Alkermes Announces First Quarter Fiscal 2009 Results and Raises Financial Expectations for Fiscal 2009

August 7, 2008

CAMBRIDGE, Mass.--(BUSINESS WIRE)--Aug. 7, 2008--Alkermes, Inc. (NASDAQ: ALKS) today announced financial results for its first quarter of fiscal 2009. Financial highlights for the quarter ended June 30, 2008 include:

- A profitable quarter on a GAAP basis, with net income of $29.7 million. Net income included $25.5 million of revenue from Eli Lilly and Company (Lilly).
- Quarterly revenues of $80.0 million. Worldwide sales of RISPERDAL(R) CONSTA(R) by Janssen, Division of Ortho-McNeil-Janssen Pharmaceuticals, Inc. and Janssen-Cilag (Janssen) were approximately $343 million, an increase of 11% from the previous quarter.
- A strong financial position, with cash and total investments of $473 million.
- The repurchase of an additional 1.0 million shares of common stock as part of an ongoing stock repurchase program. To date, the company has repurchased 8.0 million shares of common stock for approximately $106 million.
- The improvement of financial expectations for fiscal 2009 based on higher anticipated revenues from RISPERDAL CONSTA and lower selling, general and administrative (SG&A) expenses.

"We are pleased to report a successful quarter, which reflects the growth of RISPERDAL CONSTA in the marketplace and continued discipline in managing our business," stated James Frates, chief financial officer of Alkermes. "With more than $473 million in cash and investments, we are in a strong financial position and are making strategic investments in our pipeline while continuing to repurchase our outstanding shares."

Key operating results for the quarter ended June 30, 2008 include the following:

- Net income was $29.7 million or a basic and diluted earnings per share of $0.31, including $4.5 million in share-based compensation expense. Net income for the quarter included $24.7 million, net of taxes, received as part of a one-time $40 million payment from Lilly in conjunction with the AIR(R) Insulin program. For the same period in 2007, net income was $8.7 million or a basic earnings per share of $0.09 and a diluted earnings per share of $0.08, which included $5.7 million in share-based compensation expense.
- Pro forma net income was $9.5 million or a basic and diluted earnings per share of $0.10, compared to a net income of $14.3 million or a basic and diluted earnings per share of $0.14 for the same period in 2007.

Alkermes is providing pro forma results as a complement to GAAP results. The pro forma net income excludes certain noncash or nonrecurring items, and Alkermes' management believes these pro forma measures help to indicate underlying trends in the company's ongoing operations. The reconciliation between pro forma and reported diluted earnings per share for the first quarters of fiscal 2009 and 2008 is provided in the following table:

	Pro Forma Diluted Earnings	Income from Lilly Associated with AIR Insulin Program (Net of Taxes)	Share-Based Compensation Expense	Reported GAAP Diluted Earnings
Q1 FY 2009	$0.10	$0.26	($0.05)	$0.31
Q1 FY 2008	$0.14	--	($0.06)	$0.08

The following financial results are reported on a GAAP basis and include share-based compensation expense:

Revenues

- Total revenues for the quarter ended June 30, 2008 were $80.0 million, compared to $68.9 million for the same period in 2007.
- Manufacturing revenues for the quarter ended June 30, 2008 were $38.6 million compared to $31.5 million for the same period in 2007, an increase of 23% year over year. Manufacturing revenues for the quarter ended June 30, 2008 consisted of $36.0 million for RISPERDAL CONSTA and $2.6 million for VIVITROL(R), compared to $30.2 million for RISPERDAL CONSTA and $1.3 million for VIVITROL for the same period in 2007.
- Royalty revenues for the quarter ended June 30, 2008 were $8.6 million compared to $7.0 million for the same period in

2007, an increase of 23% year over year. Royalty revenues for the quarter ended June 30, 2008 were based on RISPERDAL CONSTA sales of $343.1 million compared to RISPERDAL CONSTA sales of $278.7 million for the same period in 2007.

