Alkermes Reports Second Quarter Fiscal 2010 Financial Results

November 5, 2009

— RISPERDAL® CONSTA® Shows Strong Operational Growth —

— Company Updates Financial Expectations for Fiscal 2010 —

CAMBRIDGE, Mass.--(BUSINESS WIRE)--Nov. 5, 2009-- Alkermes, Inc. (NASDAQ: ALKS) today reported financial results for its second quarter of fiscal 2010, which ended on September 30, 2009.

Financial highlights:

- Quarterly revenues of $48.2 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 $353 million, growing 9.9% on an operational basis year-over-year. U.S. sales growth for the quarter ended September 30, 2009, was 9.3% while sales outside the U.S. were up 10.2% operationally driven by increased share.
- GAAP net loss of $8.7 million and pro forma net income of $1.1 million.
- Strong financial position with cash and total investments of $369.5 million.

Other recent highlights:

- Positive data reported for two phase 1 studies of ALKS 33, an oral opioid modulator for the potential treatment of addiction and other central nervous system disorders.
- Phase 1 clinical study initiated for ALKS 37, an oral, peripherally-restricted opioid antagonist for the treatment of opioid-induced constipation.
- Richard Pops assumed the role of President and Chief Executive Officer of Alkermes while maintaining his role as Chairman of the Board.

“Our financial and operating results remain strong and serve as the foundation for our future. Our team is now focused on taking Alkermes to the next level of significant growth with initiatives throughout the company, including our traditional areas of innovation in new product development, as well as the business and strategy areas,” commented Richard Pops, Chief Executive Officer of Alkermes. “We very much look forward to executing on our plan and creating major value for our shareholders.”

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

- GAAP net loss of $8.7 million or a basic and diluted loss per share of $0.09, including $5.6 million of share-based compensation and severance expense and $4.1 million of charges associated with the planned relocation of the company’s headquarters. For the same period in 2008, GAAP net income was $1.7 million or a basic and diluted earnings per share of $0.02, including $3.8 million of share-based compensation expense.
- Pro forma net income was $1.1 million or a basic and diluted earnings per share of $0.01, compared to a pro forma net income of $5.5 million or a basic and diluted earnings per share of $0.06 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 diluted earnings per share and reported diluted (loss) earnings per share for the second quarters of fiscal 2010 and 2009 is provided in the following table:

	Pro Forma Diluted Earnings	Charges Related to the Relocation of the Company's Headquarters	Share-Based Compensation and Severance Expense	Reported GAAP Diluted (Loss) Earnings
Q2 FY 2010	$0.01	($0.04)	($0.06)	($0.09)

Q2 FY 2009	$0.06	$ --	($0.04	) $ 0.02

"We are pleased to report a solid quarter, which reflects the continued growth of RISPERDAL CONSTA in the marketplace, as well as the financial strength of our balance sheet," commented James Frates, Chief Financial Officer of Alkermes. "Looking forward, we continue to expect strong performance from RISPERDAL CONSTA, as well as progress throughout our pipeline. Now that we are more than halfway through our fiscal year, we are refining our financial guidance to better reflect our results year-to-date and expectations for the second half of the fiscal year."

Revenues

- Total revenues for the quarter ended September 30, 2009, were $48.2 million, compared to $47.3 million for the same period in 2008.
- Manufacturing revenues for the quarter ended September 30, 2009, were $32.8 million, compared to $33.0 million for the same period in 2008. Manufacturing revenues for the quarter ended September 30, 2009, included $31.9 million related to RISPERDAL CONSTA, compared to $30.7 million for RISPERDAL CONSTA and $2.3 million for VIVITROL® for the same period in 2008.
- Royalty revenues for the quarter ended September 30, 2009, were $8.8 million, based on RISPERDAL CONSTA sales of $352.6 million, compared to $8.4 million, based on RISPERDAL CONSTA sales of $337.5 million for the same period in 2008.
- Net sales from VIVITROL recorded by Alkermes for the quarter ended September 30, 2009, were $4.6 million, compared to net sales of $4.1 million recorded by Cephalon, Inc. (Cephalon) for the same period in 2008.
- Research and development (R&D) revenue under collaborative arrangements for the quarter ended September 30, 2009, was $1.2 million, compared to $5.3 million for the same period in 2008.
- Net collaborative profit for the quarter ended September 30, 2009, was $0.7 million, compared to $0.6 million for the same period in 2008, completing the recognition of the $11.0 million payment received from Cephalon to cover its share of VIVITROL losses.

