Alkermes Reports Financial Results for Fiscal 2010 and Provides Financial Expectations for Fiscal 2011

May 13, 2010

-- Reports Record RISPERDAL® CONSTA® Revenue in Fiscal 2010 --
-- Strong Financial Position Enables Rapid Pipeline Expansion --

WALTHAM, Mass., May 13, 2010 (BUSINESS WIRE) --Alkermes, Inc. (NASDAQ: ALKS) today reported financial results for its fiscal year ended March 31, 2010, and provided financial expectations for fiscal 2011.

Financial highlights:

- Total revenues of $178.3 million for fiscal 2010.
- Record manufacturing and royalty revenues from RISPERDAL® CONSTA® of $146.0 million. Worldwide sales of RISPERDAL CONSTA by Janssen, Division of Ortho-McNeil-Janssen Pharmaceuticals, Inc. and Janssen-Cilag (Janssen) were approximately $1.5 billion in fiscal 2010, an 11.5 percent increase over sales of RISPERDAL CONSTA in fiscal 2009.
- Strong financial position, with cash and investments of $350.2 million.
- Significant recurring revenues from RISPERDAL CONSTA and strong cash balance enabled company to introduce two new proprietary technology platforms and advance six pipeline candidates.

Other recent highlights:

- Received U.S. Food and Drug Administration (FDA) classification of the BYDUREON(TM) (exenatide for extended-release injectable suspension) complete response as a Class 2 resubmission and designation of a new Prescription Drug User Fee Act (PDUFA) action date of October 22, 2010.
- Disclosed BYDUREON royalty rate of 8% of net sales from the first 40 million units of BYDUREON sold in a particular calendar year and 5.5% of net sales from units sold beyond the first 40 million for that year. Alkermes will also receive a $7 million milestone payment upon the first commercial sale of BYDUREON in the U.S. and an additional $7 million milestone upon the first commercial sale in Europe.
- Announced submission of Marketing Authorization Application to European Medicines Agency for BYDUREON.
- Unveiled proprietary long-acting olanzapine candidate, ALKS 7921, a once-monthly, injectable, extended-release version of olanzapine for the treatment of schizophrenia.
- Initiated phase 2 study of ALKS 37, an orally active, peripherally-restricted opioid antagonist with potential to block the effects of opioid agonists on gastrointestinal motility, for the treatment of opioid-induced constipation.
- Expanded development of ALKS 33, an oral opioid modulator, for the treatment of binge eating disorder and as a combination therapy with buprenorphine for the treatment of addiction and mood disorders. Alkermes is also testing ALKS 33 in a phase 2 study in alcohol dependent patients.
- Submitted a supplemental New Drug Application (sNDA) for VIVITROL® for the treatment of opioid dependence.

"We enter fiscal 2011 in a strong position, with RISPERDAL CONSTA sales continuing to provide a solid financial foundation and the potential for two new product approvals, BYDUREON for type 2 diabetes and VIVITROL for opioid dependence, in the coming months," commented Richard Pops, Chief Executive Officer of Alkermes. "Fiscal 2011 will be a transformational year for Alkermes as we continue to leverage our proprietary product platforms to advance and expand our pipeline."

Key operating results for fiscal 2010 include the following:

- GAAP net loss of $39.6 million or a basic and diluted loss per share of $0.42, including $15.3 million of share-based compensation and severance expense and $18.9 million of charges associated with the relocation of the company's headquarters. For the same period in 2009, GAAP net income was $130.5 million or a basic earnings per share of $1.37 and diluted earnings per share of $1.36, driven by significant one-time items, including $145.3 million of net income related to the company's previous agreements with Cephalon, Inc. (Cephalon) and Eli Lilly & Company (Lilly). Fiscal 2009 also included $14.8 million of share-based compensation expense.
- Pro forma net loss of $5.4 million or a basic and diluted loss per share of $0.06, compared to a pro forma net income of $0.0 million or a basic and diluted income per share of $0.00 for fiscal 2009.