- Research and development (R&D) revenue under collaborative arrangements for the quarter ended June 30, 2008 was $31.4 million, which included $25.5 million of the one-time $40 million payment from Lilly. R&D revenue was $23.4 million for the same period in 2007.
- Net collaborative profit for the quarter ended June 30, 2008 was $1.4 million, compared to $7.0 million for the same period in 2007. Gross sales of VIVITROL during the quarter were $4.8 million, compared to $4.1 million for the same period in 2007.

Costs and Expenses

- Cost of goods manufactured for the quarter ended June 30, 2008 was $14.3 million, of which $10.8 million related to RISPERDAL CONSTA and $3.5 million related to VIVITROL, compared to $10.1 million for the same period in 2007, of which $9.0 million related to RISPERDAL CONSTA and $1.1 million related to VIVITROL.
- R&D expenses for the quarter ended June 30, 2008 were $22.3 million, compared to $32.6 million for the same period in 2007.
- SG&A expenses for the quarter ended June 30, 2008 were $11.9 million, compared to $15.4 million for the same period in 2007.
- Share-based compensation expense (included in the expenses above) for the quarter ended June 30, 2008 was $4.5 million, of which $0.4 million related to cost of goods manufactured, $1.6 million related to R&D expenses and $2.5 million related to SG&A expenses. Share-based compensation expense for the quarter ended June 30, 2007 was $5.7 million, of which $0.6 million related to cost of goods manufactured, $1.8 million related to R&D expenses and $3.3 million related to SG&A expenses.
- Interest income for the quarter ended June 30, 2008 was $3.6 million, compared to $4.4 million for the same period in 2007. Interest expense for the quarter ended June 30, 2008 was $4.2 million, compared to $4.1 million for the same period in 2007.
- Income tax expense for the quarter ended June 30, 2008 was $1.0 million, compared to $2.4 million for the same period in 2007.

At June 30, 2008, Alkermes had cash and total investments of $473.3 million, compared to $460.4 million at March 31, 2008.

Recent Highlights

- VIVITROL Approved in Russia: Alkermes announced that its partner, Cilag GmbH International, a subsidiary of Johnson & Johnson, received approval from the Russian Regulatory Authorities to market VIVITROL for the treatment of alcohol dependence in Russia. The product will be manufactured by Alkermes and commercialized by Janssen-Cilag, an affiliate company of Cilag GmbH International. Alkermes will receive manufacturing revenues and a royalty based on product sales.
- Supplemental New Drug Application Submitted for RISPERDAL CONSTA for Bipolar Disorder: Alkermes announced that its partner, Johnson & Johnson Pharmaceutical Research & Development, L.L.C., submitted a supplemental New Drug Application for RISPERDAL CONSTA to the U.S. Food and Drug Administration (FDA) for approval as monotherapy in the maintenance treatment of bipolar I disorder to delay the time to occurrence of mood episodes in adults.
- Positive 52-Week Data for Exenatide Once Weekly Presented: Alkermes, Amylin Pharmaceuticals, Inc. and Lilly announced results from an open-label clinical study that showed the durable efficacy of exenatide once weekly for the treatment of type 2 diabetes. At 52 weeks, patients taking exenatide once weekly showed an average A1C improvement of 2% and an average weight loss of 9.5 pounds. Exenatide once weekly was well tolerated, with no major hypoglycemia events regardless of background therapy.
- Registration Study of VIVITROL Initiated for the Treatment of Opioid Dependence: Alkermes initiated a registration study of VIVITROL for the treatment of opioid dependence. The multi-center, 200-patient study is designed to assess the efficacy and safety of VIVITROL compared to placebo treatment in combination with counseling for six months.
- Stock Repurchase Program Expanded: Alkermes expanded its previously announced common stock repurchase program by an additional $40 million following the receipt of the $40 million payment from Lilly, bringing the total authorization to $215 million. To date, the company has repurchased 8.0 million shares of common stock for approximately $106 million under this program.
- Debt Repurchased Below Par: Alkermes repurchased a principal amount of $15 million of its Non-Recourse RISPERDAL CONSTA Secured 7% Notes (7% Notes) for $14.1 million. Subsequent to the end of the first fiscal quarter, Alkermes repurchased a further principal amount of $60 million of the 7% Notes for $57.7 million. To date, Alkermes has repurchased a total of $75 million, or approximately 44%, of the 7% Notes.

