Alkermes Reports Third Quarter Fiscal 2010 Financial Results

February 4, 2010

-- Record Sales of RISPERDAL® CONSTA® --
-- Company Expands Proprietary Pipeline to Include Long-Acting Versions of Two Blockbuster Medications --

WALTHAM, Mass., Feb 04, 2010 (BUSINESS WIRE) -- Alkermes, Inc. (NASDAQ: ALKS) today reported financial results for its third quarter of fiscal 2010, which ended on December 31, 2009.

Financial highlights:

- Quarterly revenues of $44.2 million, driven by record 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 $399 million, growing 18.1% on an operational basis year-over-year. U.S. sales growth for the quarter ended December 31, 2009, was 13.7%, reflecting increased share and market growth while sales outside the U.S. were up 20.6% operationally.
- Net sales of VIVITROL® of $5.5 million, growing 17.4% over the prior quarter.
- GAAP net loss of $6.8 million and pro forma net income of $0.1 million.
- Strong financial position with cash and total investments of $357.5 million.

Other recent highlights:

- Alkermes announced a novel, proprietary LinkeRx(TM) technology platform that enables the creation of injectable extended-release versions of antipsychotics and other central nervous system (CNS) therapies. The company's lead candidate that leverages this platform, designated as ALKS 9070, is a once-monthly, injectable, extended-release version of aripiprazole, commercially available under the name ABILIFY® , for the treatment of schizophrenia.
- Positive data reported for phase 3 study of naltrexone for extended-release injectable suspension (XR-NTX) for the treatment of opioid dependence. XR-NTX, marketed by Alkermes as VIVITROL, is an opioid antagonist administered once-monthly by intramuscular injection and is approved in the U.S. and Russia for the treatment of alcohol dependence.
- Positive data reported for DURATION-5 head-to-head study comparing exenatide once weekly, an investigational diabetes therapy, to BYETTA® (exenatide) injection taken twice daily, in patients with type 2 diabetes.
- DURATION-6 clinical study initiated comparing exenatide once weekly to liraglutide, commercially available under the name VICTOZA® .
- Medifusion(TM) technology licensed from Acceleron Pharma, Inc. (Acceleron). The first drug candidate being developed with this technology, ALKS 6931, is a long-acting form of a TNF receptor-Fc fusion protein for the treatment of rheumatoid arthritis and related autoimmune diseases. ALKS 6931 is structurally similar to etanercept, commercially available under the name ENBREL® .
- Phase 2 clinical study initiated for ALKS 33, an oral opioid modulator for the potential treatment of addiction and other CNS disorders.

"The record RISPERDAL CONSTA sales in our third quarter underscore the increasing importance of this medication in the marketplace," commented James Frates, Chief Financial Officer of Alkermes. "VIVITROL also had a strong quarter with double-digit growth. We will continue to focus on financial performance while leveraging our financial strength to invest in Alkermes' proprietary pipeline and research and development efforts."

Key operating results for the quarter ended December 31, 2009, include the following:

- GAAP net loss of $6.8 million or a basic and diluted loss per share of $0.07, including $3.4 million of share-based compensation expense and $3.6 million of charges associated with the relocation of the company's headquarters. For the same period in 2008, GAAP net income was $112.7 million or a basic and diluted earnings per share of $1.18, including $120.6 million of one-time net income related to the company's previous agreements with Cephalon, Inc. (Cephalon) for the commercialization of VIVITROL and $3.3 million of share-based compensation expense.
- Pro forma net income of $0.1 million or a basic and diluted earnings per share of $0.00, compared to a pro forma net loss of $4.6 million or a basic and diluted loss per share of $0.05 for the same period in 2008.

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

	Pro Forma Diluted Earnings (Loss)	Charges Related to the Relocation of the Company's Headquarters	Impact of the Termination of the Collaborative Agreements with Cephalon	Share-Based Compensation Expense	Reported GAAP Diluted (Loss) Earnings
Q3 FY 2010	$0.00	($0.04)	$--	($0.04)	($0.07)
Q3 FY 2009	($0.05)	$--	$1.27	($0.03)	$1.18

Note: Amounts do not sum due to rounding.

Revenues

- Total revenues for the quarter ended December 31, 2009, were $44.2 million, compared to $155.7 million for the same period in 2008 which included the recognition of $120.7 million of one-time revenue related to the company's previous agreements with Cephalon.
- Manufacturing revenues for the quarter ended December 31, 2009, were $28.7 million, compared to $20.5 million for the same period in 2008. Manufacturing revenues for the quarter ended December 31, 2009, included $27.2 million related to RISPERDAL CONSTA and $1.5 million related to the manufacture of polymer for exenatide once weekly. In the quarter ended December 31, 2008, Alkermes recorded manufacturing revenue of $21.3 million for RISPERDAL CONSTA and reversed $0.8 million of manufacturing revenue related to VIVITROL, as a result of the termination of the collaborative agreements with Cephalon.
- Royalty revenues for the quarter ended December 31, 2009, were $10.0 million, based on RISPERDAL CONSTA sales of $398.7 million, compared to $8.0 million, based on RISPERDAL CONSTA sales of $318.8 million for the same period in 2008.
- Net sales of VIVITROL recorded by Alkermes for the quarter ended December 31, 2009, were $5.5 million, growing 17.4% over the prior quarter.
- Research and development (R&D) revenue under collaborative arrangements for the quarter ended December 31, 2009, was $0.1 million, compared to $3.7 million for the same period in 2008.
- Net collaborative profit for the quarter ended December 31, 2009, was $0. Net collaborative profit for the quarter ended December 31, 2008, was $123.4 million and included the recognition of $120.7 million of one-time milestone and deferred revenue related to the company's previous agreements with Cephalon and $1.2 million of deferred revenue prepaid by Cephalon to cover its share of VIVITROL losses.

