Alkermes Reports Third Quarter Fiscal 2011 Financial Results

February 3, 2011

-- Company Increases RISPERDAL® CONSTA® Revenue Guidance and Improves Overall Financial Expectations for Fiscal 2011 --
-- Multiple Milestones Expected for First Half of Calendar 2011 --

WALTHAM, Mass., Feb 03, 2011 (BUSINESS WIRE) -- Alkermes, Inc. (NASDAQ: ALKS) today reported financial results for its third quarter of fiscal year 2011, which ended on December 31, 2010.

Quarterly financial highlights:

- Revenues of $44.0 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 $388 million. For the calendar year ended December 31, 2010, worldwide sales of RISPERDAL CONSTA were $1.5 billion.
- GAAP net loss of $11.4 million and pro forma net loss of $5.6 million.
- Positive cash flow from operations of $12.9 million.
- Strong financial position, with cash and total investments of $285.0 million as of December 31, 2010.

Additional highlights:

- Alkermes' collaborative partner, Amylin Pharmaceuticals, Inc. (Amylin), announced that the U.S. Food and Drug Administration (FDA) provided written approval of the study design for a thorough QT (tQT) study for BYDUREON(TM). With the approval of the study design, Amylin intends to commence the study in February 2011 and plans to submit the results of this study to the FDA in the second half of calendar 2011.
- Expanded ALKS 33 clinical program into treatment-resistant depression (TRD). Phase 1/2 study to commence in the second half of calendar 2011.
- Announced positive interim phase 4 data for VIVITROL® in the treatment of healthcare professionals with opioid dependence.
- Reported results from a phase 2 study of ALKS 33, a novel oral opioid modulator, for alcohol dependence. The safety, dose response and efficacy profile demonstrated in the study support the unique pharmacologic properties of ALKS 33 and the further study of ALKS 33 for reward disorders and other central nervous system disorders.
- Presented promising preclinical data on ALKS 33 for multiple disease indications at the Annual Meeting of the Society for Neuroscience.

"We are pleased to raise guidance as we enter the last quarter of our fiscal year, based on strong worldwide demand for RISPERDAL CONSTA as well as our own disciplined financial management. Looking forward, we believe that VIVITROL in the new opioid dependence indication and upcoming approvals of BYDUREON for the treatment of type 2 diabetes will provide Alkermes with meaningful revenue streams," commented James Frates, Chief Financial Officer of Alkermes. "We are also looking forward to results from three clinical programs in the months ahead that will validate the potential of the candidates we are pursuing."

Key operating results for the quarter ended December 31, 2010, include the following:

- GAAP net loss was $11.4 million, or a basic and diluted loss per share of $0.12, including $5.8 million in share-based compensation expense. For the same period in 2009, GAAP net loss was $6.8 million, or a basic and diluted loss per share of $0.07, including $3.4 million in share-based compensation expense and $3.6 million in charges associated with the relocation of the company's headquarters.
- Pro forma net loss was $5.6 million, or a basic and diluted loss per share of $0.06, compared to a pro forma net income of $0.1 million, or a basic and diluted earnings per share of $0.00 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 diluted (loss) earnings and reported diluted (loss) per share for the third quarters of fiscal years 2011 and 2010 is provided in the following table:

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

Q3 FY 2011	($0.06)	$--	($0.06)	($0.12)
Q3 FY 2010	$0.00	($0.04)	($0.04)	($0.07)

Note: Amounts do not sum due to rounding.

Revenues

- Total revenues for the quarter ended December 31, 2010, were $44.0 million, compared to $44.2 million for the same period in 2009.
- Total manufacturing revenues for the quarter ended December 31, 2010, were $26.2 million, which included $25.5 million related to RISPERDAL CONSTA, $0.6 million related to the sale of polymer for BYDUREON and $0.1 million related to VIVITROL sold in the Russian market, compared to $28.7 million, which included $27.2 million related to RISPERDAL CONSTA and $1.5 million related to the sale of polymer for BYDUREON, for the same period in 2009.
- Royalty revenues for the quarter ended December 31, 2010, were $9.8 million, primarily based on RISPERDAL CONSTA sales of $387.8 million, compared to $10.0 million, based on RISPERDAL CONSTA sales of $398.7 million, for the same period in 2009.
- Net sales of VIVITROL for the quarter ended December 31, 2010, were $7.7 million, compared to net sales of $5.5 million for the same period in 2009.
- Research and development (R&D) revenue under collaborative arrangements for the quarter ended December 31, 2010, was $0.3 million, compared to $0.1 million for the same period in 2009.

