Alkermes Reports First Quarter Fiscal 2011 Financial Results

August 5, 2010

-- Company Preparing for FDA Action in October on VIVITROL® and BYDUREON(TM) --
-- Financial Strength Enables Early Redemption of All Outstanding Debt --

WALTHAM, Mass., Aug 05, 2010 (BUSINESS WIRE) --Alkermes, Inc. (NASDAQ: ALKS) today reported financial results for its first quarter of fiscal 2011, which ended on June 30, 2010.

Financial highlights:

- Quarterly revenues of $42.3 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 $356 million, an increase of 3.4 percent on an operational basis year-over-year, and are based on product sales in more than 70 countries.
- GAAP net loss of $13.4 million and pro forma net loss of $9.0 million.
- Strong financial position, with cash and total investments of $328.5 million, prior to redemption of all remaining non-recourse RISPERDAL CONSTA secured 7% Notes on July 1, 2010, at a total cost of approximately $46.4 million.

Additional highlights:

- Company preparing for upcoming October 12, 2010, Prescription Drug User Fee Act (PDUFA) date for VIVITROL® for opioid dependence and October 22, 2010, PDUFA date for BYDUREON(TM) for type 2 diabetes.
- Presented positive data from the pivotal phase 3 study of VIVITROL for the treatment of opioid dependence at the 2010 American Psychiatric Association Annual Meeting in New Orleans, Louisiana.
- Announced results from a pooled analysis of safety data from three completed randomized controlled trials showing that BYDUREON was generally well-tolerated with a low discontinuation rate due to serious adverse events similar to comparators in patients with type 2 diabetes. The data were presented at the 70th Annual Scientific Sessions of the American Diabetes Association in Orlando, Florida.
- Reported positive data from the head-to-head DURATION-4 study comparing BYDUREON to once-daily therapies ACTOS® (pioglitazone HCl), JANUVIA® (sitagliptin) and metformin in patients with type 2 diabetes.
- The company announced that the U.S. Food and Drug Administration (FDA) granted priority review for the VIVITROL supplemental New Drug Application (sNDA) for opioid dependence.
- The FDA notified the company of the scheduling of a Psychopharmacologic Drugs Advisory Committee meeting on September 16, 2010, for the review of the company's sNDA submission for VIVITROL for opioid dependence.

"We reported another solid quarter as we prepare for our next growth phase with near-term opportunities to add additional sources of revenue," commented James Frates, Chief Financial Officer of Alkermes. "By the end of calendar 2010, we anticipate several important milestones, including FDA action on both BYDUREON for the treatment of type 2 diabetes and VIVITROL for the treatment of opioid dependence, as well as an interim analysis from the phase 2 study of ALKS 33 for the treatment of alcohol dependence."

Key operating results for the quarter ended June 30, 2010, include the following:

- GAAP net loss was $13.4 million or a basic and diluted loss per share of $0.14, including $4.5 million in share-based compensation expense. For the same period in 2009, 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.
- Pro forma net loss was $9.0 million or a basic and diluted loss per share of $0.09, compared to a pro forma net income of $1.2 million or a basic and diluted earnings per share of $0.01 for the same period in 2009.

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 2011 and 2010 is provided in the following table:

Pro Forma Diluted (Loss) Earnings	Charges Related to the Relocation of the Company's	Share-Based Compensation Expense	Reported GAAP Diluted (Loss)

		Headquarters		
Q1 FY 2011	($0.09)	$--	($0.05)	($0.14)
Q1 FY 2010	$0.01	($0.09)	($0.03)	($0.11)

Revenues

- Total revenues for the quarter ended June 30, 2010, were $42.3 million, compared to $47.5 million for the same period in 2009.
- Total manufacturing revenues for the quarter ended June 30, 2010, were $26.9 million, which included $26.3 million related to RISPERDAL CONSTA and $0.6 million related to polymer for BYDUREON, compared to $28.8 million, which included $27.9 million related to RISPERDAL CONSTA and $0.9 million related to polymer for BYDUREON, for the same period in 2009.
- Royalty revenues for the quarter ended June 30, 2010, were $8.9 million, based on RISPERDAL CONSTA sales of $355.7 million, compared to $8.7 million, based on RISPERDAL CONSTA sales of $347.8 million, for the same period in 2009.
- Net sales of VIVITROL for the quarter ended June 30, 2010, were $6.2 million, compared to net sales of $4.2 million for the same period in 2009.
- Research and development (R&D) revenue under collaborative arrangements for the quarter ended June 30, 2010, was $0.3 million, compared to $1.5 million for the same period in 2009.
- The company no longer records net collaborative profit. Net collaborative profit for the quarter ended June 30, 2009, was $4.3 million.