Costs and Expenses

- Cost of goods manufactured and sold for the quarter ended December 31, 2009, was $10.1 million, 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 exenatide once weekly. This compared to $5.5 million for the same period in 2008, of which $5.0 million related to RISPERDAL CONSTA and $0.5 million related to VIVITROL.
- R&D expenses for the quarter ended December 31, 2009, were $22.6 million, compared to $22.7 million for the same period in 2008.
- Selling, general and administrative (SG&A) expenses for the quarter ended December 31, 2009, were $17.7 million, compared to $14.6 million for the same period in 2008.
- Share-based compensation expense (included in the expenses above) for the quarter ended December 31, 2009, was $3.4 million, of which $0.4 million related to cost of goods manufactured and sold, $0.8 million related to R&D expenses and $2.2 million related to SG&A expenses. Share-based compensation expense for the same period in 2008 was $3.3 million, of which $0.3 million related to cost of goods manufactured and sold, $0.5 million related to R&D expenses and $2.5 million related to SG&A expenses.
- Interest income for the quarter ended December 31, 2009, was $1.0 million, compared to $2.6 million for the same period in 2008. Interest expense for the quarter ended December 31, 2009, was $1.4 million, compared to $2.4 million for the same period in 2008.

At December 31, 2009, Alkermes had cash and total investments of $357.5 million, compared to $369.5 million at September 30, 2009. During the quarter, the company used $10 million to license the Medifusion technology platform from Acceleron, including a $2 million upfront payment and an $8 million equity investment in Acceleron. The company also 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, February 4, 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, February 4, 2010, through 5:00 p.m. ET on Thursday, February 11, 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, pulmonary 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 successful manufacture and commercialization of VIVITROL and RISPERDAL CONSTA; continued revenue growth from RISPERDAL CONSTA and VIVITROL; 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 U.S. Food and Drug Administration (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 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	Three Months Ended December 31,	Three Months Ended December 31,
(In thousands, except per share data)	2009	2008
Revenues:		
Manufacturing revenues	$ 28,650	$ 20,533
Royalty revenues	9,970	7,970
Product sales, net	5,451	-
Research and development revenue under collaborative arrangements	81	3,736
Net collaborative profit	-	123,422
Total Revenues	44,152	155,661
Expenses:		
Cost of goods manufactured and sold	10,072	5,536
Research and development	22,577	22,669
Selling, general and administrative	17,739	14,568
Total Expenses	50,388	42,773
Operating (Loss) Income	(6,236)	112,888
Other Expense, net:		
Interest income	1,017	2,574
Interest expense	(1,423)	(2,436)
Other expense, net	(160)	(641)
Total Other Expense, net	(566)	(503)
(Loss) Income Before Income Taxes	(6,802)	112,385

Income tax provision (benefit)	15	(330)
Net (Loss) Income	$ (6,817)	$ 112,715
(Loss) Earnings per Common Share:		
Basic	$ (0.07)	$ 1.18
Diluted	$ (0.07)	$ 1.18
Weighted Average Number of Common Shares Outstanding (GAAP):		
Basic	94,784	95,316
Diluted	94,784	95,818
Pro Forma Reconciliation:		
Net (Loss) Income - GAAP	$ (6,817)	$ 112,715
Share-based compensation expense	3,372	3,281
Costs incurred related to the relocation of the company's corporate headquarters	3,592	-
Impact of the termination of the collaboration agreements with Cephalon, Inc. for VIVITROL	-	(120,582)
Net Income (Loss) - Pro Forma	$ 147	$ (4,586)
Pro Forma Earnings (Loss) per Common Share:		
Basic	$ 0.00	$ (0.05)
Diluted	$ 0.00	$ (0.05)
Weighted Average Number of Common Shares Outstanding (Pro Forma):		
Basic	94,784	95,316
Diluted	95,485	95,316

Condensed Consolidated Balance Sheets	December 31,	March 31,
(In thousands)	2009	2009
Cash, cash equivalents and total investments	$ 357,479	$ 404,482
Receivables	28,233	24,588
Inventory	20,049	20,297
Prepaid expenses and other current assets	5,950	7,500
Property, plant and equipment, net	96,332	106,461
Other assets	11,857	3,158
Total Assets	$ 519,900	$ 566,486
Non-recourse RISPERDAL CONSTA secured 7% notes - current	$ 25,667	$ 25,667
Other current liabilities	31,865	43,323
Non-recourse RISPERDAL CONSTA secured 7% notes - long-term	31,636	50,221
Deferred revenue - long-term	5,120	5,238
Other long-term liabilities	6,386	7,149
Total shareholders' equity	419,226	434,888
Total Liabilities and Shareholders' Equity	$ 519,900	$ 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 December 31, 2009, which the company intends to file in February 2010.

SOURCE: Alkermes, Inc.

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