



## Kamada Announces Third Quarter 2014 Financial Results

*Affirms 2014 Revenue Guidance*

*Conference Call Begins Today at 8:30 a.m. Eastern Time*

**NESS ZIONA, Israel (November 12, 2014) – Kamada Ltd. (NASDAQ and TASE: KMDA)**, a plasma-derived protein therapeutics company focused on orphan indications, announces financial results for the three and nine months ended September 30, 2014 and affirms 2014 revenue guidance.

Financial highlights of the third quarter of 2014 include:

- Total revenue was \$17.2 million compared with \$17.5 million for the third quarter of 2013 and compared with \$15.8 million for the second quarter of 2014; and
- Gross profit was \$4.4 million compared with \$5.9 million in the year-ago third quarter and compared to gross loss of \$1.0 million for the second quarter of 2014.

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

- Granted orphan drug designation by the U.S. Food and Drug Administration (FDA) for Glassia<sup>®</sup>, the Company's proprietary human Alpha-1 Antitrypsin (AAT), to treat Graft-versus-host-disease;
- Reported that a comprehensive literature review in support of the mechanism of action of AAT for the treatment of type 1 diabetes was published in the August 2014 edition of the peer-reviewed *Journal of Diabetes Science and Technology*;
- Announced a second extension to its strategic agreement with Baxter International Inc., through which Kamada secured \$26 million in additional Glassia revenues, bringing Baxter's purchase obligation to a minimum of \$191 million from October 2010 through the end of 2017; and
- Announced results from the complete analysis of the European Phase 2/3 clinical study of its inhaled AAT therapy for the treatment of AAT deficiency (AATD), which confirmed the study did not meet its primary or secondary endpoints, but did show concordance of exacerbation data and positive lung function differences.

### **Management Commentary**

"During the third quarter we continued to strengthen and grow core commercial activities while advancing a robust clinical development program for our proprietary plasma-derived protein therapeutics focused on orphan indications," stated David Tsur, Co-founder and Chief Executive Officer of Kamada.

"Our commercial business was strengthened by the second extension to the purchase obligation of our strategic agreement with Baxter, which validates growing market acceptance of Glassia in the U.S. and underscores the strength of our partnership. In addition, revenue from our Distributed Products Segment grew nearly 50% compared with the year-ago quarter, highlighting the potential to further increase our revenue base and enhance cash flow.

"We have a comprehensive clinical development plan featuring a mix of early- and late-stage programs in orphan indications with unmet medical need. The recent peer-reviewed publication of the literature

review in support of the mechanism of action of AAT for the treatment of type 1 diabetes provides the scientific rationale that corroborates the positive clinical results achieved in our Phase 1/2 clinical study and validates our enthusiasm as we continue to enroll patients in our Phase 2/3 clinical study to treat this serious and life-threatening autoimmune disease.

“We expect to report positive data from our U.S. Phase 3 study of KamRAB, a human rabies immune globulin for the post-exposure prophylactic treatment of rabies, by the end of the year and to file a Biologics License Application with the FDA in the first half of 2015. We have a strategic partnership for the clinical development, sales and marketing of KamRAB in the U.S. with Kedrion Biopharma. With favorable data and high quality product, we look forward to Kedrion commercializing KamRAB in an approximate \$100 million market opportunity.

“We were pleased to receive U.S. orphan drug designation for Glassia to treat GVHD, a key milestone in our regulatory and development strategy. The Phase 1/2 study in GVHD is being conducted at the Fred Hutchinson Cancer Research Center in Seattle, Washington in cooperation with Baxter International Inc. Baxter has rights to Glassia in the U.S. The results from the Phase 1/2 study are expected to support our plans for global clinical development activities and may serve as a platform to expand AAT indications to include general organ transplantation, based on a similar mechanism of action.

“Despite not meeting the primary or secondary endpoints in our European Phase 2/3 study of inhaled AAT to treat AATD, important lung function parameters showed concordance of a potential treatment effect in the reduction of the inflammatory injury to the lung that is known to be associated with a reduced loss of respiratory function. Based on orphan designation of the drug, prior discussions with the regulator, the additional knowledge of these data and the persistent unmet need in this indication, we will advance discussions with the European Medicines Agency with the intent of submitting for conditional approval in order to bring our inhaled AAT to patients with AATD in Europe.

