

News Release



AUGUST 14, 2014

Kamada Reports Second Quarter Financial Results

Introduces 2014 Revenue Guidance

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

NESS ZIONA, Israel (August 14, 2014) – 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, 2014.

Financial highlights of the second quarter of 2014 and recent weeks include:

- Revenues for the quarter were \$15.8 million compared with \$16.1 million for the second quarter of 2013; the second quarter of 2013 included a one-time payment of \$4.5 million received from Baxter International Inc. (Baxter) related to a technology transfer milestone
- Gross loss for the quarter of \$0.10 million compared with gross profit of \$7.4 million in the year-ago second quarter; excluding a one-time \$3.0 million write-off of inventory in the current quarter and the one-time payment from Baxter in the prior-year quarter, gross profit for the second quarter of 2014 was \$3.0 million, compared with \$2.9 million in the second quarter of 2013
- Introducing 2014 revenue guidance, with total revenue for the year ending December 31, 2014 expected to be between \$70 million and \$72 million

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

- Received approval from the U.S. Food and Drug Administration (FDA) for enhancements to the Company's manufacturing process that significantly improve capacity for the production of its Alpha-1 Antitrypsin (AAT) therapeutics
- Announced preliminary top-line results from the Phase 2/3 pivotal clinical trial in Europe and Canada of the Company's proprietary inhaled AAT therapy for the treatment of Alpha-1 Antitrypsin Deficiency (AATD or inherited emphysema), with final results expected in September 2014
- 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 AATD, marketed in the U.S. by Baxter
- Announced a proof-of-concept study with Glassia to treat graft-versus-host disease (GVHD) in cooperation with Baxter; the study is being conducted at the Fred Hutchinson Cancer Research Center in Seattle

Management Commentary

"Building upon the launch in the first quarter of a Phase 2/3 trial with Glassia to treat newly diagnosed pediatric patients with type 1 diabetes and a U.S. Phase 2 trial with inhaled AAT for treating AATD, during the second quarter we further expanded and advanced our clinical development programs with the initiation of a study with Glassia in GVHD, an orphan indication. In addition, we were particularly pleased to receive FDA approval for our significantly enhanced infusion rate for Glassia, as it represents

another competitive distinction for our intravenous AAT therapy. These unique features are key to Glassia's continually increasing market share in a greater than \$750 million global market that is growing at about 10% per year. The recent FDA approval of our enhanced manufacturing process provides improved efficiencies and capacity that will serve us well as we increase sales of our proprietary protein plasma therapeutics," stated David Tsur, Co-founder and Chief Executive Officer of Kamada.

"We reported preliminary, top-line results from the European Phase 2/3 clinical trial of our proprietary inhaled AAT therapy for the treatment of AATD. We are continuing to review the full data set and expect to complete the final analysis and to report those data in September. We are looking forward to presenting the clinical findings that may support our efforts to bring the first inhaled therapy to patients suffering from this debilitating, life-threatening, orphan lung disease. Subject to the final results, we are preparing to submit for review for regulatory approval with the European Medicines Agency during the fourth quarter of this year.

"Revenues for the second quarter of 2014 increased from the first quarter of this year, and the full-year revenue guidance we are introducing today reflects our expectations for significant growth in the second half of the year compared with the first half.

"We are pleased with our recent progress and look forward to a productive second half of the year as we prepare to report final data from our inhaled AAT program and advance other clinical programs. We have a number of milestones in the coming months and expect that these, along with growing revenues, will support our commitment to enhance shareholder value," added Mr. Tsur.

Second Quarter Financial Results

Total revenue for the second quarter of 2014 of \$15.8 million compared with \$16.1 million for the second quarter of 2013. Revenue from the Proprietary Products Segment was \$8.7 million compared with \$11.9 million in the year-ago quarter, which included a one-time payment of \$4.5 million received from Baxter related to a technology transfer milestone. Excluding this one-time payment, our revenues this quarter increased 18% compared with the second quarter of 2013 and increased 18% compared with the first quarter of 2014. Revenue from the Distribution Segment of \$7.1 million increased from \$4.2 million in the second quarter of 2013, primarily due to higher IVIG sales in the Israeli market.

Research and development (R&D) expenses in the second quarter of 2014 of \$5.1 million increased from \$2.6 million in the second quarter of 2013 and from \$3.4 million in the first quarter of 2014, due to increased activity in support of various clinical studies including the launch of three important clinical trials, the closing and analysis of the European Phase 2/3 study of inhaled AAT, as well as by facility costs allocated to research and development use.