Alkermes is providing pro forma results as a complement to reported GAAP results. The pro forma measures exclude certain non-cash or non-recurring 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 fiscal 2010 and fiscal 2009 is provided in the following table:

	Pro Forma Diluted (Loss) Earnings	Charges Related to the Relocation of the Company's Headquarters	Impact of the Termination of the Collaborative Agreements with Cephalon and Lilly	Share-Based Compensation and Severance Expense	Reported GAAP Diluted (Loss) Earnings
FY 2010	($0.06)	($0.20)	-	($0.16)	($0.42)
FY 2009	$0.00	-	$1.51	($0.15)	$1.36

Revenues

- Total revenues for fiscal 2010 were $178.3 million. This compares to $181.4 million in fiscal 2009, excluding $145.4 million of significant one-time revenues from Cephalon and Lilly.
- Total manufacturing revenues for fiscal 2010 were $112.9 million, consisting of $109.0 million for RISPERDAL CONSTA, $3.4 million related to the manufacture of polymer for BYDUREON and $0.5 million for VIVITROL. Total manufacturing revenues for fiscal 2009 were $116.8 million, consisting of $112.4 million for RISPERDAL CONSTA and $4.4 million for VIVITROL.
- Royalty revenues for fiscal 2010 were $37.0 million, of which $36.9 million related to RISPERDAL CONSTA, based on net sales of approximately $1.5 billion, compared to $33.2 million in fiscal 2009, of which $33.1 million related to RISPERDAL CONSTA, based on net sales of approximately $1.3 billion.
- Net sales from VIVITROL were $20.2 million for fiscal 2010, compared to $4.5 million for fiscal 2009. Alkermes started to record net sales effective December 1, 2008. On a comparable basis, net sales for full fiscal 2009 were $16.9 million for Alkermes and Cephalon.
- Research and development (R&D) revenue under collaborative arrangements for fiscal 2010 was $3.1 million, compared to $42.1 million in fiscal 2009.
- Net collaborative profit for fiscal 2010 was $5.0 million, compared to $130.2 million for fiscal 2009. Fiscal 2009 net collaborative profit included the recognition of $120.7 million of milestone and deferred revenue upon termination of the company's previous agreements with Cephalon.

Costs and Expenses

- Cost of goods manufactured for fiscal 2010 was $49.4 million, of which $40.2 million related to RISPERDAL CONSTA, $6.9 million related to VIVITROL and $2.3 million related to polymer for BYDUREON, compared to $43.4 million for fiscal 2009, of which $31.4 million related to RISPERDAL CONSTA, $11.8 million related to VIVITROL and $0.2 million related to polymer for BYDUREON.
- R&D expenses for fiscal 2010 were $95.4 million, compared to $89.5 million for fiscal 2009. Fiscal 2010 R&D expenses included $18.7 million of charges related to the relocation of the company's headquarters.
- Selling, general and administrative (SG&A) expenses for fiscal 2010 were $76.5 million, compared to $59.0 million for fiscal 2009.
- Share-based compensation expense (included in the expenses above) for fiscal 2010 was $13.9 million, of which $1.5 million related to cost of goods manufactured, $3.5 million related to R&D expenses and $8.9 million related to SG&A expenses. Share-based compensation expense for fiscal 2009 was $14.8 million, of which $1.4 million related to cost of goods manufactured, $4.4 million related to R&D expenses and $9.0 million related to SG&A expenses.
- Interest income for fiscal 2010 was $4.7 million, compared to $11.4 million for fiscal 2009. Interest expense for fiscal 2010 was $6.0 million, compared to $13.8 million for fiscal 2009.
- Income tax benefit for fiscal 2010 was $5.1 million, compared to an income tax expense of $0.5 million for fiscal 2009.

At March 31, 2010, Alkermes had cash and investments of $350.2 million, compared to $357.5 million at December 31, 2009, and $404.5 million at March 31, 2009. During the fiscal year, Alkermes made principal and interest payments in the amount of $30.6 million related to its non-recourse RISPERDAL CONSTA secured 7% notes. The company has provided notice that it plans to redeem the remaining notes in full on July 1, 2010, at a cost of approximately $46.4 million.

Financial Expectations for Fiscal 2011

The following outlines Alkermes' financial expectations for the fiscal year ending March 31, 2011. These financial expectations are highly dependent on the timing of regulatory approvals of BYDUREON for type 2 diabetes and VIVITROL for opioid dependence and also include 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.