“The advances we’ve made in our commercial and clinical programs allow us to balance a growing revenue stream from sales of proprietary and distributed products with investments in development-stage programs in order to bring important new medicines to patients, and build value for our shareholders,” concluded Mr. Tsur.

### **Third Quarter Financial Results**

Total revenue for the third quarter of 2014 of \$17.2 million compares with \$17.5 million for the third quarter of 2013. Revenue from the Proprietary Products Segment was \$9.1 million compared with \$8.7 million in the second quarter of this year and \$12.1 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 of \$8.0 million increased from \$5.4 million in the third quarter of 2013, primarily due to higher IVIG sales in Israel.

Research and development (R&D) expenses in the third quarter of 2014 of \$4.2 million increased from \$2.8 million in the third quarter of 2013 and decreased from \$5.1 million in the second 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 facility costs allocated to R&D use in prior quarters.

Selling, general and administrative (SG&A) expenses in the third quarter of 2014 of \$2.7 million increased from \$2.1 million in the third quarter of 2013, largely due to share based compensation expense.

Gross profit for the third quarter of 2014 was \$4.4 million compared with \$5.9 million in the third quarter of 2013, reflecting lower revenue and product mix within the Proprietary Product Segment, as

well as higher revenue in the Distributed Products Segment and compared with \$0.7 million loss in the second quarter of 2014 which included a write-off of inventory in that quarter.

Gross margin declined to 26% from 34% in the third quarter of 2013 due to product mix favoring the lower-margin Distributed Products Segment and increased from 0% in the second quarter of 2014.

For the third quarter of 2014, the Company reported an operating loss of \$2.5 million compared with operating income of \$1.0 million for the third quarter of 2013 and compared to an operating loss of \$7.9 million in the second quarter of 2014. Net loss for the third quarter of 2014 was \$2.9 million or \$0.09 per share, compared with net income of \$0.4 million or \$0.00 per diluted share for the same period in 2013 and compared to a net loss of \$8.4 million or \$0.23 per diluted share in the second quarter of 2014. Adjusted net loss for the third quarter of 2014 was \$1.9 million compared with adjusted net income of \$0.3 million for the same period in 2013 and compared to an adjusted net loss of \$7.4 million in the second quarter of 2014.

Adjusted EBITDA for the third quarter of 2014 was a loss of \$0.8 million compared with positive \$2.0 million for the third quarter of 2013 and compared to a loss of \$6.2 million in the second quarter of 2014.

### **Nine Month Financial Results**

Total revenue for the first nine months of 2014 was \$46.1 million, compared with \$46.2 million for the first nine months of 2013. Year-to-date revenue in the Proprietary Products Segment was \$25.3 million, compared with \$32.0 million for the same period in 2013, which included a \$4.5 milestone payment. Excluding this payment, total revenue for the first nine months of 2014 increased by 11%. Year-to-date revenue in the Distributed Product Segment increased 46% to \$20.8 million from \$14.2 million in the first nine months of 2013.

Gross profit for the first nine months of 2014 decreased to \$7.6 million from \$17.5 million in the same period of 2013, with gross margin declining to 16% from 39%. 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 the first nine months of 2014 decreased to \$10.6 million from \$13.0 million in the prior-year period.

Operating loss for the first nine months of 2014 of \$10.6 million compares with operating income of \$0.4 million for the first nine months of 2013. Net loss for the first nine months of 2014 was \$11.5 million or \$0.32 per share, compared with a net loss of \$1.1 million or \$0.04 per share for the same period in 2013.

Adjusted EBITDA for the first nine months of 2014 was negative \$8.0 million, compared with positive \$5.9 million for the same period last year.

### **Balance Sheet Highlights**

As of September 30, 2014, Kamada had cash, cash equivalents and short-term investments of \$60.2 million, compared with \$74.2 million as of December 31, 2013. During the first nine months of 2014, the Company used \$10.6 million in cash to fund operations and \$2.4 million for capital expenditures.