Costs and Expenses

- Cost of goods manufactured and sold for the quarter ended September 30, 2009, was $15.1 million, which included $12.1 million related to RISPERDAL CONSTA and $2.6 million related to VIVITROL, compared to $12.1 million for the same period in 2008, of which $8.1 million related to RISPERDAL CONSTA and $4.0 million related to VIVITROL.
- R&D expenses for the quarter ended September 30, 2009, were $20.7 million, compared to $19.7 million for the same period in 2008.
- Selling, general and administrative (SG&A) expenses for the quarter ended September 30, 2009, were $20.6 million, compared to $11.7 million for the same period in 2008. SG&A expenses for the quarter ended September 30, 2009 included $1.4 million of severance and $0.9 million of share-based compensation expense related to the resignation of the former CEO.
- Share-based compensation expense (included in the expenses above) for the quarter ended September 30, 2009, was $4.2 million, of which $0.5 million related to cost of goods manufactured and sold, $0.9 million related to R&D expenses and $2.8 million related to SG&A expenses. Share-based compensation expense for the same period in 2008 was $3.8 million, of which $0.4 million related to cost of goods manufactured and sold, $1.3 million related to R&D expenses and $2.1 million related to SG&A expenses.
- Interest income for the quarter ended September 30, 2009, was $1.1 million, compared to $2.7 million for the same period in 2008. Interest expense for the quarter ended September 30, 2009, was $1.6 million, compared to $4.2 million for the same period in 2008.

At September 30, 2009, Alkermes had cash and total investments of $369.5 million, compared to $380.4 million at June 30, 2009. During the quarter, the company retired $6.4 million of the non-recourse RISPERDAL CONSTA secured 7% Notes through a scheduled principal payment.

Updated Financial Expectations for Fiscal 2010

Alkermes today updated its financial expectations for the fiscal year ending March 31, 2010. 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, 2009, as filed with the U.S. Securities and Exchange Commission.

- **Manufacturing Revenues:** The company is adjusting its expectation for manufacturing revenues to a range of $105 to $111 million, revised from an expectation of $116 to $122 million, due to changes in the purchase forecasts from Janssen. These revised expectations include manufacturing revenues related to RISPERDAL CONSTA in the range of $105 to $110 million, revised from an expectation of $115 to $120 million, and manufacturing revenue related to VIVITROL for the Russian market in the range of $0 to $1 million, revised from an expectation of $1 to $2 million.

- **Royalty Revenues:** The company expects royalty revenues from RISPERDAL CONSTA to remain in the range of $36 to $38 million.
- **Product Sales, Net:** The company is adjusting its expectation for net sales from VIVITROL to a range of $20 to $25 million, revised from an expectation of $23 to $28 million, due to lower than anticipated sales in the first half of fiscal 2010.
- **R&D Revenues:** The company expects R&D revenues to remain in the range of $2 to $4 million.
- **Net Collaborative Profit:** The company expects net collaborative profit to remain at $5 million, as the company has recognized all of the funds received from Cephalon to cover its share of VIVITROL losses.
- **Total Revenues:** The company is adjusting its expectation for total revenues for fiscal 2010 to a range of $168 to $183 million, revised from an expectation of $182 to $197 million.
- **Cost of Goods Manufactured and Sold:** The company is adjusting its expectation for cost of goods manufactured and sold to a range of $47 to $56 million, revised from an expectation of $50 to $60 million. This revised expectation includes cost of goods manufactured and sold related to RISPERDAL CONSTA in the range of $38 to $42 million, revised from an expectation of $40 to $44 million, and cost of goods manufactured and sold related to VIVITROL in the range of $9 to $14 million, revised from an expectation of $10 to $16 million.
- **R&D Expenses:** The company expects R&D expenses to remain in the range of $93 to $100 million.
- **SG&A Expenses:** The company is adjusting its expectation for SG&A expenses to a range of $73 to $79 million, revised from an expectation of $69 to $77 million, largely due to expenses related to severance.
- **Operating Loss:** The company is adjusting its expectation for operating loss to a range of $45 to $52 million, revised from an expectation of $30 to $40 million.
- **Other Income/Expense:** The company is adjusting its expectation for other income/expense to a net expense in the range of $0 to $3 million, revised from an expectation of $0.
- **Income Taxes:** The company continues to expect no income taxes payable.
- **GAAP Net Loss:** The company is adjusting its expectation for net loss to a range of $45 to $55 million, revised from an expectation of $30 to $40 million.
- **Cash Flow from Operations:** The company is adjusting its expectation for cash flow from operations to an outflow of $10 to $15 million, revised from an expectation of an inflow of $1 to $5 million.
- **SFAS 123R:** The company expects share-based compensation expense, included in the operating expenses above, to remain in the range of $10 to $15 million.
- **Relocation of Company's Headquarters:** The company expects the non-cash charges related to the relocation of its headquarters, included in the operating expenses above, to remain in the range of $18 to $23 million.