Selling, general and administrative (SG&A) expenses in the second quarter of 2014 of \$2.8 million decreased from \$3.2 million in the second quarter of 2013, largely due to one-time costs in the prior-year quarter associated with our U.S. IPO.

Gross loss for the second quarter of 2014 was \$0.10 million compared with gross profit of \$7.4 million in the second quarter of 2013. Gross loss in the second quarter of 2014 included a one-time write-off of inventory of \$3.0 million, and gross profit in the second quarter of 2013 was favorably impacted by the \$4.5 million milestone payment. Excluding these one-time events, gross profit for the second quarter of 2014 increased to \$3.0 million from \$2.9 million in the second quarter of 2013, reflecting the level of revenue and product mix within the Proprietary Segment as well as the increase in revenue in the Distributed Products segment.

Gross margin decreased to 0% from 46% in the second quarter of 2013 due to product mix as the Distribution Segment revenues increased during the quarter and to the product write-off described above. Gross margin in the second quarter of 2013 benefitted from milestone revenue received under the technology transfer agreement with Baxter.

For the second quarter of 2014, the Company reported an operating loss of \$7.9 million compared with operating income of \$1.7 million for the second quarter of 2013. Net loss for the second quarter of 2014 was \$8.4 million or \$0.23 per share, compared with net income of \$0.89 million or \$0.03 per diluted share for the same period in 2013. Adjusted net loss for the second quarter of 2014 was \$7.4 million compared with adjusted net income of \$2.7 million for the same period in 2013.

Adjusted EBITDA for the second quarter of 2014 was negative \$6.2 million compared with positive \$4.2 million for the second quarter of 2013.

Six Month Financial Results

Total revenue for the first half of 2014 of \$29.0 million compared with \$28.7 million for the first half of 2013. Revenue in the Proprietary Products Segment was \$16.1 million, compared with \$20.0 million for the same period in 2013, which included a \$4.5 milestone payment. Excluding this payment, Proprietary Products revenues in the first half of 2014 increased by 4% to \$16.1 million compared with \$15.5 million in the first half of 2013. Revenue in the Distribution Segment increased 45% to \$12.8 million from \$8.8 million in the first half of 2013.

Gross profit for the first half of 2014 decreased to \$3.2 million from \$11.6 million in the first half of 2013, with gross margin declining to 11% from 40% in the comparable prior-year period. Excluding the inventory write-off in the 2014 period and the milestone payment in the 2013 period, gross profit for the first half of 2014 decreased to \$6.2 million from \$7.1 million in the first half of 2013.

Operating loss for the first six months of 2014 of \$10.6 million compared with operating income of \$0.35 million for the first six months of 2013. Net loss for the first half of 2014 was \$11.5 million or \$0.32 per share, compared with a net loss of \$1.1million or \$0.04 per share for the same period in 2013.

Adjusted EBITDA for the first six months of 2014 was negative \$7.2 million, compared with positive \$3.9 million for the same period last year.

Balance Sheet Highlights

As of June 30, 2014, Kamada had cash, cash equivalents and short-term investments of \$67.7 million, compared with \$74.2 million as of December 31, 2013. During the first half of 2014, the Company used \$5.3 million in cash to fund operations and \$1.5 million for capital expenditures.

Financial Guidance

For the year ending December 31, 2014, Kamada expects total revenue to be between \$70 million and \$72 million, with revenue from its Distribution Segment projected to be between \$25 million to \$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: 76337212.

A replay of the call will be accessible two hours after its completion through August 20, 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: 76337212. The call will also be archived for 90 days at www.streetevents.com and 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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-Tables to Follow-

