

# News Release



February 2, 2016

## **Kamada Reports 2015 Fourth Quarter and Full Year Financial Results**

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

**NESS ZIONA, Israel (February 2, 2016) – Kamada Ltd. (NASDAQ and TASE: KMDA)**, a plasma-derived protein therapeutics company focused on orphan indications, reports financial results for the three and 12 months ended December 31, 2015.

Financial highlights of the 2015 fourth quarter and full year 2015 included:

- Full year total revenues of \$70.1 million, including \$43.1 million from the Proprietary Product segment and \$27.0 million from the Distributed Product segment;
- Fourth quarter total revenues of \$25.9 million compared with \$24.9 million in the 2014 fourth quarter;
- Proprietary Product revenues of \$17.7 million in the fourth quarter of 2015 compared with \$19.1 million in the 2014 fourth quarter;
- Distributed Product revenues of \$8.1 million in the fourth quarter of 2015 compared with \$5.8 million in the 2014 fourth quarter;
- Gross profit in the fourth quarter of 2015 of \$8.3 million compared with \$7.5 million in the 2014 fourth quarter; and
- Net income in the fourth quarter of 2015 of \$1.0 million compared with \$1.1 million in the 2014 fourth quarter.

Other highlights of the 2015 fourth quarter and recent weeks included:

- Reported further positive interim results from the U.S. Phase 1/2 clinical trial with the Company's proprietary intravenous (IV) Alpha-1 Antitrypsin (AAT) therapy for the treatment of Graft Versus Host Disease (GvHD);
- Reported top-line results from the U.S. pivotal Phase 2/3 clinical trial with the Company's Rabies IgG, which demonstrated that the study met its primary endpoint;
- Completed enrollment in the U.S. Phase 2 clinical trial with the Company's inhaled AAT therapy for the treatment of AAT Deficiency (AATD, or Inherited Emphysema);
- Announced plans to un-blind the Phase 2 clinical trial with the Company's IV AAT to treat newly diagnosed pediatric and young adult patients with type 1 diabetes (T1D) at the planned interim analysis, which will accelerate the timeline for future commercialization of the product, should the analysis be positive; and
- Executed a third extension to the Company's Glassia® (IV AAT) supply agreement with Baxalta originally executed in 2010, which extends manufacturing supply through 2018 and increases minimum Glassia purchases by approximately \$50 million to a total of \$240 million for the period 2010 through 2018.

Expected milestones over the coming months include:

- Submission of a Marketing Authorization Application (MAA) with the European Medicines Agency (EMA) for the Company's inhaled AAT for the treatment of AATD;
- Submission of a Biologics License Application (BLA) with the U.S. Food and Drug Administration (FDA) for the Company's Rabies IgG;
- Initiation of a Phase 2 clinical trial in collaboration with Baxalta with the Company's IV AAT for the prevention of lung transplant rejection;
- Readout of top-line data from the U.S. Phase 2 clinical trial of the Company's inhaled AAT to treat AATD; and plans for a meeting with the FDA to present the results of the European Inhaled AAT study seeking a regulatory path for product registration in the U.S.

### **Management Commentary**

"We made considerable progress throughout 2015 and are particularly pleased with the number of important commercial and clinical milestones achieved during the fourth quarter," stated Amir London, Chief Executive Officer of Kamada. "The latest extension to our agreement with Baxalta increases their minimum purchase commitment through 2018 by \$50 million and underscores Glassia's growing market acceptance in the U.S. as well as its importance to Baxalta's AATD franchise. Importantly, this third extension also extends our manufacturing supply through the end of 2018 and gives us confidence in our ability to achieve growth in the Proprietary Products segment and to attain our 2017 revenue goal of \$100 million based on this commitment, as well as the increasing number of patients treated with Glassia, which is not yet reflected in our 2015 revenues but continues to grow by double-digit percentage year over year. We are also encouraged with the improved gross margin in our Proprietary Products segment, which increased to 40% this quarter.

"Our clinical development activities are broadly distributed across a number of disease states and include programs in various stages of development. We are excited to be just months away from two significant regulatory submissions, including the MAA for our inhaled AAT to treat AATD in Europe and a BLA for our Rabies IgG as a prophylactic treatment for rabies exposure in the U.S. Each indication offers significant market opportunity and we look forward to working with our commercial partners for these products to realize their potential.

