



Alkermes Reports First Quarter Fiscal 2010 Financial Results

August 6, 2009

- RISPERDAL(R) CONSTA(R) Continues to Show Strong Operational Growth -

- New Drug Application for Exenatide Once Weekly Submitted and Accepted; Positive Data Announced for DURATION-3 -

CAMBRIDGE, Mass.--(BUSINESS WIRE)--Aug. 6, 2009-- Alkermes, Inc. (NASDAQ: ALKS) today reported financial results for its first quarter of fiscal 2010, which ended on June 30, 2009.

Financial highlights:

- Quarterly revenues of \$47.5 million, driven by strong manufacturing and royalty revenues from RISPERDAL® CONSTA®. Worldwide sales of RISPERDAL CONSTA by Janssen, Division of Ortho-McNeil-Janssen Pharmaceuticals, Inc. and Janssen-Cilag (Janssen) were approximately \$348 million, an increase of 6.9 percent from the previous quarter and are based on product sales in approximately 60 countries.
- GAAP net loss of \$10.2 million and pro forma net income of \$1.2 million. The GAAP net loss was driven primarily by \$8.2 million of charges associated with the planned relocation of the company's headquarters.
- Strong financial position, with cash and total investments of \$380.4 million.

Additional highlights:

- Positive data reported for DURATION-3 which demonstrated superiority of exenatide once weekly compared to LANTUS® (insulin glargine) in patients with type 2 diabetes.
- New Drug Application (NDA) submission for exenatide once weekly accepted by the U.S. Food and Drug Administration (FDA).
- RISPERDAL CONSTA launched in Japan by Janssen Pharmaceutica K.K. for the treatment of schizophrenia.
- RISPERDAL CONSTA approved in the European Union for use as a deltoid injection for the treatment of schizophrenia. RISPERDAL CONSTA was previously approved in the EU as a gluteal injection only.

"RISPERDAL CONSTA continues to serve as a platform for growth. We also have a near-term opportunity to add a new revenue stream with royalties from exenatide once weekly, with several major milestones accomplished recently, including the acceptance of the NDA and positive data from the DURATION-3 study," commented James Frates, chief financial officer of Alkermes. "In the second half of calendar 2009, we anticipate several development milestones, including data from the registration study of VIVITROL® in patients with opioid dependence and the initiation of a phase 1 study for ALKS 36 for the treatment of pain."

Key operating results for the quarter ended June 30, 2009, include the following:

- GAAP net loss was \$10.2 million or a basic and diluted loss per share of \$0.11, including \$3.2 million in share-based compensation expense and \$8.2 million of charges associated with the relocation of the company's headquarters. For the same period in 2008, 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 and \$24.7 million of income, net of taxes, received from Eli Lilly and Company (Lilly) in conjunction with the AIR® Insulin program.
- Pro forma net income was \$1.2 million or a basic and diluted earnings per share of \$0.01, compared to a pro forma net income of \$9.5 million or a basic and diluted earnings per share of \$0.10 for the same period in 2008.

Alkermes is providing pro forma results as a complement to GAAP results. The pro forma measure 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 (loss) earnings per share for the first quarters of fiscal 2010 and 2009 is provided in the following table:

	Pro Forma Diluted Earnings	Impact of the Termination of the Collaborative Agreements with Lilly, Net of Taxes	Charges Related to the Relocation of the Company's Headquarters	Share-Based Compensation Expense	Reported GAAP Diluted (Loss) Earnings
Q1 FY 2010	\$0.01	--	(\$0.09)	(\$0.03)	(\$0.11)
Q1 FY 2009	\$0.10	\$0.26	--	(\$0.05)	\$0.31