Conference Call

Alkermes will host a conference call at 4:30 p.m. ET on Thursday, November 5, 2009, to discuss these financial results and provide an update on the company. The conference call may be accessed by dialing 1 (888) 424-8151 for domestic callers and 1 (847) 585-4422 for international callers. The conference call ID number is 6332284. In addition, a replay of the conference call will be available from 7:30 p.m. ET on Thursday, November 5, 2009, through 5:00 p.m. ET on Thursday, November 12, 2009, and may be accessed by visiting Alkermes' website or by dialing 1 (888) 843-8996 for domestic callers and 1 (630) 652-3044 for international callers. The replay access code is 6332284.

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; 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 International 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® is a registered trademark of Alkermes, Inc. and RISPERDAL® CONSTA® is a registered trademark of Janssen-Cilag group of companies.

(tables follow)

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

Condensed Consolidated Statements of Operations **(In thousands, except per share data)**	Three Months Ended September 30, 2009	Three Months Ended September 30, 2008
Revenues:		
Manufacturing revenues	$ 32,835	$ 33,039
Royalty revenues	8,818	8,439
Product sales, net	4,643	-
Research and development revenue under collaborative arrangements	1,174	5,252
Net collaborative profit	687	581
Total Revenues	48,157	47,311
Expenses:		
Cost of goods manufactured and sold	15,092	12,071
Research and development	20,664	19,710
Selling, general and administrative	20,625	11,679
Total Expenses	56,381	43,460
Operating (Loss) Income	(8,224)	3,851
Other Expense, net:		
Interest income	1,088	2,693
Interest expense	(1,566)	(4,243)
Other expense, net	(67)	(666)
Total Other Expense, net	(545)	(2,216)
(Loss) Income Before Income Taxes	(8,769)	1,635
Income tax benefit	(60)	(63)
Net (Loss) Income	$ (8,709)	$ 1,698
(Loss) Earnings per Common Share:		
Basic	$ (0.09)	$ 0.02
Diluted	$ (0.09)	$ 0.02
Weighted Average Number of Common Shares Outstanding (GAAP):		
Basic	94,886	95,637
Diluted	94,886	97,356
Pro Forma Reconciliation:		
Net (Loss) Income - GAAP	$ (8,709)	$ 1,698
Share-based compensation expense	4,208	3,814
Costs incurred related to the move of corporate headquarters	4,149	-
Severance charges	1,406	-
Net Income - Pro Forma	$ 1,054	$ 5,512
Pro Forma Earnings per Common Share:		
Basic	$ 0.01	$ 0.06
Diluted	$ 0.01	$ 0.06
Weighted Average Number of Common Shares Outstanding (Pro Forma):		
Basic	94,886	95,637
Diluted	95,969	97,356

Condensed Consolidated Balance Sheets **(In thousands)**	September 30, 2009	March 31, 2009
Cash, cash equivalents and total investments	$ 369,525	$ 404,482

Receivables	33,699	24,588
Inventory	18,524	20,297
Prepaid expenses and other current assets	7,856	7,500
Property, plant and equipment, net	94,467	106,461
Other assets	3,206	3,158
Total Assets	$ 527,277	$ 566,486
Non-recourse RISPERDAL CONSTA secured 7% Notes - current	$ 25,667	$ 25,667
Other current liabilities	30,152	43,323
Non-recourse RISPERDAL CONSTA secured 7% Notes - long-term	37,862	50,221
Deferred revenue - long-term	5,115	5,238
Other long-term liabilities	6,450	7,149
Total shareholders' equity	422,031	434,888
Total Liabilities and Shareholders' Equity	$ 527,277	$ 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 September 30, 2009, which the company intends to file in November 2009.

Source: Alkermes, Inc.

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