- **Revenues:** The company expects total revenues for fiscal 2011 to range from $170 to $195 million.
- The company expects total manufacturing revenues to range from $103 to $115 million. The expected manufacturing revenues for RISPERDAL CONSTA range from $100 to $110 million and are based on a purchase forecast from Janssen and assume no significant changes in exchange rates. The expected manufacturing revenues from polymer for BYDUREON range from $3 to $5 million and are based on a purchase forecast from Amylin Pharmaceuticals, Inc. (Amylin). Both Janssen and Amylin have the right to change the timing and amount of their purchases. Alkermes' revenue estimates are also dependent upon its ability to manufacture sufficient quantities of RISPERDAL CONSTA and polymer for BYDUREON to meet its partners' estimates.
- The company expects total royalty revenues to range from $35 to $42 million. The expected royalty revenues from RISPERDAL CONSTA range from $35 to $37 million. The company expects royalty revenues from BYDUREON to range from $0 to $5 million. RISPERDAL CONSTA and BYDUREON sales are dependent on the company's partners. These expectations assume no significant changes in exchange rates.
- The company expects net product sales from VIVITROL to range from $25 to $30 million.
- The company expects R&D revenues to range from $7 to $8 million. This expectation includes a $7 million milestone receivable from Amylin upon first commercial sale of BYDUREON in the U.S.
- **Cost of Goods Manufactured:** The company expects total cost of goods manufactured to range from $47 to $60 million. The expected cost of goods manufactured related to RISPERDAL CONSTA range from $39 to $46 million. The expected cost of goods manufactured related to VIVITROL range from $6 to $10 million. The expected cost of goods manufactured related to polymer for BYDUREON range from $2 to $4 million. These cost estimates are based on expected sales by Alkermes in the U.S., projected orders from Janssen and Amylin and the company's historical manufacturing yields. Margins on RISPERDAL CONSTA, VIVITROL and polymer for BYDUREON are dependent on many factors and may fluctuate. Orders from Janssen and Amylin are subject to change at any time.
- **R&D Expenses:** The company expects R&D expenses to range from $90 to $105 million to support the company's continuing efforts to advance its product candidates toward commercialization.
- **SG&A Expenses:** The company expects SG&A expenses to range from $78 to $85 million. These expectations include the company's continuing efforts to commercialize VIVITROL.
- **Operating Loss:** The company expects operating loss to range from $45 to $55 million.
- **Net Interest and Income Taxes:** The company expects interest income and interest expense to offset each other, and does not expect to incur any income taxes in fiscal 2011.
- **Net Loss:** The company expects net loss to range from $45 to $55 million, or a basic and diluted loss per share of approximately $0.47 to $0.58 per share. The basic loss per share is based on the current basic share count of 95 million shares outstanding.
- **SFAS 123R:** The company has included share-based compensation expense in the expense expectations provided. The company expects to recognize this expense within cost of goods manufactured, R&D expenses and SG&A expenses in the approximate ratio of 10 percent, 30 percent and 60 percent, respectively. Based on the company's expectations with respect to fiscal 2011 stock grants and the estimates used to value such grants, the company expects share-based compensation expense to be in the range of $15 to $20 million or $0.16 to $0.21 per share for fiscal 2011.
- **Cash Flow from Operations:** The company expects net cash outflow from operations to range from $25 to $35 million in fiscal 2011.

Conference Call

Alkermes will host a conference call at 4:30 p.m. ET on Thursday, May 13, 2010, 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, May 13, 2010, through 5:00 p.m. ET on Thursday, May 20, 2010, 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 and oral products for the treatment of prevalent, chronic diseases, such as central nervous system disorders, addiction and diabetes. Headquartered in Waltham, Massachusetts, Alkermes has a research facility 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 redemption of our non-recourse RISPERDAL CONSTA secured 7% notes; the successful manufacture and commercialization of VIVITROL and RISPERDAL CONSTA; continued revenue growth from RISPERDAL CONSTA and VIVITROL; the regulatory approval of BYDUREON and VIVITROL for opioid dependence by the FDA; the pace at which we are able to develop our pipeline products; 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 and the CIS; 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 BYDUREON and VIVITROL for opioid dependence will be approved by the FDA; whether BYDUREON and VIVITROL for opioid dependence, if approved by the FDA, will be commercialized successfully; 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 and partners' product candidates; potential changes in cost, scope and duration of clinical trials; and whether RISPERDAL CONSTA, VIVITROL, BYDUREON and the company's other 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.