Financial Expectations

The following outlines Alkermes' financial expectations for the fiscal year ending March 31, 2009. These financial expectations include the impact of share-based compensation expense. Certain statements set forth below constitute forward-looking statements within the meaning of the Private

Securities Litigation Reform Act of 1995. For information with respect to factors that could cause Alkermes' actual results to differ materially from its expectations, please see the risk factors provided at the end of this press release and in Alkermes' Form 10-K for the fiscal year ended March 31, 2008, as filed with the Securities & Exchange Commission.

As a result of anticipated higher revenues from RISPERDAL CONSTA and lower SG&A expenses, Alkermes today improved its financial expectations for fiscal year 2009.

- Revenues: The company is increasing its expectation for total revenues for fiscal 2009 to a range of $205 to $230 million, revised from an earlier expectation of $200 to $225 million.
- Manufacturing Revenues: The company is increasing its expectation for manufacturing revenues to a range of $116 to $129 million, revised from an earlier expectation of $113 to $125 million. The company is increasing its expectation for manufacturing revenues related to RISPERDAL CONSTA to a range of $109 to $118 million, revised from an earlier expectation of $106 to $114 million. The company expects manufacturing revenues related to VIVITROL to remain in the range of $7 to $11 million.
- Royalty Revenues: The company is increasing its expectation for royalty revenues from RISPERDAL CONSTA to a range of $34 to $36 million, revised from an earlier expectation of $32 to $35 million.
- R&D Revenues: The company expects R&D revenues to remain in the range of $45 to $50 million.
- Net Collaborative Profit: The company expects net collaborative profit to remain in the range of $10 to $15 million.
- Cost of Goods Manufactured: The company expects cost of goods manufactured to remain in the range of $40 to $50 million.
- R&D Expenses: The company expects R&D expenses to remain in the range of $95 to $100 million.
- SG&A Expenses: The company is decreasing its expectation for SG&A expenses to a range of $50 to $55 million, revised from an earlier expectation of $55 to $60 million.
- Operating Income: The company is increasing its expectation for operating income to a range of $20 to $25 million, revised from an earlier expectation of $10 to $15 million.
- Net Interest Income/Expense: The company expects net interest income/expense to remain unchanged at $0.
- Income Taxes: The company now expects income taxes of $1 million, revised from an earlier expectation of $0.
- GAAP Net Income: The company is increasing its expectation for GAAP net income to a range of $19 to $24 million, or a basic earnings per share in the range of $0.20 to $0.26. This compares to an earlier net income expectation of $10 to $15 million, or an earnings per share of $0.11 to $0.16. These per share calculations are based on the current share count of 94 million shares outstanding. The actual number of shares outstanding is expected to decrease during the year as the company continues to repurchase its common stock.
- Cash Flow from Operations: The company is increasing its expectation for cash flow from operations to a range of $50 to $55 million, revised from an earlier expectation of $25 to $30 million.
- SFAS 123R: The company expects share-based compensation expense to remain in the range of $15 to $20 million.

Conference Call

Alkermes will host a conference call at 4:30 p.m. EDT on Thursday, August 7, 2008 to discuss these financial results and provide an update on the company. The conference call may be accessed by dialing 1-866-793-1306 for domestic callers and 1-703-639-1308 for international callers. The conference call ID number is 1262420. In addition, a replay of the conference call will be available from 7:30 p.m. EDT on Thursday, August 7, 2008 through 5:00 p.m. EDT on Thursday, August 14, 2008, and may be accessed by visiting Alkermes' website or by dialing 1-888-266-2081 for domestic callers and 1-703-925-2533 for international callers. The replay access code is 1262420. Alkermes is also providing a podcast MP3 file available for download on the Alkermes website, which will be available shortly following the conference call and will be available until Thursday, August 14, 2008.