Revenues

- Total revenues for the quarter ended June 30, 2009, were \$47.5 million, compared to \$80.0 million for the same period in 2008.
- Total manufacturing revenues for the quarter ended June 30, 2009, were \$28.8 million, which included \$27.9 million related to RISPERDAL CONSTA, compared to \$38.6 million, which included \$36.0 million related to RISPERDAL CONSTA and \$2.6 million related to VIVITROL, for the same period in 2008.
- Royalty revenues for the quarter ended June 30, 2009, were \$8.7 million, based on RISPERDAL CONSTA sales of \$347.8 million, compared to \$8.6 million, based on RISPERDAL CONSTA sales of \$343.1 million for the same period in 2008.
- Net sales from VIVITROL recorded by Alkermes for the quarter ended June 30, 2009, were \$4.2 million, compared to net sales of \$4.1 million recorded by Cephalon, Inc. for the same period in 2008.
- Research and development (R&D) revenue under collaborative arrangements for the quarter ended June 30, 2009, was \$1.5 million, compared to \$31.4 million for the same period in 2008.
- Net collaborative profit for the quarter ended June 30, 2009, was \$4.3 million, compared to \$1.4 million for the same period in 2008.

Costs and Expenses

- Cost of goods manufactured and sold for the quarter ended June 30, 2009, was \$12.7 million, which included \$9.7 million related to RISPERDAL CONSTA and \$2.0 million related to VIVITROL, compared to \$14.3 million for the same period in 2008, of which \$10.8 million related to RISPERDAL CONSTA and \$3.5 million related to VIVITROL.
- R&D expenses for the quarter ended June 30, 2009, were \$25.6 million, which included \$8.0 million of charges associated with the planned relocation of the company's headquarters, primarily related to the accelerated depreciation of certain R&D-related assets. R&D expenses were \$22.3 million for the same period in 2008.
- Selling, general and administrative (SG&A) expenses for the quarter ended June 30, 2009, were \$19.3 million, compared to \$11.9 million for the same period in 2008.
- Share-based compensation expense (included in the expenses above) for the quarter ended June 30, 2009, was \$3.2 million, of which \$0.3 million related to cost of goods manufactured, \$0.8 million related to R&D expenses and \$2.1 million related to SG&A expenses. Share-based compensation expense for the same period in 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.
- Interest income for the quarter ended June 30, 2009, was \$1.6 million, compared to \$3.6 million for the same period in 2008. Interest expense for the quarter ended June 30, 2009, was \$1.7 million, compared to \$4.2 million for the same period in 2008.
- Income tax benefit for the quarter ended June 30, 2009, was \$0.1 million, compared to an income tax expense of \$1.0 million for the same period in 2008.

At June 30, 2009, Alkermes had cash and total investments of \$380.4 million, compared to \$404.5 million at March 31, 2009, and \$473.3 million at June 30, 2008. During the quarter, the company repurchased approximately 310,000 shares of common stock for \$2.5 million as part of an ongoing stock repurchase program and retired \$6.4 million of the non-recourse RISPERDAL CONSTA secured 7% Notes through a scheduled principal payment.

Conference Call

Alkermes will host a conference call at 4:30 p.m. ET on Thursday, August 6, 2009, to discuss these financial results and provide an update on the company. The conference call may be accessed by dialing 1-866-814-8482 for domestic callers and 1-703-639-1372 for international callers. The conference call ID number is 1383340. In addition, a replay of the conference call will be available from 7:30 p.m. ET on Thursday, August 6, 2009, through 5:00 p.m. ET on Thursday, August 13, 2009, 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 1383340.

About Alkermes

Alkermes, Inc. is a fully integrated biotechnology company committed to developing innovative medicines to improve patients' lives. Alkermes developed, manufactures and commercializes VIVITROL® for alcohol dependence and manufactures RISPERDAL® CONSTA® for schizophrenia and bipolar I disorder. 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 facilities in Massachusetts and a commercial manufacturing facility in 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; the successful manufacture and commercialization of VIVITROL and RISPERDAL CONSTA; continued revenue growth from RISPERDAL CONSTA; the superiority of exenatide once weekly over LANTUS in real-world use; and the successful continuation of development activities for the company's 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: whether the company will achieve the financial expectations provided; whether the company can continue to manufacture RISPERDAL CONSTA and VIVITROL on a commercial scale, economically or in sufficient quantities to supply the market; whether VIVITROL will be commercialized successfully by Alkermes in the U.S. or by

