Alkermes Reports Second Quarter Fiscal 2011 Financial Results

November 4, 2010

-- Company Receives FDA Approval for VIVITROL® in Opioid Dependence --

-- Company Adjusts Financial Expectations for Fiscal 2011 Based on BYDUREON™ Complete Response Letter --

WALTHAM, Mass., Nov 04, 2010 (BUSINESS WIRE) -- Alkermes, Inc. (NASDAQ: ALKS) today reported financial results for its second quarter of fiscal 2011, which ended on September 30, 2010.

Financial highlights:

- Quarterly revenues of $49.2 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 $378 million, an increase of 7.1 percent year-over-year, and are based on product sales in more than 70 countries.
- GAAP net loss of $7.7 million and pro forma net loss of $0.5 million.
- Strong financial position, with cash and total investments of $273.6 million, after the early redemption of all remaining non-recourse RISPERDAL CONSTA secured 7% Notes during the quarter, leaving Alkermes debt-free.

Additional highlights:

- Positive results announced from a phase 1 study of ALKS 33 in combination with buprenorphine for the treatment of cocaine addiction. The company expects to initiate a phase 2a study in the first half of calendar 2011, which will be funded through a grant of up to $2.4 million from the National Institute on Drug Abuse (NIDA).
- Data from a two year study of RISPERDAL CONSTA, published in the journal *Neuropsychopharmacology,* showed that RISPERDAL CONSTA was associated with a significantly lower rate of relapse compared to a leading oral antipsychotic, SEROQUEL®.
- Amylin Pharmaceuticals, Inc. (Amylin) received a complete response letter from the U.S. Food and Drug Administration (FDA) for BYDUREON™.
- VIVITROL® received FDA approval on October 12, 2010, for the prevention of relapse to opioid dependence, following opioid detoxification.
- The FDA Psychopharmacologic Drugs Advisory Committee recommended approval of VIVITROL for opioid dependence.
- BYDUREON data was presented at the Annual Meeting of the European Association for the Study of Diabetes (EASD).

"During the second quarter, Alkermes reported solid financial results driven largely by RISPERDAL CONSTA, which posted strong sales during the quarter, particularly outside of the U.S.," commented James Frates, Chief Financial Officer of Alkermes. "In addition, the approval of VIVITROL in the opioid dependence indication marks the beginning of an important new revenue stream for Alkermes. We are taking this opportunity to adjust our financial guidance for fiscal year 2011 based on the BYDUREON complete response letter."

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

- GAAP net loss was $7.7 million or a basic and diluted loss per share of $0.08, including $4.9 million in share-based compensation expense. For the same period in 2009, GAAP net loss was $8.7 million or a basic and diluted loss per share of $0.09, including $5.6 million in share-based compensation and severance expense and $4.1 million of charges associated with the relocation of the company's headquarters.
- Pro forma net loss was $0.5 million or a basic and diluted loss per share of $0.01, compared to a pro forma net income of $1.1 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 second 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 Headquarters	Costs Related to Redemption of the Non-Recourse 7% Notes	Share-Based Compensation and Severance Expense	Reported GAAP Diluted (Loss)
Q2 FY 2011	($0.01)	$--	($0.02)	($0.05)	($0.08)
Q2 FY 2010	$0.01	($0.04)	$--	($0.06)	($0.09)

Revenues

- Total revenues for the quarter ended September 30, 2010, were $49.2 million, compared to $48.2 million for the same period in 2009.
- Total manufacturing revenues for the quarter ended September 30, 2010, were $33.2 million, which included $32.6 million related to RISPERDAL CONSTA and $0.6 million related to polymer for BYDUREON, compared to $32.8 million, which included $31.9 million related to RISPERDAL CONSTA, $0.5 million related to VIVITROL for Russia and $0.4 million related to polymer for BYDUREON, for the same period in 2009.
- Royalty revenues for the quarter ended September 30, 2010, were $9.5 million, based on RISPERDAL CONSTA sales of $377.7 million, compared to $8.8 million, based on RISPERDAL CONSTA sales of $352.6 million, for the same period in 2009.
- Net sales of VIVITROL for the quarter ended September 30, 2010, were $6.5 million, compared to net sales of $4.6 million for the same period in 2009.
- Research and development (R&D) revenue under collaborative arrangements for the quarter ended September 30, 2010, was $0.2 million, compared to $1.2 million for the same period in 2009.
- The company no longer records net collaborative profit. Net collaborative profit for the quarter ended September 30, 2009, was $0.7 million.