"We are encouraged by the positive interim data recently reported from the ongoing U.S. Phase 1/2 clinical trial with our IV AAT to treat steroid-resistant GvHD. We look forward to the final results of this study and to developing plans for further development in this indication. In addition, we will be initiating a Phase 1/2 clinical trial with our IV AAT to prevent lung transplantation rejection. Both programs, which add up to over a billion dollar market potential, are being conducted in collaboration with Baxalta.

"The progress we made in 2015 positions us well to continue executing our growth strategy, while advancing our clinical development programs across several important orphan indications of unmet medical need. We look forward to achieving a number of notable, value-creating milestones in the coming months," concluded Mr. London.

## **Fourth Quarter Financial Results**

Total revenues for the fourth quarter of 2015 were \$25.9 million compared with \$24.9 million for the fourth quarter of 2014. Revenues from the Proprietary Product segment were \$17.7 million compared with \$19.1 million in the year-ago fourth quarter, primarily due to ordering patterns from Baxalta during the year. Revenues from the Distributed Product segment were \$8.1 million for the fourth quarter of 2015 compared with \$5.8 million in the same quarter of 2014.

Gross profit for the fourth quarter of 2015 was \$8.3 million compared with \$7.5 million for the fourth quarter of 2014. Gross margin increased to 32% from 30% in the fourth quarter of 2014. Gross margin in the Proprietary Products segment was 40% in the fourth quarter, a two-year record high, and compared with gross margin of 36% in the 2014 fourth quarter.

Research and development expenses in the fourth quarter of 2015 were \$4.4 million, an increase from \$3.4 million in the fourth quarter of 2014, as the Company continued to support various clinical trials and to allocate facility capacity for research and development in preparation for regulatory submissions in 2016.

Selling, general and administrative expenses in the fourth quarter of 2015 of \$3.0 million increased from \$2.4 million in the fourth quarter of 2014.

For the fourth quarter of 2015, the Company reported operating income of \$0.8 million compared with operating income of \$1.6 million for the fourth quarter of 2014. The Company recorded net income for the fourth quarter of 2015 of \$1.0 million or \$0.03 per diluted share, compared with net income of \$1.2 million or \$0.03 per diluted share for the same period in 2014. Adjusted net income for the fourth quarter of 2015 was \$1.4 million compared with adjusted net income of \$1.8 million for the same period in 2014.

Adjusted EBITDA for the fourth quarter of 2015 was an income of \$2.0 million compared with income of \$2.8 million for the fourth quarter of 2014.

## **Full Year Financial Results**

Total revenues for 2015 were \$70.1 million compared with \$71.1 million for 2014. Revenues in the Proprietary Product segment were \$43.2 million compared with \$44.4 million for 2014, and revenues in the Distributed Product segment were \$27.0 million compared with \$26.7 million in 2014. These results met the lower range of the Company's projection for the year 2015, which was \$70 million to \$73 million.

Gross profit for 2015 was \$16.0 million compared with \$15.0 million for 2014, and 2015 gross margin increased to 23% from 21% in 2014.

Operating loss for 2015 of \$11.4 million compared with an operating loss of \$11.5 million for 2014. Net loss for 2015 was \$11.3 million or \$0.31 per share, compared with a net loss of \$13.2 million or \$0.37 per share for 2014. The adjusted net loss for 2015 was \$9.4 million compared with an adjusted net loss of \$9.5 million for 2014.

Adjusted EBITDA for 2015 was a loss of \$6.3 million compared with a loss of \$4.9 million for 2014.

### **Balance Sheet Highlights**

As of December 31, 2015, Kamada had cash, cash equivalents and short-term investments of \$28.3 million, compared with \$51.9 million as of December 31, 2014. During 2015, the Company used \$13.9 million in cash to fund operations, \$2.8 million for capital expenditures and \$7.8 million for repayment of convertible debt.

### **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 1-809-315-362 (toll-free from Israel) and entering the conference identification number: 38830870. The call will also be webcast live on the internet on the Company's website at [www.kamada.com](http://www.kamada.com).