Costs and Expenses

- Cost of goods manufactured and sold for the quarter ended June 30, 2010, was $12.7 million, which included $10.4 million related to RISPERDAL CONSTA, $1.7 million related to VIVITROL and $0.6 million related to polymer for BYDUREON, compared to $12.7 million for the same period in 2009, of which $9.7 million related to RISPERDAL CONSTA, $2.0 million related to VIVITROL and $1.0 million related to polymer for BYDUREON.
- R&D expenses for the quarter ended June 30, 2010, were $23.0 million. R&D expenses were $25.6 million for the same period in 2009, which included $8.0 million of charges associated with the relocation of the company's headquarters, primarily related to the accelerated depreciation of certain R&D-related assets.
- Selling, general and administrative (SG&A) expenses for the quarter ended June 30, 2010, were $19.7 million, compared to $19.3 million for the same period in 2009.
- Share-based compensation expense (included in the operating expenses above) for the quarter ended June 30, 2010, was $4.5 million, of which $0.4 million related to cost of goods manufactured, $1.5 million related to R&D expenses and $2.6 million related to SG&A expenses. Share-based compensation expense for the same period in 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.
- Interest income for the quarter ended June 30, 2010, was $0.9 million, compared to $1.6 million for the same period in 2009. Interest expense for the quarter ended June 30, 2010, was $1.1 million, compared to $1.7 million for the same period in 2009.
- Income tax benefit for both the quarter ended June 30, 2010, and the quarter ended June 30, 2009, was $0.1 million.

At June 30, 2010, Alkermes had cash and total investments of $328.5 million, compared to $350.2 million at March 31, 2010. During the quarter, the company retired $6.4 million of the non-recourse RISPERDAL CONSTA secured 7% Notes through a scheduled principal payment. The company redeemed the remaining 7% Notes in full on July 1, 2010, at a total cost of approximately $46.4 million.

Conference Call

Alkermes will host a conference call at 4:30 p.m. ET on Thursday, August 5, 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 6037988. In addition, a replay of the conference call will be available from 7:30 p.m. ET on Thursday, August 5, 2010, through 5:00 p.m. ET on Thursday, August 12, 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 6037988.

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 financial, business and operating results; the successful manufacture and commercialization of VIVITROL and RISPERDAL CONSTA; continued revenue growth from RISPERDAL CONSTA; the occurrence of an advisory committee meeting for the review of the VIVITROL sNDA; the timeline for FDA review and regulatory action relating to the sNDA submission for VIVITROL for the treatment of opioid dependence and the NDA for BYDUREON for the treatment of type 2 diabetes; and the successful continuation of development activities for

the company's programs, including ALKS 33 for the treatment of alcohol dependence. 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. 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 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 for the treatment of alcohol dependence; whether RISPERDAL CONSTA will be commercialized effectively by its partner Janssen; whether the company is able to successfully and efficiently scale up and manufacture its product candidates; whether the advisory committee will recommend approving VIVITROL for the treatment of opioid dependence; whether clinical trial results for BYDUREON and VIVITROL for the treatment of opioid dependence 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, BYDUREON 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.

Alkermes, Inc. and Subsidiaries

Selected Financial Information (Unaudited)

Condensed Consolidated Statements of Operations **(In thousands, except per share data)**	Three Months Ended June 30, 2010	Three Months Ended June 30, 2009
Revenues:		
Manufacturing revenues	$ 26,891	$ 28,804
Royalty revenues	8,917	8,701
Product sales, net	6,204	4,226
Research and development revenue under collaborative arrangements	268	1,450
Net collaborative profit	-	4,315
Total Revenues	42,280	47,496
Expenses:		
Cost of goods manufactured and sold	12,665	12,666
Research and development	22,977	25,586
Selling, general and administrative	19,726	19,268
Total Expenses	55,368	57,520
Operating Loss	(13,088)	(10,024)
Other Expense, net:		
Interest income	852	1,561
Interest expense	(1,130)	(1,709)
Other expense, net	(101)	(63)
Total Other Expense, net	(379)	(211)
Loss Before Income Taxes	(13,467)	(10,235)
Income Tax Benefit	(58)	(70)
Net Loss	$ (13,409)	$ (10,165)
Loss per Common Share:		
Basic and Diluted	$ (0.14)	$ (0.11)
Weighted Average Number of Common Shares Outstanding (GAAP):		
Basic and Diluted	95,326	94,883
Pro Forma Reconciliation:		
Net Loss - GAAP	$ (13,409)	$ (10,165)
Share-based compensation	4,456	3,230
Costs incurred related to the relocation of the company's corporate headquarters	-	8,171
Net (Loss) Income - Pro Forma	$ (8,953)	$ 1,236
Pro Forma (Loss) Earnings per Common Share:		
Basic	$ (0.09)	$ 0.01
Diluted	$ (0.09)	$ 0.01

Weighted Average Number of Common Shares Outstanding (Pro Forma):		
Basic	95,326	94,883
Diluted	95,326	95,462

Condensed Consolidated Balance Sheets	June 30,	March 31,
(In thousands)	2010	2010
Cash, cash equivalents and total investments	$ 328,523	$ 350,193
Receivables	24,266	25,316
Inventory	20,472	20,653
Prepaid expenses and other current assets	10,501	10,936
Property, plant and equipment, net	97,896	96,905
Other assets	10,083	11,597
Total Assets	$ 491,741	$ 515,600
Non-recourse RISPERDAL CONSTA secured 7% notes - current	$ 44,750	$ 51,043
Other current liabilities	31,173	40,101
Deferred revenue - long-term	5,054	5,105
Other long-term liabilities	7,214	6,735
Total shareholders' equity	403,550	412,616
Total Liabilities and Shareholders' Equity	$ 491,741	$ 515,600

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, and the company's report on Form 10-Q for the three months ended June 30, 2010, which the company intends to file in August 2010.

SOURCE: Alkermes, Inc.

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