CONSOLIDATED BALANCE SHEETS

	As of June 30,		As of December
	2014	2013	31,
	Unaudited		2013
	In thousands		Audited
Current Assets			
Cash and cash equivalents	\$ 25,083	\$ 73,403	\$ 59,110
Short-term investments	42,603	9,152	15,067
Trade receivables, net	15,215	12,340	17,882
Other accounts receivables	2,299	1,400	3,694
Inventories	23,871	23,901	21,933
	<u>109,071</u>	<u>120,196</u>	<u>117,686</u>
Non-Current Assets			
Long-term inventories	-	165	-
Property, plant and equipment, net	21,668	19,993	21,443
Other long-term assets	160	193	250
	<u>21,828</u>	<u>20,351</u>	<u>21,693</u>
	<u>130,899</u>	<u>140,547</u>	<u>139,379</u>
Current Liabilities			
Short term credit and Current maturities of convertible debentures	8,798	5,534	8,718
Trade payables	15,942	9,098	14,093
Other accounts payables	4,510	5,481	4,313
Deferred revenues	5,264	8,596	5,454
	<u>34,514</u>	<u>28,709</u>	<u>32,578</u>
Non-Current Liabilities			
Convertible debentures	8,039	19,930	7,498
Employee benefit liabilities, net	834	770	827
Deferred revenues	6,867	10,149	8,506
	<u>15,740</u>	<u>30,849</u>	<u>16,831</u>
Equity			
Share capital	9,203	8,983	9,201
Share premium	157,212	148,655	157,100
Conversion option in convertible debentures	2,217	3,794	2,218
Capital reserve due to translation to presentation currency	(3,490)	(3,490)	(3,490)
Capital reserve from hedges	54	121	156
Capital reserve from available for sale financial assets	93	-	(27)
Capital reserve from share-based payments	7,217	4,903	5,189
Capital reserve from employee benefits	(129)	(141)	(129)
Accumulated deficit	(91,732)	(81,836)	(80,248)
	<u>80,645</u>	<u>80,989</u>	<u>89,970</u>
	<u>\$ 130,899</u>	<u>\$ 140,547</u>	<u>\$ 139,379</u>

Consolidated Statements of Comprehensive Income (loss)

	Six months period ended June 30,		Three months period ended June 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	\$ 16,142	\$ 19,957	\$ 8,721	\$ 11,897	\$ 50,658
Revenues from distribution	12,842	8,754	7,076	4,218	19,965
Total revenues	28,984	28,711	15,797	16,115	70,623
Cost of revenues from proprietary products	14,706	9,682	9,703	5,121	27,104
Cost of revenues from distribution	11,082	7,412	6,160	3,573	17,112
Total cost of revenues	25,788	17,094	15,863	8,694	44,216
Gross profit (loss)	3,196	11,617	(66)	7,421	26,407
Research and development expenses	8,433	6,334	5,068	2,604	12,745
Selling and marketing expenses	1,366	963	719	450	2,100
General and administrative expenses	3,994	3,975	2,037	2,719	7,862
Operating income (loss)	(10,597)	345	(7,890)	1,648	3,700
Financial income	421	165	179	79	289
Income (expense) in respect of currency exchange and translation differences and derivatives instruments, net	136	(70)	97	(132)	(369)
Financial expense	(1,410)	(1,549)	(737)	(693)	(3,153)
Income (loss) before taxes on income	(11,450)	(1,109)	(8,351)	902	467
Taxes on income	34	36	11	12	24
Net Income (loss)	(11,484)	(1,145)	(8,362)	890	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	120	-	81	-	(27)
Net loss on cash flow hedge	(102)	(108)	(33)	(67)	(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)	\$ (11,466)	\$ (1,253)	\$ (8,314)	\$ 823	\$ 355
Income (loss) per share attributable to equity holders of the Company:					
Basic income (loss) per share	\$ (0.32)	\$ (0.04)	\$ (0.23)	\$ (0.03)	\$ 0.01
Diluted income (loss) per share	\$ (0.32)	\$ (0.04)	\$ (0.23)	\$ (0.03)	\$ 0.01

CONSOLIDATED STATEMENTS OF CASH FLOWS

	Six months period Ended June 30,		Three months period Ended June 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)	\$ (11,484)	\$ (1,145)	\$ (8,362)	\$ 890	\$ 443
Adjustments to reconcile loss to net cash provided by (used in) operating activities:					
Adjustments to the profit or loss items:					
Depreciation and amortization	1,315	1,515	652	692	3,001
Finance expenses, net	853	1,454	461	747	3,233
Cost of share-based payment	2,095	649	1,009	436	1,327
Loss from sale of fixed assets	-	67	-	67	24
Taxes on income	34	36	11	12	73
Change in employee benefit liabilities, net	<u>7</u>	<u>52</u>	<u>33</u>	<u>32</u>	<u>121</u>
	<u>4,304</u>	<u>3,773</u>	<u>2,166</u>	<u>1,986</u>	<u>7,779</u>
Changes in asset and liability items:					
Decrease (increase) in trade receivables	2,764	1,743	(2,472)	(3,097)	(3,445)
Decrease (increase) in other accounts receivables	530	207	770	649	(444)
Decrease (increase) in inventories and long-term inventories	(1,938)	(3,315)	4,743	(85)	(1,182)
Decrease (increase) in deferred expenses	814	28	255	139	(1,231)
Increase (decrease) in trade payables	1,898	(3,178)	(342)	(3,716)	1,579
Increase (decrease) in other accounts payables	196	960	759	1,190	264
Decrease in deferred revenues	<u>(1,829)</u>	<u>(1,485)</u>	<u>(983)</u>	<u>(1,351)</u>	<u>(6,270)</u>
	<u>2,435</u>	<u>(5,040)</u>	<u>2,730</u>	<u>(6,271)</u>	<u>(10,729)</u>
Cash paid and received during the period for:					
Interest paid	(602)	(1,062)	(301)	(527)	(1,968)
Interest received	132	195	38	112	663
Taxes paid	<u>(64)</u>	<u>(54)</u>	<u>(4)</u>	<u>(23)</u>	<u>(42)</u>
	<u>(534)</u>	<u>(921)</u>	<u>(267)</u>	<u>(438)</u>	<u>(1,347)</u>
Net cash used in operating activities	\$ (5,279)	\$ (3,333)	\$ (3,733)	\$ (3,833)	\$ (3,854)