About Alkermes

Alkermes, Inc., a biotechnology company committed to developing innovative medicines to improve patients' lives, manufactures RISPERDAL(R) CONSTA(R) for schizophrenia and developed and manufactures VIVITROL(R) for alcohol dependence. Alkermes' robust pipeline includes extended-release injectable, pulmonary and oral products for the treatment of prevalent, chronic diseases, such as central nervous system disorders, addiction and diabetes. Headquartered in Cambridge, Massachusetts, Alkermes has research and manufacturing facilities in Massachusetts and Ohio.

Certain statements set forth above may constitute forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, including, but not limited to: statements concerning future business and operating results and profitability; the purchase by the company of up to $215 million of its common stock; the therapeutic value of the company's product candidates to patients; and the successful continuation of development activities for proprietary and partnered programs. Although the company believes that such statements are based on reasonable assumptions within the bounds of its knowledge of its business and operations, the forward-looking statements are neither promises nor guarantees and the company's business is subject to significant risk and uncertainties and there can be no assurance that its actual results will not differ materially from its expectations. These risks and uncertainties include, among others: the timing, cost and amount of share repurchases; actions or decisions by the company's partners with regard to development and regulatory strategy, timing and funding of the company's proprietary and partnered product candidates, which are out of the company's control, and the outcome of clinical and preclinical work the company is pursuing, both on its own and with partners; decisions by the FDA or foreign regulatory authorities regarding the company's product candidates; potential changes in cost, scope and duration of clinical trials; and the occurrence of unintended side effects, adverse reactions or incidents of misuse related to the company's products and product candidates that could cause the FDA or other foreign regulatory authorities to require post approval studies, new labeling, or removal of such products from the market. For further information with respect to factors that could cause the company's actual results to differ materially from expectations, reference is made to the reports the company filed with the Securities and Exchange Commission under the Securities Exchange Act of 1934, as amended. The forward-looking statements made in this release are made only as of the date hereof and the company disclaims any intention

or responsibility for updating predictions or financial expectations contained in this release.

VIVITROL(R) is a registered trademark of Cephalon, Inc.; RISPERDAL(R) CONSTA(R) is a registered trademark of Janssen-Cilag group of companies.

Alkermes, Inc. and Subsidiaries
Selected Financial Information (Unaudited)

Condensed Consolidated Statements of Income (In thousands, except per share data)	Three Months Ended June 30, 2008	Three Months Ended June 30, 2007
Revenues:		
Manufacturing revenues	$38,610	$31,517
Royalty revenues	8,581	6,982
Research and development revenue under collaborative arrangements	31,450	23,450
Net collaborative profit	1,351	6,989
Total Revenues	79,992	68,938
Expenses:		
Cost of goods manufactured	14,314	10,145
Research and development	22,261	32,619
Selling, general and administrative	11,926	15,400
Total Expenses	48,501	58,164
Operating Income	31,491	10,774
Other (Expense) Income:		
Interest income	3,616	4,402
Interest expense	(4,226)	(4,073)
Other (expense) income, net	(164)	26
Total Other (Expense) Income	(774)	355
Income before Income Taxes	30,717	11,129
Income taxes	1,030	2,382
Net Income	$29,687	$8,747
Earnings per Common Share:		
Basic	$0.31	$0.09
Diluted	$0.31	$0.08
Weighted Average Number of Common Shares Outstanding (GAAP and Pro Forma):		
Basic	95,361	101,324
Diluted	96,631	104,191
Pro Forma Reconciliation:		
Net Income - GAAP	$29,687	$8,747
Share-based compensation expense	4,495	5,747
Income from Lilly related to termination of the AIR(R) Insulin program (net of taxes)	(24,709)	-
Net increase in the fair value of warrants	-	(196)
Net Income - Pro Forma	$9,473	$14,298
Pro Forma Earnings per Common Share:		
Basic	$0.10	$0.14
Diluted	$0.10	$0.14