Costs and Expenses

- Cost of goods manufactured and sold for the quarter ended September 30, 2010, was $13.9 million, which included $11.3 million related to RISPERDAL CONSTA, $2.4 million related to VIVITROL and $0.2 million related to polymer for BYDUREON, compared to $15.1 million for the same period in 2009, of which $12.1 million related to RISPERDAL CONSTA, $2.6 million related to VIVITROL and $0.4 million related to polymer for BYDUREON.
- R&D expenses for the quarter ended September 30, 2010, were $23.9 million. R&D expenses were $20.7 million for the same period in 2009, which included $4.1 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 September 30, 2010, were $18.4 million, compared to $20.6 million for the same period in 2009, which 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 operating expenses above) for the quarter ended September 30, 2010, was $4.9 million, of which $0.5 million related to cost of goods manufactured, $1.6 million related to R&D expenses and $2.8 million related to SG&A expenses. Share-based compensation expense for the same period in 2009 was $4.2 million, of which $0.5 million related to cost of goods manufactured, $0.9 million related to R&D expenses and $2.8 million related to SG&A expenses.
- Interest income for the quarter ended September 30, 2010, was $0.7 million, compared to $1.1 million for the same period in 2009. Interest expense for the quarter ended September 30, 2010, was $2.2 million, reflecting expense associated with the early redemption of all remaining non-recourse RISPERDAL CONSTA secured 7% Notes. This compared to interest expense of $1.6 million for the same period in 2009.
- Income tax benefit for the quarter ended September 30, 2010, was $0.9 million, compared to $0.1 million for the same period in 2009.

At September 30, 2010, Alkermes had cash and total investments of $273.6 million, compared to $328.5 million at June 30, 2010, and $350.2 million at March 31, 2010. During the quarter, the company redeemed the remaining 7% Notes in full on July 1, 2010, for a total cash outflow of approximately $46.4 million.

Adjusted Financial Expectations for Fiscal 2011

Alkermes today adjusted its financial expectations for the fiscal year ending March 31, 2011, based on the complete response letter for BYDUREON. 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 for a description of certain risk factors and Alkermes' annual and quarterly reports on file with the U.S. Securities and Exchange Commission (SEC) for a more complete description of risks.

- **Revenues:** The company is adjusting its expectation for total revenues for fiscal 2011 to a range of $161 to $180 million, revised from an expectation of $170 to $195 million, based on the complete response letter for BYDUREON.
- **Manufacturing Revenues:** The company is adjusting its expectation for manufacturing revenues to a range of $101 to $112 million, revised from an expectation of $103 to $115 million, due to changes in the anticipated orders of polymer for BYDUREON. Manufacturing revenues related to RISPERDAL CONSTA remain in the range of $100 to $110 million and the company is adjusting its expectations for manufacturing revenues from polymer for BYDUREON to a range of $1 to $2 million, revised from an expectation of $3 to $5 million.
- **Royalty Revenues:** The company is adjusting its expectation for royalty revenues to a range of $35 to $37 million, revised from an expectation of $35 to $42 million, based on the complete response letter for BYDUREON. Royalty revenues from RISPERDAL CONSTA remain in the range of $35 to $37 million.
- **Product Sales, Net:** The company expects net sales from VIVITROL to remain in the range of $25 to $30 million.
- **R&D Revenues:** The company is adjusting its expectation for R&D revenues to a range of $0 to $1 million, revised from an expectation of $7 to $8 million, due to the expectation that a previously anticipated $7 million milestone payment from Amylin will be deferred.
- **Cost of Goods Manufactured:** The company is adjusting its expectation for cost of goods manufactured to a range of $46 to $58 million, revised from an expectation of $47 to $60 million. Cost of goods manufactured related to RISPERDAL CONSTA remain in the range of $39 to $46 million, the cost of goods manufactured related to VIVITROL remain in the range of $6 to $10 million, and the company is adjusting its expectation for cost of goods manufactured related to polymer for BYDUREON to a range of $1 to $2 million, revised from an expectation of $2 to $4 million.
- **R&D Expenses:** The company expects R&D expenses to remain in the range of $90 to $105 million.
- **SG&A Expenses:** The company expects SG&A expenses to remain in the range of $78 to $85 million.
- **Operating Loss:** The company is adjusting its expectation for operating loss to a range of $53 to $68 million, revised from an expectation of $45 to $55 million.
- **Net Interest and Income Taxes:** The company continues to expect interest income and interest expense to offset and not to incur any income taxes in fiscal 2011.
- **Net Loss:** The company is adjusting its expectation for net loss to a range of $53 to $68 million, revised from an expectation of $45 to $55 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 $33 to $48 million, revised from an expectation of an outflow of $25 to $35 million.