A replay of the call will be accessible two hours after its completion through February 8, 2016 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: 38830870. The call will also be archived for 90 days on the Company's website at [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 Immune globulins. 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 Baxalta. 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 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 is in Phase 2 clinical trials in the U.S. and its intravenous AAT to treat type-1 diabetes, GvHD and to prevent lung transplant rejection. 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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-Financial Tables to Follow-

## Consolidated Balance Sheets

	As of December 31,	
	2015	2014
	In thousands	
<b>Current Assets</b>		
Cash and cash equivalents	\$ 5,047	\$ 14,546
Short-term investments	23,259	37,350
Trade receivables	23,071	17,514
Other accounts receivables	2,881	2,359
Inventories	26,336	25,423
	<u>80,594</u>	<u>97,192</u>
<b>Non-Current Assets</b>		
Long-term inventories		
Property, plant and equipment, net	21,309	21,769
Long term assets	89	179
	<u>21,398</u>	<u>21,948</u>
	<u>101,992</u>	<u>119,140</u>
<b>Current Liabilities</b>		
Current maturities of convertible debentures and bank loans	37	7,492
Trade payables	16,917	16,530
Other accounts payables	4,064	4,045
Deferred revenues	1,921	2,919
	<u>22,939</u>	<u>30,986</u>
<b>Non-Current Liabilities</b>		
Bank loans	151	-
Employee benefit liabilities, net	787	722
Deferred revenues	5,608	7,015
	<u>6,546</u>	<u>7,737</u>
<b>Shareholder's Equity</b>		
Kamada Ltd.'s shareholders' equity:		
Ordinary shares of NIS 1 par value:		
Authorized - 60,000,000 ordinary shares; Issued and outstanding – 36,418,741 and 35,988,563 shares at December 31, 2015 and 2014, respectively	9,320	9,208
Additional paid in capital	162,238	158,417
Conversion option in convertible debentures	-	1,147
Capital reserve due to translation to presentation currency	(3,490)	(3,490)
Capital reserve from hedges	(1)	(116)
Available for sale reserve	73	10
Capital reserve from share-based payments	9,157	8,783
Capital reserve from employee benefits	(59)	(81)
Accumulated deficit	(104,731)	(93,461)
	<u>72,507</u>	<u>80,417</u>
	<u>\$ 101,992</u>	<u>\$ 119,140</u>

## Consolidated Statements of Comprehensive Income

	For the year ended December 31,		For the 3 months ended December 31,	
	2015	2014	2015	2014
	In thousands			
Revenues from proprietary products	\$ 43,159	\$ 44,389	\$ 17,725	\$ 19,104
Revenues from distribution	26,954	26,676	8,143	5,827
Total revenues	70,113	71,065	25,868	24,931
Cost of revenues from proprietary products	30,468	32,617	10,649	12,172
Cost of revenues from distribution	23,640	23,406	6,954	5,288
Total cost of revenues	54,108	56,023	17,603	17,460
Gross profit	16,005	15,042	8,265	7,471
Research and development expenses	16,530	16,030	4,425	3,417
Selling and marketing expenses	3,859	2,898	1,166	857
General and administrative expenses	7,040	7,593	1,881	1,582
Operating income (loss)	(11,424)	(11,479)	793	1,615
Financial income	463	*404	100	*43
Expense in respect of currency exchange and translation differences and derivatives instruments, net	625	-	205	(92)
Financial expense	(934)	*(2,086)	(110)	*(416)
Income before taxes on income	(11,270)	(13,161)	988	1,150
Taxes on income	-	52	-	(18)
Net Income (loss)	(11,270)	(13,213)	988	1,168
Other Comprehensive Income:				
Net gain on available for sale	63	37	(48)	(32)
Actuarial net gain of defined benefit	22	48	22	48
Net gain on cash flow hedge	115	(272)	48	(61)
Total comprehensive income ( loss)	\$ (11,070)	\$ (13,400)	\$ 1,010	\$ 1,123
*Reclassified				
<u>Income per share attributable to equity holders of the Company:</u>				
Basic income (loss) per share	\$ (0.31)	\$ (0.37)	\$0.03	\$0.03
Diluted income (loss) per share	\$ (0.31)	\$ (0.37)	\$0.03	\$0.03
Weighted-average number of ordinary shares used to compute income (loss) per share attributable to equity holders:				
Basic	36,245,813	35,971,335	36,418,741	35,984,299
Diluted	36,245,813	35,971,335	36,418,741	37,324,697