### **Financial Guidance**

The Company affirms guidance for total revenue for the year ending December 31, 2014 to be between \$70 million and \$72 million, with revenue from its Distribution Segment to be between \$25 million and \$26 million and revenue from its Proprietary Products Segment to be between \$45 million and \$47 million. The Company notes that U.S. revenues from the agreement with Baxter remain on track.

## Conference Call

Kamada management will host an investment community conference call today beginning 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: 22669538.

A replay of the call will be accessible two hours after its completion through November 18, 2014 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: 22669538. The call will also be archived for 90 days at [www.streetevents.com](http://www.streetevents.com) and [www.kamada.com](http://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 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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## CONSOLIDATED BALANCE SHEETS

	As of September 30,		As of December
	2014	2013	31,
	Unaudited		Audited
	In thousands		
<u>Current Assets</u>			
Cash and cash equivalents	\$ 18,071	\$ 71,232	\$ 59,110
Short-term investments	42,207	4,707	15,067
Trade receivables, net	16,408	17,285	17,882
Other accounts receivables	2,078	2,532	3,694
Inventories	25,549	22,279	21,933
	<u>104,313</u>	<u>118,035</u>	<u>117,686</u>
<u>Non-Current Assets</u>			
Long-term inventories	-	165	-
Property, plant and equipment, net	21,780	20,951	21,443
Other long-term assets	143	177	250
	<u>21,923</u>	<u>21,293</u>	<u>21,693</u>
	<u>126,236</u>	<u>139,328</u>	<u>139,379</u>
<u>Current Liabilities</u>			
Short term credit and Current maturities of convertible debentures	8,186	5,658	8,718
Trade payables	15,740	9,124	14,093
Deferred revenues	3,898	7,603	5,454
Other accounts payables	3,627	4,312	4,313
	<u>31,451</u>	<u>26,697</u>	<u>32,578</u>
<u>Non-Current Liabilities</u>			
Convertible debentures	7,711	20,653	7,498
Deferred revenues	7,590	9,489	8,506
Employee benefit liabilities, net	890	866	827
	<u>16,191</u>	<u>31,008</u>	<u>16,831</u>
<u>Equity</u>			
Share capital	9,206	9,010	9,201
Share premium	157,278	149,219	157,100
Conversion option in convertible debentures	2,217	3,789	2,218
Capital reserve due to translation to presentation currency	(3,490)	(3,490)	(3,490)
Capital reserve from hedges	(55)	185	156
Capital reserve from available for sale financial assets	42	-	(27)
Capital reserve from share-based payments	8,154	4,850	5,189
Capital reserve from employee benefits	(129)	(141)	(129)
Accumulated deficit	(94,629)	(81,799)	(80,248)
	<u>78,594</u>	<u>81,623</u>	<u>89,970</u>
	<u>\$ 126,236</u>	<u>\$ 139,328</u>	<u>\$ 139,379</u>

## Consolidated Statements of Comprehensive Income (loss)

	For the 9 months period ended September 30,		For the 3 months period ended September 30,		Year ended December 31
	2014	2013	2014	2013	2013
	Unaudited				Audited
	Thousands of US dollar (Except for per-share income (loss) data)				
Revenues from proprietary products	\$ 25,285	\$ 32,023	\$ 9,143	\$ 12,066	\$ 50,658
Revenues from distribution	20,849	14,168	8,007	5,414	19,965
Total revenues	46,134	46,191	17,150	17,480	70,623
Cost of revenues from proprietary products	20,445	16,516	5,739	6,834	27,104
Cost of revenues from distribution	18,118	12,133	7,036	4,721	17,112
Total cost of revenues	38,563	28,649	12,775	11,555	44,216
Gross profit	7,571	17,542	4,375	5,925	26,407
Research and development expenses	12,613	9,167	4,180	2,833	12,745
Selling and marketing expenses	2,041	1,554	675	591	2,100
General and administrative expenses	6,011	5,514	2,017	1,543	7,862
Operating income (loss)	(13,094)	1,307	(2,497)	958	3,700
Financial income	1,041	245	439	80	289
Income (expense) in respect of currency exchange and derivatives instruments, net	92	(166)	(44)	(96)	(369)
Financial expense	(2,350)	(2,479)	(759)	(926)	(3,153)
Income (loss) before taxes on income	(14,311)	(1,093)	(2,861)	16	467
Taxes on income	70	15	36	(21)	24
Net Income (loss)	(14,381)	(1,108)	(2,897)	37	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	69	(44)	(51)	64	(27)
Net loss on cash flow hedge	(211)	-	(109)	-	(73)
Items that will not be reclassified to profit or loss in subsequent periods:					
Actuarial net gain of defined benefit plans	-	-	-	-	12
Total comprehensive income (loss)	<u>\$ (14,523)</u>	<u>\$ (1,152)</u>	<u>\$ (3,057)</u>	<u>\$ 101</u>	<u>\$ 355</u>
				-	
<u>Income (loss) per share attributable to equity holders of the Company:</u>					
Basic income (loss) per share	<u>\$ (0.41)</u>	<u>\$ (0.04)</u>	<u>\$ (0.09)</u>	<u>\$ 0.00</u>	<u>\$ 0.01</u>
Diluted income (loss) per share	<u>\$ (0.41)</u>	<u>\$ (0.04)</u>	<u>\$ (0.09)</u>	<u>\$ 0.00</u>	<u>\$ 0.01</u>

