net gain of defined benefit Net gain on cash flow hedge	37 48 (272)	(27) 12 (73)	(32) 48 (61)	(27)		
Total comprehensive income ( loss)	\$ (12,823)	\$ 355	\$ 1,700	\$ 1,524		
Income per share attributable to equity holders of the Company:						
Basic income (loss) per share	\$ (0.35)	\$0.01	\$0.05	\$ 0.04		
Diluted income (loss) per share	\$ (0.35)	\$0.01	\$0.05	\$ 0.04		
Weighted-average number of ordinary shares used to compute income (loss) per share attributable to equity holders:						
Basic	35,971,335	32,714,631	35,984,299	35,863,463		
Diluted	35,971,335	33,674,337	37,324,697	36,179,510		

## **Adjusted EBITDA**

	For the	•	Three months			
	ended Dece		ended Dec			
	2014	2013	2014	2013		
		US dollar				
Net income (loss)	\$ (12,636)	\$ 443	\$ 1,745	\$ 1,551		
Income tax expense (income)	52	24	(18)	9		
Financial expense, net	1,483	2,864	172	630		
Depreciation and amortization expense	2,788	3,001	747	734		
Share-based compensation charges	3,751	1,327	676	412		
Expense in respect of translation differences and derivatives instruments, net	199	369	293	203		
One time management compensation		1,386				
Adjusted EBITDA	\$ (4,363)	\$ 9,414	\$ 3,615	\$ 3,539		

## Adjusted net income (loss)

	For the ended Dec	•	Three n ended Dec			
	2014	2013	2014	2013		
	Thousands of US dollar					
Net income	\$ (12,636)	\$ 443	\$ 1,745	\$ 1,551		
Share-based compensation charges	3,751	1,327	676	412		
One time management compensation Adjusted net income (loss)	\$ (8,885)	1,386 \$ 3,156	\$ 2,421	\$ 1,963		

## **Consolidated Statements of Cash Flows**

	For the ye Decemb		For the 3 months ended December 31,			
	2014	2013	2014	2013		
		In thousa	nds			
Cash Flows from Operating Activities						
Net Income (loss)	\$ (12,636)	\$ 443	\$ 1,745	\$ 1,551		
Adjustments to reconcile net loss to net cash provided by operating activities:						
Adjustments to the profit or loss items:						
Depreciation and amortization	2,788	3,001	747	734		
Financial expenses, net	1,682	3,233	465	833		
Cost of share-based payment	3,751	1,327	676	412		
Income tax expense	52	24	(18)	9		
Loss from sale of property and equipment	(2)	73	(2)	4		
Change in employee benefit liabilities, net	(57)	121	(120)	(27)		
	8,214	7,779	1,748	1,961		
Changes in asset and liability items:						
Decrease (increase) in trade receivables Decrease (Increase) in other accounts	(1,347)	(3,445)	(3,524)	(462)		
receivables	(50)	(911)	(345)	164		
Increase in inventories	(3,490)	(1,182)	126	511		
Decrease (increase) in deferred expenses	1,209	(1,231)	(17)	(1,387)		
Increase (decrease) in trade payables	3,261	1,579	2,151	4,868		
Decrease in other accounts payables	(344)	731	342	85		
Increase (decrease) in deferred revenues	(4,125)	(6,270)	(1,653)	(3,132)		
	(4,886)	(10,729)	(2,920)	647		
Cash paid during the year for:						
Interest paid	(1,210)	(1,968)	(247)	(395)		
Interest received	758	663	373	252		
Taxes paid	(158)	(42)		(4)		
	(610)	(1,347)	126	(147)		
Not seek and ideal (word) by according						
Net cash provided (used) by operating activities	\$ (9,918)	\$ (3,854)	\$ 699	\$ 4,012		

## **Consolidated Statements of Cash Flows**

	For the Year ended December 31,			F	or the 3 mo			
		2014	2	013		2014	20	013
				In thou	sanas	<b>;</b>		
Cash Flows from Investing Activities								
Short-term investments Purchase of property and equipment and intangible	\$	(23,746)	\$	1,732	\$	2,878	\$	(10,427)
assets Restricted cash, net		(3,076)		(5,643)		(720)		(1,218) (3)
Proceeds from sale of property and equipment		3		8		3		8
Net cash used in investing activities		(26,819)		(3,903)		2,161		(11,640)
Proceeds from exercise of warrants and options Proceeds from issuance of ordinary shares, net		88		562 52,953		23		17 (146)
Short term credit from bank and others, net Repayment of convertible debentures		(7,728)		(12) (4,295)		(7,728)		(6) (4,295 <u>)</u>
Net cash provided by (used in) financing activities		(7,640)		49,208		(7,705)		(4,430)
Exchange differences on balances of cash and cash equivalent		(187)		793		1,320		(64 <u>)</u>
Increase (Decrease) in cash and cash equivalents		(44,564)		42,244		(3,525)		(12,122)
Cash and cash equivalents at the beginning of the year/period		59,110		16,866		18,071		71,232
Cash and cash equivalents at the end of the year /period		\$14,546	\$	59,110		\$14,546	\$	59,110
Significant non-cash transactions Purchase of Property, Plant and equipment and intangible assets on credit	Ś	_	Ś	_	\$	_	Ś	_
Issuance expenses accrued in other accounts payable	\$	-	\$	151	\$	_	\$	(84)
Exercise of warrants presented as liability	\$	-	\$	23	\$	-	\$	-
Exercise of convertible debentures into shares	\$	7	\$	6,507	\$	-	\$	6,472