Condensed Consolidated Balance Sheets (In thousands)	June 30, 2008	March 31, 2008
Cash, cash equivalents and total investments	$473,341	$460,361
Receivables	31,699	47,249
Prepaid expenses and other current assets	5,305	5,720
Inventory	16,375	18,884
Property, plant and equipment, net	110,817	112,539
Other assets	11,302	11,558

Total Assets	$648,839	$656,311
Unearned milestone revenue - current portion	$5,848	$5,927
Non-recourse RISPERDAL CONSTA secured 7% notes - current portion	12,917	-
Other current liabilities	20,576	36,093
Non-recourse RISPERDAL CONSTA secured 7% notes - long-term portion	134,375	160,324
Unearned milestone revenue - long-term portion	110,257	111,730
Deferred revenue - long-term portion	27,584	27,837
Other long-term liabilities	8,658	9,086
Total shareholders' equity	328,624	305,314
Total Liabilities and Shareholders' Equity	$648,839	$656,311

This selected financial information should be read in conjunction with the consolidated financial statements and notes thereto included in the company's Annual Report on Form 10-K for the year ended March 31, 2008, and the company's report on Form 10-Q for the three months ended June 30, 2008, which the company intends to file in August 2008.

VIVITROL(R) Selected Financial Information (Unaudited, in thousands)	Three Months Ended June 30, 2008	Three Months Ended June 30, 2007
VIVITROL Income Statement		
Alkermes' expenses	$3,328	$5,680
Cephalon's net losses	3,383	19,083
VIVITROL net losses	$6,711	$24,763
Flow of funds		
Alkermes paid Cephalon: net losses up to the $124.6M net loss cap (1)	$0	($5,223)
Cephalon paid Alkermes: Alkermes' expenses in excess of the net loss cap through December 31, 2007	0	5,647
Cephalon paid Alkermes: Alkermes' expenses in excess of its share of net product losses after December 31, 2007	39	0
Net flow of funds from Cephalon (3)	$39	$424
Net Collaborative Profit		
Milestone revenue recognized to offset collaboration expenses and Alkermes' non-shared expenses up to the net loss cap (1)	$0	$5,256
Milestone revenue recognized with respect to the license (2)	1,312	1,309
Net flow of funds from Cephalon (3)	39	424
Net collaborative profit	$1,351	$6,989

Notes

(1) Expenses incurred on behalf of the collaboration by Alkermes, Inc. ("Alkermes") and net losses incurred on behalf of the collaboration by Cephalon, Inc. ("Cephalon") contribute to the cumulative net product losses incurred on VIVITROL. Alkermes was responsible for the first $124.6 million of these cumulative net product losses (the "net loss cap"). Alkermes recognized milestone revenue to offset the net product losses incurred up to the net loss cap. The collaboration reached the net loss cap in April 2007, at which point the recognition of milestone revenue related to this accounting unit stopped. In addition, in prior periods, Alkermes recognized $19.9 million of milestone revenue to offset expenses it incurred for which it was solely

responsible, related to the successful FDA approval of VIVITROL and the successful completion of the first VIVITROL manufacturing line. These $19.9 million of expenses did not contribute to the cumulative net product losses.

(2) Milestone revenue related to the license commenced upon approval of VIVITROL, by the FDA, on April 13, 2006 and is being recognized on a straight line basis over 10 years, at the rate of approximately $1.3 million per quarter.

(3) Alkermes was responsible for net losses up to the net loss cap and reimbursed Cephalon for their net losses during this period. Once the net loss cap was reached in April 2007, Cephalon reimbursed Alkermes for its VIVITROL expenses through December 31, 2007. Effective January 1, 2008, the two companies share any net profits or losses on the product.

Through June 30, 2008, Alkermes has recognized $158.6 million of milestone revenue out of the $274.6 million received from Cephalon. In addition to (1) and (2) above, this recognition includes $2.4 million of milestone revenue related to a 10% mark-up on manufacturing revenue, which is reported by Alkermes within manufacturing revenues in the condensed consolidated statements of income.

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