Cilag GmbH in Russia; whether RISPERDAL CONSTA will be commercialized effectively by its partner Janssen; whether the company and its partners are able to successfully and efficiently scale up and manufacture their product candidates; whether exenatide once weekly will be approved by the FDA and whether clinical trial results regarding superiority of exenatide once weekly will be predictive of real-world results; whether advancement of the company's partnered product candidates will be delayed due to actions or decisions by its partners with regard to development and regulatory strategy, timing and funding which are out of its control; the outcome of clinical and preclinical work the company and its partners are pursuing; 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 whether RISPERDAL CONSTA, VIVITROL, exenatide once weekly and the company's product candidates, in commercial use, may have unintended side effects, adverse reactions or incidents of misuse that could cause the FDA or other health authorities to require post-approval studies or require removal of its 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® and AIR® are registered trademarks of Alkermes, Inc. and RISPERDAL® CONSTA® is a registered trademark of Janssen-Cilag group of companies. LANTUS® is a registered trademark of Sanofi-aventis.

(tables follow)

Alkermes, Inc. and Subsidiaries

Selected Financial Information (Unaudited)

	Three Months Ended June 30, 2009	Three Months Ended June 30, 2008
Condensed Consolidated Statements of Operations		
(In thousands, except per share data)		
Revenues:		
Manufacturing revenues	\$ 28,804	\$ 38,610
Royalty revenues	8,701	8,581
Product sales, net	4,226	-
Research and development revenue under collaborative arrangements	1,450	31,450
Net collaborative profit	4,315	1,351
Total Revenues	47,496	79,992
Expenses:		
Cost of goods manufactured and sold	12,666	14,314
Research and development	25,586	22,261
Selling, general and administrative	19,268	11,926
Total Expenses	57,520	48,501
Operating (Loss) Income	(10,024)) 31,491
Other Expense, net:		
Interest income	1,561	3,616
Interest expense	(1,709)) (4,226)
Other expense, net	(63)) (164)
Total Other Expense, net	(211)) (774)
(Loss) Income Before Income Taxes	(10,235)) 30,717
(Benefit) Provision for Income Taxes	(70)) 1,030
Net (Loss) Income	\$ (10,165)) \$ 29,687
(Loss) Earnings per Common Share:		
Basic	\$ (0.11)) \$ 0.31
Diluted	\$ (0.11)) \$ 0.31
Weighted Average Number of Common Shares Outstanding (GAAP):		
Basic	94,883	95,361
Diluted	94,883	96,631
Pro Forma Reconciliation:		
Net (Loss) Income - GAAP	\$ (10,165)) \$ 29,687
Share-based compensation expense	3,230	4,495
Costs incurred related to the move of corporate headquarters	8,171	-
Income from Lilly related to termination of the AIR® Insulin program (net of income taxes)	-	(24,709)
Net Income - Pro Forma	\$ 1,236	\$ 9,473
Pro Forma Earnings per Common Share:		
Basic	\$ 0.01	\$ 0.10

Diluted	\$ 0.01	\$ 0.10
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Weighted Average Number of Common Shares Outstanding (Pro Forma):

Basic	94,883	95,361
Diluted	95,462	96,631

Condensed Consolidated Balance Sheets	June 30,	March 31,
(In thousands)	2009	2009
Cash, cash equivalents and total investments	\$ 380,419	\$ 404,482
Receivables	27,899	24,588
Inventory	20,528	20,297
Prepaid expenses and other current assets	5,403	7,500
Property, plant and equipment, net	97,520	106,461
Other assets	3,442	3,158
Total Assets	\$ 535,211	\$ 566,486
Non-recourse RISPERDAL CONSTA secured 7% notes - current	\$ 25,667	\$ 25,667
Other current liabilities	26,570	43,323
Non-recourse RISPERDAL CONSTA secured 7% notes - long-term	44,057	50,221
Deferred revenue - long-term	5,204	5,238
Other long-term liabilities	6,846	7,149
Total shareholders' equity	426,867	434,888
Total Liabilities and Shareholders' Equity	\$ 535,211	\$ 566,486

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, 2009, and the company's report on Form 10-Q for the three months ended June 30, 2009, which the company intends to file in August 2009.

Source: Alkermes, Inc.

Alkermes, Inc.

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