Conference Call

Alkermes will host a conference call at 4:30 p.m. ET on Thursday, November 4, 2010, to discuss these financial results and provide an update on the company. The conference call may be accessed by dialing 1-888-517-2470 for domestic callers and 1-630-827-6818 for international callers. The conference call ID number is 7262488. In addition, a replay of the conference call will be available from 7:30 p.m. ET on Thursday, November 4, 2010, through 5:00 p.m. ET on Thursday, November 11, 2010, 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 7262488.

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.

Note Regarding Forward-Looking Statements

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, including continued revenue growth from VIVITROL and RISPERDAL CONSTA; the timing, funding and feasibility of clinical trials for our products; and the therapeutic value of the company's products. 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: 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; whether clinical trial results for the company's products will be predictive of real-world results or of results in subsequent clinical trials; clinical trials may take more time or consume more resources than initially envisioned and they may not be completed on time or at all; 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 the company's 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 products, including the timeline for FDA review of, and the outcome of regulatory action relating to, the New Drug Application (NDA) submission for BYDUREON; and 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 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.

(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, 2010	Three Months Ended September 30, 2009
Revenues:		
Manufacturing revenues	$ 33,163	$ 32,835
Royalty revenues	9,460	8,818
Product sales, net	6,469	4,643
Research and development revenue under collaborative arrangements	155	1,174
Net collaborative profit	-	687
Total Revenues	49,247	48,157
Expenses:		
Cost of goods manufactured and sold	13,911	15,092
Research and development	23,932	20,664
Selling, general and administrative	18,436	20,625
Total Expenses	56,279	56,381
Operating Loss	(7,032)	(8,224)
Other Expense, net:		
Interest income	673	1,088
Interest expense	(2,168)	(1,566)
Other expense, net	(82)	(67)
Total Other Expense, net	(1,577)	(545)
Loss Before Income Taxes	(8,609)	(8,769)
Income Tax Benefit	(943)	(60)
Net Loss	$ (7,666)	$ (8,709)
Loss per Common Share:		
Basic and Diluted	$ (0.08)	$ (0.09)
Weighted Average Number of Common Shares Outstanding (GAAP):		
Basic and Diluted	95,511	94,886
Pro Forma Reconciliation:		
Net Loss - GAAP	$ (7,666)	$ (8,709)
Share-based compensation	4,948	4,208
Costs related to the redemption of the non-recourse 7% Notes	2,168	-
Costs incurred related to the relocation of the company's corporate headquarters	-	4,149
Severance charges	-	1,406
Net (Loss) Income - Pro Forma	$ (550)	$ 1,054
Pro Forma (Loss) Earnings per Common Share:		
Basic	$ (0.01)	$ 0.01

Diluted	$ (0.01)	$ 0.01
Weighted Average Number of Common Shares Outstanding (Pro Forma):		
Basic	95,511	94,886
Diluted	95,511	95,969

Condensed Consolidated Balance Sheets (In thousands)	September 30, 2010	March 31, 2010
Cash, cash equivalents and total investments	$ 273,565	$ 350,193
Receivables	35,770	25,316
Inventory	18,257	20,653
Prepaid expenses and other current assets	14,696	10,936
Property, plant and equipment, net	97,184	96,905
Other assets	9,660	11,597
Total Assets	$ 449,132	$ 515,600
Non-recourse RISPERDAL CONSTA secured 7% Notes - current	$ -	$ 51,043
Other current liabilities	35,017	40,101
Deferred revenue - long-term	5,123	5,105
Other long-term liabilities	6,901	6,735
Total shareholders' equity	402,091	412,616
Total Liabilities and Shareholders' Equity	$ 449,132	$ 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 six months ended September 30, 2010, which the company intends to file in November 2010.

SOURCE: Alkermes

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