CONSOLIDATED STATEMENTS OF CASH FLOWS

	Six months period Ended June 30,		Three months period Ended June 30,		Year Ended December 31,
	2014	2013	2014	2013	2013
	Unaudited				Audited
	Thousands of US dollar				
<u>Cash Flows from Investing Activities</u>					
Short-term investments	\$ (26,784)	\$ 7,848	\$ (3,352)	\$ 1,279	\$ 1,732
Purchase of property and equipment	(1,535)	(2,747)	(919)	(1,473)	(5,643)
Proceeds from sale of equipment	-	3	-	3	8
Net cash provided by (used in) investing activities	(28,319)	5,104	(4,271)	(191)	(3,903)
<u>Cash Flows from Financing Activities</u>					
Exercise of options into shares	39	309	39	136	562
Proceeds from issuance of ordinary shares, net	-	53,958	-	54,479	52,953
Short term credit from bank and others, net	-	(6)	-	(6)	(12)
Repayment of convertible debentures	-	-	-	-	(4,295)
Net cash provided by financing activities	39	54,261	39	54,609	49,208
<u>Exchange differences on balances of cash and cash equivalent</u>	(468)	505	(266)	177	793
<u>Increase (decrease) in cash and cash equivalents</u>	(34,024)	56,537	(8,231)	50,762	42,244
<u>Cash and cash equivalents at the beginning of the period</u>	59,110	16,866	33,314	22,641	16,866
<u>Cash and cash equivalents at the end of the period</u>	\$ 25,083	\$ 73,403	\$ 25,083	\$ 73,403	\$ 59,110
<u>Significant non-cash transactions</u>					
Purchase of property, equipment and intangible assets on credit	\$ -	\$ -	\$ -	\$ -	\$ 151
Exercise of options presented as liability	\$ -	\$ 23	\$ -	\$ -	\$ 23
Exercise of convertible debentures into shares	\$ 7	\$ -	\$ -	\$ -	\$ 6,508
Issuance expenses accrued in other accounts payables	\$ -	\$ 1,094	\$ -	\$ 994	\$ -

Adjusted EBITDA

	Six months period Ended June 30		Three months period Ended June 30		Year ended December 31
	2014	2013	2014	2013	2013
Thousands of US dollar					
Net Income (loss)	\$ (11,484)	\$ (1,145)	\$ (8,362)	\$ 890	\$ 443
Income tax expense	34	36	11	12	24
Financial expense, net	853	1,384	461	614	2,864
Depreciation and amortization expense	1,315	1,515	652	692	3,001
Share-based compensation charges	2,095	649	1,009	436	1,327
Expense (income) in respect of translation differences and derivatives instruments, net	-	70	-	132	369
one-time management compensation		1,386		1,386	1,386
Adjusted EBITDA	<u>\$ (7,187)</u>	<u>\$ 3,895</u>	<u>\$ (6,229)</u>	<u>\$ 4,162</u>	<u>\$ 9,414</u>

Adjusted net income

	Six months period Ended June 30		Three months period Ended June 30		Year ended December 31
	2014	2013	2014	2013	2013
Thousands of US dollar					
Net income (loss)	\$ (11,484)	\$ (1,145)	\$ (8,362)	\$ 890	\$ 443
Share-based compensation charges	2,095	649	1,009	436	1,327
One time management compensation		1,386		1,386	1,386
Adjusted net income	<u>\$ (9,389)</u>	<u>\$ 890</u>	<u>\$ (7,353)</u>	<u>\$ 2,712</u>	<u>\$ 3,156</u>

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