Costs and Expenses

- Cost of goods manufactured and sold for the quarter ended December 31, 2010, was $12.9 million, which included $9.5 million related to RISPERDAL CONSTA, $2.4 million related to VIVITROL and $1.0 million related to the manufacture of polymer for BYDUREON, compared to $10.1 million for the same period in 2009, of which $8.4 million related to RISPERDAL CONSTA, $1.1 million related to VIVITROL and $0.6 million related to the manufacture of polymer for BYDUREON.
- R&D expenses for the quarter ended December 31, 2010, were $22.5 million. R&D expenses were $22.6 million for the same period in 2009, which included $3.5 million in 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 December 31, 2010, were $20.5 million, compared to $17.7 million for the same period in 2009.
- Share-based compensation expense (included in the operating expenses above) for the quarter ended December 31, 2010, was $5.8 million, of which $0.4 million related to cost of goods manufactured, $1.6 million related to R&D expenses and $3.8 million related to SG&A expenses. Share-based compensation expense for the same period in 2009 was $3.4 million, of which $0.4 million related to cost of goods manufactured, $0.8 million related to R&D expenses and $2.2 million related to SG&A expenses.
- Interest income for the quarter ended December 31, 2010, was $0.6 million, compared to $1.0 million for the same period in 2009. Interest expense for the quarter ended December 31, 2010, was $0, compared to interest expense of $1.4 million for the same period in 2009, following the redemption in full of the non-recourse RISPERDAL CONSTA secured 7% Notes.

At December 31, 2010, Alkermes had cash and total investments of $285.0 million, compared to $273.6 million at September 30, 2010, and $328.5 million at June 30, 2010.

Adjusted Financial Expectations for Fiscal 2011

Alkermes today adjusted its financial expectations for the fiscal year ending March 31, 2011, based predominantly on an increase in anticipated revenues from RISPERDAL CONSTA. These financial expectations include the impact of share-based compensation expense. The following statements are forward-looking, and actual results may differ materially. Please see "Note Regarding Forward-Looking Statements" at the end of this release and Alkermes' annual and quarterly reports on file with the U.S. Securities and Exchange Commission (SEC) for a description of risks that could cause results to differ materially from these forward-looking statements.

- **Revenues:** The company is adjusting its expectation for total revenues for fiscal 2011 to a range of $172 to $186 million, revised from an expectation of $161 to $180 million, based on an increase in anticipated revenues from RISPERDAL CONSTA.
- **Manufacturing Revenues:** The company is adjusting its expectation for manufacturing revenues to a range of $111 to $117 million, revised from an expectation of $101 to $112 million, due to an increase in the orders of RISPERDAL CONSTA. The company is adjusting its expectations for manufacturing revenues related to RISPERDAL CONSTA to a range of $110 to $115 million, revised from an expectation of $100 to $110 million. Manufacturing revenues from polymer for BYDUREON remain in the range of $1 to $2 million.
- **Royalty Revenues:** The company is adjusting its expectation for royalty revenues to a range of $36 to $38 million, revised from an expectation of $35 to $37 million, based on higher than expected royalty revenues from RISPERDAL CONSTA.
- **Cost of Goods Manufactured:** The company expects cost of goods manufactured to remain in the range of $46 to $58

million.

- **R&D Expenses:** The company is adjusting its expectation for R&D expenses to a range of $90 to $100 million, revised from an expectation of $90 to $105 million.
- **SG&A Expenses:** The company expects SG&A expenses to remain inthe range of $78 to $85 million.
- **Operating Loss:** The company is adjusting its expectation for operating loss to a range of $42 to $57 million, revised from an expectation of $53 to $68 million.
- **Net Interest and Income Taxes:** The company continues to expect net interest and income taxes to net to approximately $0 in fiscal 2011.
- **Net Loss:** The company is adjusting its expectation for net loss to a range of $42 to $57 million, revised from an expectation of $53 to $68 million.
- **Share-based Compensation Expense:** The company expects share-based compensation expense, included in the operating expenses above, to remain in the range of $15 to $20 million.
- **Cash Flow from Operations:** The company is adjusting its expectation for cash flow from operations to an outflow of $22 to $37 million, revised from an expectation of an outflow of $33 to $48 million.

Conference Call

Alkermes will host a conference call at 4:30 p.m. ET on Thursday, February 3, 2011, 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, February 3, 2011, through 5:00 p.m. ET on Thursday, February 10, 2011, and may be accessed by visiting Alkermes' website or by dialing 1-888-843-7419 for domestic callers and 1-630-652-3042 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 and opioid 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. For more information, please visit Alkermes' website at http://www.alkermes.com/.