## CONSOLIDATED STATEMENTS OF CASH FLOWS

	For the 9 months period Ended September 30,		For the 3 months period Ended September 30,		Year Ended December 31,
	2014	2013	2014	2013	2013
	Unaudited				Audited
	Thousands of US dollar				
<u>Cash Flows from Operating Activities</u>					
Net income (loss)	\$ (14,381)	\$ (1,108)	\$ (2,897)	\$ 37	\$ 443
Adjustments to reconcile loss to net cash used in operating activities:					
Adjustments to the profit or loss items:					
Depreciation and amortization	2,041	2,267	726	752	3,001
Finance expenses, net	1,217	2,400	364	942	3,233
Cost of share-based payment	3,075	915	980	266	1,327
Loss from sale of fixed assets	-	73	-	6	73
Taxes on income	70	15	36	(21)	24
Change in employee benefit liabilities, net	63	148	56	96	121
	<u>6,466</u>	<u>5,818</u>	<u>2,162</u>	<u>2,045</u>	<u>7,779</u>
Changes in asset and liability items:					
Decrease (increase) in trade receivables	2,177	(2,983)	(587)	(4,726)	(3,445)
Decrease (increase) in other accounts receivables	295	(1,075)	(235)	(1,282)	(444)
Decrease (increase) in inventories and long-term inventories	(3,616)	(1,693)	(1,678)	1,622	(1,182)
Decrease (increase) in deferred expenses	1,226	156	412	128	(1,231)
Increase (decrease) in trade payables	1,110	(3,289)	(788)	(111)	1,579
Increase (decrease) in other accounts payables	(686)	646	(882)	(314)	264
Decrease in deferred revenues	(2,472)	(3,138)	(643)	(1,653)	(6,270)
	<u>(1,966)</u>	<u>(11,376)</u>	<u>(4,401)</u>	<u>(6,336)</u>	<u>(10,729)</u>
Cash paid and received during the period for:					
Interest paid	(963)	(1,573)	(361)	(511)	(1,968)
Interest received	385	411	253	216	663
Taxes paid	(158)	(97)	(94)	(43)	(42)

	<u>(736)</u>	<u>(1,259)</u>	<u>(202)</u>	<u>(338)</u>	<u>(1,347)</u>
Net cash used in operating activities	<u>\$ (10,617)</u>	<u>\$ (7,925)</u>	<u>\$ (5,338)</u>	<u>\$ (4,592)</u>	<u>\$ (3,854)</u>