**Adjusted EBITDA**

	For the year ended December 31		Three months ended December 31	
	2015	2014	2015	2014
	Thousands of US dollar			
Net income (loss)	\$ (11,270)	\$ (13,213)	\$ 988	\$ 1,168
Income tax expense (income)	-	52	-	(18)
Financial expense, net	471	1,682	10	373
Depreciation and amortization expense	3,227	2,788	789	747
Share-based compensation charges	1,907	3,751	380	676
Expense in respect of translation differences and derivatives instruments, net	(625)	-	(205)	(92)
Adjusted EBITDA	<u>\$ (6,290)</u>	<u>\$ (4,940)</u>	<u>\$ 1,962</u>	<u>\$ 2,854</u>

**Adjusted net income (loss)**

	For the year ended December 31		Three months ended December 31	
	2015	2014	2015	2014
	Thousands of US dollar			
Net income (loss)	\$ (11,270)	\$ (13,213)	\$ 988	\$ 1,168
Share-based compensation charges	1,907	3,751	380	676
Adjusted net income (loss)	<u>\$ (9,363)</u>	<u>\$ (9,462)</u>	<u>\$ 1,368</u>	<u>\$ 1,844</u>



## Consolidated Statements of Cash Flows

	For the year ended December 31,		For the 3 months ended December 31,	
	2015	2014	2015	2014
	In thousands			
<u>Cash Flows from Operating Activities</u>				
Net Income (loss)	\$ (11,270)	\$ (13,213)	\$ 988	\$ 1,168
Adjustments to reconcile net loss to net cash provided by operating activities:				
Adjustments to the profit or loss items:				
Depreciation and amortization	3,227	2,788	789	747
Financial expenses (income), net	(154)	1,682	(195)	465
Cost of share-based payment	1,907	3,751	380	676
Income tax expense	-	52	-	52
Loss from sale of property and equipment	-	(2)	-	(72)
Change in employee benefit liabilities, net	87	(57)	196	(120)
	5,067	8,214	1,170	1,748
Changes in asset and liability items:				
increase in trade receivables	(5,604)	(869)	(8,167)	(3,046)
Decrease (Increase) in other accounts receivables	118	(50)	(242)	(345)
Decrease (increase) in inventories	(913)	(3,490)	475	126
Decrease (increase) in deferred expenses	(565)	1,209	564	(17)
Increase in trade payables	887	3,261	244	2,151
Increase (decrease) in other accounts payables	94	(344)	197	342
Increase (decrease) in deferred revenues	(2,405)	(4,026)	(762)	(1,554)
	(8,388)	(4,309)	(7,691)	(2,343)
Cash paid during the year for:				
Interest paid	(484)	(1,210)	(122)	(247)
Interest received	1,143	758	231	373
Withholding taxes paid	(47)	(158)	-	-
	612	(610)	109	126
Net cash provided by (used in) operating activities	\$ (13,979)	\$ (9,918)	\$ (5,424)	\$ 699

## Consolidated Statements of Cash Flows

	For the Year ended December 31,		For the 3 months ended December 31,	
	2015	2014	2015	2014
	In thousands			
<u>Cash Flows from Investing Activities</u>				
Short-term investments	\$ 13,971	\$ (23,746)	\$ 13,330	\$ 2,878
Purchase of property and equipment and intangible assets	(2,718)	(3,076)	(786)	(720)
Proceeds from sale of property and equipment	-	3	-	3
Net cash provided by (used in) investing activities	11,253	(26,819)	12,544	2,161
Proceeds from exercise of options	1,254	88	-	23
Receipt of long-term loans	197	-	197	-
Repayment Long-term loans	(9)	-	(9)	-
Repayment of convertible debentures	(7,797)	(7,728)	(7,797)	(7,728)
Net cash provided by (used in) financing activities	(6,355)	(7,640)	(7,609)	(7,705)
<u>Exchange differences on balances of cash and cash equivalent</u>	(418)	(187)	(251)	1,320
<u>Increase (Decrease) in cash and cash equivalents</u>	(9,499)	(44,564)	(740)	(3,525)
<u>Cash and cash equivalents at the beginning of the year</u>	14,546	59,110	5,787	18,071
Cash and cash equivalents at the end of the year	\$5,047	\$14,546	\$5,047	\$14,546

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