Note Regarding Forward-Looking Statements

Certain statements set forth in this press release constitute "forward-looking statements" within the meaning of Section 27A of the Securities Act and Section 21E of the Exchange Act, including, but not limited to: statements concerning financial, business and operating results made by Alkermes (the "company"); the successful manufacture and commercialization of VIVITROL and RISPERDAL CONSTA, including continued revenue growth from VIVITROL and RISPERDAL CONSTA; statements by Amylin concerning the expected commencement date and duration of the tQT study as well as when it plans to submit results of such study to the FDA; the timing, funding and feasibility of clinical trials for our products; and the therapeutic value of the company's products. You are cautioned that forward-looking statements are inherently uncertain.

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 they are necessarily subject to a high degree of uncertainty and risk. Actual performance and results may differ materially from those projected or suggested in the forward-looking statements due to various risks and uncertainties. These risks and uncertainties include, among others: the company's ability to manufacture RISPERDAL CONSTA and VIVITROL on a commercial scale, economically or in sufficient quantities to supply the market; the company's ability to successfully commercialize VIVITROL in the U.S.; Janssen's ability to successfully commercialize RISPERDAL CONSTA; the company's ability to successfully conduct clinical trials in a timely and cost-effective manner; whether clinical trial results for the company's products will be predictive of real-world results or of results in subsequent clinical trials; whether advancement of BYDUREON will be delayed due to actions or decisions by Amylin with regard to development and regulatory strategy, timing and funding which are out of the company's control; whether Amylin and/or the FDA will change the design of the tQT study; whether the tQT study will be completed on time or at all; whether the results of the tQT study will demonstrate that exenatide causes an effect on heart rhythm; decisions by foreign regulatory authorities or the FDA regarding the company's products, including the FDA's decision regarding Amylin's New Drug Application submission for BYDUREON; whether the company's products 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 the company's products from the market; a variety of risks common to our industry including ongoing regulatory review, public and investment community perception of the industry, and legislative or regulatory changes; and those risks described in Part 1, Item 1A, "Risk Factors" of our Annual Report on Form 10-K for the year ended March 31, 2010. The information contained in this press release is provided by the company as of the date hereof, and, except as required by law, the company disclaims any intention or responsibility for updating any forward-looking information contained in this press release.

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

Condensed Consolidated Statements of Operations (In thousands, except per share data)	Three Months Ended December 31, 2010	Three Months Ended December 31, 2009
Revenues:		

Manufacturing revenues	$ 26,155	$ 28,650
Royalty revenues	9,777	9,970
Product sales, net	7,729	5,451
Research and development revenue under collaborative arrangements	314	81
Total Revenues	43,975	44,152
Expenses:		
Cost of goods manufactured and sold	12,860	10,072
Research and development	22,503	22,577
Selling, general and administrative	20,521	17,739
Total Expenses	55,884	50,388
Operating Loss	(11,909)	(6,236)
Other Income (Expense), net:		
Interest income	650	1,017
Interest expense	0	(1,423)
Other expense, net	(83)	(160)
Total Other Income (Expense), net	567	(566)
Loss Before Income Taxes	(11,342)	(6,802)
Income Tax Provision	41	15
Net Loss	$ (11,383)	$ (6,817)
Loss per Common Share:		
Basic and Diluted	$ (0.12)	$ (0.07)
Weighted Average Number of Common Shares Outstanding (GAAP):		
Basic and Diluted	95,667	94,784
Pro Forma Reconciliation:		
Net Loss - GAAP	$ (11,383)	$ (6,817)
Share-based compensation	5,792	3,372
Costs incurred related to the relocation of the company's corporate headquarters	-	3,592
Net (Loss) Income - Pro Forma	$ (5,591)	$ 147
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	95,667	94,784
Diluted	95,667	95,485

Condensed Consolidated Balance Sheets	December 31,	March 31,
(In thousands)	2010	2010
Cash, cash equivalents and total investments	$ 285,013	$ 350,193
Receivables	24,169	25,316
Inventory	19,169	20,653
Prepaid expenses and other current assets	11,897	10,936
Property, plant and equipment, net	96,219	96,905
Other assets	10,970	11,597
Total Assets	$ 447,437	$ 515,600
Non-recourse RISPERDAL CONSTA secured 7% notes - current	$ -	$ 51,043
Other current liabilities	38,425	40,101
Deferred revenue - long-term	4,972	5,105
Other long-term liabilities	7,722	6,735
Total shareholders' equity	396,318	412,616
Total Liabilities and Shareholders' Equity	$ 447,437	$ 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 nine months ended December 31, 2010, which the company intends to file in February 2011.

SOURCE: Alkermes, Inc.

Alkermes Contacts:
For Investors:
Rebecca Peterson, 781-609-6378
or
For Media:
Jennifer Snyder, 781-609-6166