## **CONSOLIDATED STATEMENTS OF CASH FLOWS**

	<b>For the 9 months period Ended September 30,</b>		<b>For the 3 months period Ended September 30,</b>		<b>Year Ended December 31,</b>
	<b>2014</b>	<b>2013</b>	<b>2014</b>	<b>2013</b>	<b>2013</b>
	<b>Unaudited</b>				<b>Audited</b>
	<b>Thousands of US dollar</b>				
<b><u>Cash Flows from Investing Activities</u></b>					
Short-term investments	(26,624)	12,159	160	4,311	\$ 1,732
Purchase of property and equipment	(2,356)	(4,425)	(821)	(1,678)	(5,643)
Proceeds from sale of equipment	-	3	-	-	8
Net cash provided by (used in) investing activities	<u>(28,980)</u>	<u>7,737</u>	<u>(661)</u>	<u>2,633</u>	<u>(3,903)</u>
<b><u>Cash Flows from Financing Activities</u></b>					
Exercise of options into shares	65	545	26	277	562
Proceeds from issuance of ordinary shares, net	-	53,099	-	(859)	52,953
Short term credit from bank and others, net	-	(6)	-	-	(12)
Repayment of convertible debentures	-	-	-	-	(4,295)
Net cash provided by (used in) financing activities	<u>65</u>	<u>53,638</u>	<u>26</u>	<u>(582)</u>	<u>49,208</u>
<b><u>Exchange differences on balances of cash and cash equivalent</u></b>	<u>(1,507)</u>	<u>916</u>	<u>(1,039)</u>	<u>370</u>	<u>793</u>
<b><u>Increase (decrease) in cash and cash equivalents</u></b>	<u>(41,039)</u>	<u>54,366</u>	<u>(7,012)</u>	<u>(2,171)</u>	<u>42,244</u>
<b><u>Cash and cash equivalents at the beginning of the period</u></b>	<u>59,110</u>	<u>16,866</u>	<u>25,083</u>	<u>73,403</u>	<u>16,866</u>
<b><u>Cash and cash equivalents at the end of the period</u></b>	<u>\$ 18,071</u>	<u>\$ 71,232</u>	<u>\$ 18,071</u>	<u>\$ 71,232</u>	<u>\$ 59,110</u>
<b><u>Significant non-cash transactions</u></b>					
Purchase of property, equipment and intangible assets on credit	<u>\$ -</u>	<u>\$ -</u>	<u>\$ -</u>	<u>\$ -</u>	<u>\$ -</u>
Exercise of options presented as liability	<u>\$ -</u>	<u>\$ 23</u>	<u>\$ -</u>	<u>\$ -</u>	<u>\$ 23</u>
Exercise of convertible debentures into shares	<u>\$ 7</u>	<u>\$ 35</u>	<u>\$ -</u>	<u>\$ 35</u>	<u>\$ 6,508</u>
Issuance expenses accrued in other accounts payables	<u>\$ -</u>	<u>\$ 235</u>	<u>\$ -</u>	<u>\$ -</u>	<u>\$ 151</u>



**Adjusted EBITDA**

	<b>9 months period Ended September 30</b>		<b>3 months period Ended September 30</b>		<b>Year ended December 31</b>
	<b>2014</b>	<b>2013</b>	<b>2014</b>	<b>2013</b>	<b>2013</b>
<b>Thousands of US dollar</b>					
Net Income (loss)	\$ (14,381)	\$ (1,108)	\$ (2,897)	\$ 37	\$ 443
Income tax expense	76	15	36	(21)	24
Financial expense, net	1,309	2,234	320	846	2,864
Depreciation and amortization expense	2,041	2,267	726	752	3,001
Share-based compensation charges	3,075	915	980	266	1,327
Expense (income) in respect of translation differences and derivatives instruments, net	(92)	166	44	96	369
one-time management compensation		1,386			1,386
Adjusted EBITDA	<u>\$ (7,972)</u>	<u>\$ 5,875</u>	<u>\$ (791)</u>	<u>\$ 1,976</u>	<u>\$ 9,414</u>

**Adjusted net income**

	<b>9 months period Ended September 30</b>		<b>3 months period Ended September 30</b>		<b>Year ended December 31</b>
	<b>2014</b>	<b>2013</b>	<b>2014</b>	<b>2013</b>	<b>2013</b>
<b>Thousands of US dollar</b>					
Net income (loss)	\$ (14,381)	\$ (1,108)	\$ (2,897)	\$ 37	\$ 443
Share-based compensation charges	3,075	915	980	266	1,327
One time management compensation		1,386			1,386
Adjusted net income	<u>\$ (11,306)</u>	<u>\$ 1,193</u>	<u>\$ (1,917)</u>	<u>\$ 303</u>	<u>\$ 3,156</u>

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