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

Condensed Consolidated Statements of Operations **(In thousands, except per share data)**	Year Ended March 31, 2010	Year Ended March 31, 2009
Revenues:		
Manufacturing revenues	$ 112,938	$ 116,844
Royalty revenues	36,979	33,247
Product sales, net	20,245	4,467
Research and development revenue under collaborative arrangements	3,117	42,087
Net collaborative profit	5,002	130,194
Total Revenues	178,281	326,839
Expenses:		
Cost of goods manufactured and sold	49,438	43,396
Research and development	95,363	89,478
Selling, general and administrative	76,514	59,008
Total Expenses	221,315	191,882
Operating (Loss) Income	(43,034)	134,957
Other Expense, net:		
Interest income	4,667	11,400
Interest expense	(5,974)	(13,756)
Other expense, net	(360)	(1,589)
Total Other Expense, net	(1,667)	(3,945)
(Loss) Income Before Income Taxes	(44,701)	131,012
Income Tax (Benefit) Provision	(5,075)	507
Net (Loss) Income	$ (39,626)	$ 130,505
(Loss) Earnings per Common Share:		
Basic	$ (0.42)	$ 1.37
Diluted	$ (0.42)	$ 1.36
Weighted Average Number of Common Shares Outstanding (GAAP):		
Basic	94,839	95,161
Diluted	94,839	96,252
Pro Forma Reconciliation:		
Net (Loss) Income - GAAP	$ (39,626)	$ 130,505
Share-based compensation and severance expense	15,327	14,810
Costs incurred related to the relocation of the company's corporate headquarters	18,949	-
Impact of the termination of the collaboration agreements with Cephalon, Inc. for VIVITROL	-	(120,582)
Income from Lilly related to termination of the AIR® Insulin program (net of income taxes)	-	(24,709)
Net (Loss) Income - Pro Forma	$ (5,350)	$ 24
Pro Forma (Loss) Earnings per Common Share:		
Basic	$ (0.06)	$ 0.00
Diluted	$ (0.06)	$ 0.00
Weighted Average Number of Common Shares Outstanding (Pro Forma):		

Basic	94,839	95,161
Diluted	94,839	96,252

Condensed Consolidated Balance Sheets	March 31,	March 31,
(In thousands)	2010	2009
Cash, cash equivalents and total investments	$ 350,193	$ 404,482
Receivables	25,316	24,588
Inventory	20,653	20,297
Prepaid expenses and other current assets	10,936	7,500
Property, plant and equipment, net	96,905	106,461
Other assets	11,597	3,158
Total Assets	$ 515,600	$ 566,486
Non-recourse RISPERDAL CONSTA secured 7% notes - current	$ 51,043	$ 25,667
Other current liabilities	40,101	43,323
Non-recourse RISPERDAL CONSTA secured 7% notes - long-term	-	50,221
Deferred revenue - long-term	5,105	5,238
Other long-term liabilities	6,735	7,149
Total shareholders' equity	412,616	434,888
Total Liabilities and Shareholders' Equity	$ 515,600	$ 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, 2010, which the company intends to file in May 2010.

Alkermes Inc. and Subsidiaries

Quarterly Financial Data (Unaudited)

	Three Months Ended				**Year Ended**
	June 30, 2009	**September 30, 2009**	**December 31, 2009**	**March 31, 2010**	**March 31, 2010**
(In thousands, except per share data)					
Revenues:					
Manufacturing revenues	$ 28,804	$ 32,835	$ 28,650	$ 22,649	$ 112,938
Royalty revenues	8,701	8,818	9,970	9,490	36,979
Product sales, net	4,226	4,643	5,451	5,925	20,245
Research and development revenue under collaborative arrangements	1,450	1,174	81	412	3,117
Net collaborative profit	4,315	687	-	-	5,002
Total Revenues	47,496	48,157	44,152	38,476	178,281
Expenses:					
Cost of goods manufactured and sold	12,666	15,092	10,072	11,608	49,438
Research and development	25,586	20,664	22,577	26,536	95,363
Selling, general and administrative	19,268	20,625	17,739	18,882	76,514
Total Expenses	57,520	56,381	50,388	57,026	221,315
Operating Loss	(10,024)	(8,224)	(6,236)	(18,550)	(43,034)
Total Other Expense, net	(211)	(545)	(566)	(345)	(1,667)
Loss Before Income Taxes	(10,235)	(8,769)	(6,802)	(18,895)	(44,701)
Income Tax (Benefit) Provision	(70)	(60)	15	(4,960)	(5,075)
Net Loss	$ (10,165)	$ (8,709)	$ (6,817)	$ (13,935)	$ (39,626)
Loss Per Common Share:					
Basic and diluted	$ (0.11)	$ (0.09)	$ (0.07)	$ (0.15)	$ (0.42)
Weighted Average Number of Common Shares Outstanding:					
Basic and diluted	94,883	94,886	94,784	94,915	94,839

SOURCE: Alkermes, Inc.

Alkermes
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