Alkermes Announces Third Quarter Fiscal 2009 Results

February 5, 2009

-- Unit Sales of RISPERDAL(R) CONSTA(R) Increased More Than 16 Percent Quarter Over Quarter --

-- Company Updates Financial Expectations for Fiscal 2009 --

CAMBRIDGE, Mass.--(BUSINESS WIRE)-- Alkermes, Inc. (NASDAQ: ALKS) today announced financial results for its third quarter of fiscal 2009. Financial highlights for the quarter ended December 31, 2008, include:

- Profitable quarter on a GAAP basis, with net income of $112.3 million.
- Quarterly revenues of $155.7 million, including the recognition of $120.7 million of one-time milestone and deferred revenue.
- Worldwide sales of RISPERDAL® CONSTA® by Janssen, Division of Ortho-McNeil-Janssen Pharmaceuticals, Inc. and Janssen–Cilag (Janssen) were $318.8 million. On a unit basis, worldwide sales of RISPERDAL CONSTA increased 16.3 percent compared to the same period in 2007. Sales of RISPERDAL CONSTA were $999.5 million for the first nine months of fiscal 2009.
- Strong financial position, with cash and total investments of $423.6 million. The business generated $4.0 million in cash from operations in the third quarter and $43.2 million for the first nine months of fiscal 2009.
- Repurchase of an additional 487,300 shares of common stock as part of an ongoing stock repurchase program. To date, the company has repurchased over 8.5 million shares of common stock for approximately $111.3 million.

“Alkermes is positioned for success in 2009. RISPERDAL CONSTA sales continue to grow on a unit basis, and a phase 1 study of a four-week formulation of this product is underway. Throughout the calendar year, we also expect significant progress across our proprietary portfolio, including topline data from multiple development programs,” commented James Frates, chief financial officer of Alkermes. “Moving forward, we have the financial resources to continue to build our business, and we expect positive cash flow from operations for the fiscal year.”

Key operating results for the quarter ended December 31, 2008, include the following:

- Net income was $112.3 million or a basic earnings per share of $1.18 and diluted earnings per share of $1.17, including $3.3 million in share-based compensation expense and $120.6 million of one-time net income related to the company’s previous agreements with Cephalon, Inc. (Cephalon) for the commercialization of VIVITROL®. For the same period in 2007, net income was $168.9 million or a basic earnings per share of $1.66 and a diluted earnings per share of $1.63, which included $5.2 million in share-based compensation expense and $171.3 million of net income from the sale of the company’s stake in Reliant Pharmaceuticals, Inc. (Reliant).
- Pro forma net loss was $5.0 million or a basic and diluted loss per share of $0.05, compared to a net income of $2.8 million or a basic and diluted earnings per share of $0.03 for the same period in 2007.

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 third quarters of fiscal 2009 and 2008 is provided in the following table:

	Pro Forma Diluted (Loss) Earnings	Impact of the Termination of the Collaborative Agreements with Cephalon	Income from Sale of Stake in Reliant, Net of Taxes	Share-Based Compensation Expense	Reported GAAP Diluted Earnings
Q3 FY 2009	$(0.05)	$1.27	--	$(0.03)	$1.17
Q3 FY 2008	$0.03	--	$1.65	$(0.05)	$1.63

Note: Amounts may not sum due to rounding. Pro forma per share calculations in Q3 FY 2009 exclude the effect of potential outstanding shares, such as stock options and restricted stock units, as the inclusion of such shares would be anti-dilutive.

The following financial results are reported on a GAAP basis and include share-based compensation expense:

Revenues

- Manufacturing revenues for the quarter ended December 31, 2008, were $20.5 million compared to $14.3 million for the

same period in 2007, an increase of 44 percent year over year. Manufacturing revenues for the quarter ended December 31, 2008, consisted of $21.3 million for RISPERDAL CONSTA and $(0.8) million for VIVITROL, compared to $12.9 million for RISPERDAL CONSTA and $1.4 million for VIVITROL for the same period in 2007. In the quarter ended December 31, 2008, the company reversed $0.8 million of manufacturing revenue for VIVITROL previously sold to Cephalon, which Alkermes is now selling in the end-market.

- Royalty revenues for the quarter ended December 31, 2008, were $8.0 million compared to $7.4 million for the same period in 2007. Royalty revenues were based on RISPERDAL CONSTA sales of $318.8 million for the quarter ended December 31, 2008, compared to $295.1 million for the same period in 2007.
- Research and development (R&D) revenue under collaborative arrangements for the quarter ended December 31, 2008, was $3.7 million, compared to $24.0 million for the same period in 2007, due to an increased focus on proprietary programs as compared to partnered programs.
- Net collaborative profit for the quarter ended December 31, 2008, was $123.4 million, compared to $5.1 million for the same period in 2007. Net collaborative profit for the quarter ended December 31, 2008, 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.
- During the quarter, Alkermes regained commercial rights to VIVITROL in the U.S. and, effective December 1, 2008, changed the revenue recognition policy for the product. Under the previous policy which recognized sales upon shipment into the distribution channel, gross sales of VIVITROL during the quarter would have been $4.7 million, of which $3.1 million were recognized by the collaboration in October and November 2008. Due to the introduction of a return policy, Alkermes deferred its VIVITROL net sales in December 2008 as the company establishes a return history. The company expects to recognize product sales beginning in January 2009 as product is shipped out of the distribution channel.

Costs and Expenses

- Cost of goods manufactured for the quarter ended December 31, 2008, was $5.5 million, of which $5.0 million related to RISPERDAL CONSTA and $0.5 million related to VIVITROL, compared to $7.5 million for the same period in 2007, of which $5.9 million related to RISPERDAL CONSTA and $1.6 million related to VIVITROL. In the quarter ended December 31, 2008, the company reversed $0.7 million of cost of goods sold for VIVITROL related to product previously sold to Cephalon which Alkermes is now selling in the end-market.
- R&D expenses for the quarter ended December 31, 2008, were $22.7 million, compared to $30.4 million for the same period in 2007.
- Selling, general and administrative (SG&A) expenses for the quarter ended December 31, 2008, were $14.6 million, compared to $15.2 million for the same period in 2007.
- Share-based compensation expense (included in the expenses above) for the quarter ended December 31, 2008, was $3.3 million, of which $0.3 million related to cost of goods manufactured, $0.5 million related to R&D expenses and $2.5 million related to SG&A expenses. Share-based compensation expense for the quarter ended December 31, 2007, was $5.2 million, of which $0.3 million related to cost of goods manufactured, $2.1 million related to R&D expenses and $2.8 million related to SG&A expenses.
- Interest income for the quarter ended December 31, 2008, was $2.6 million, compared to $4.3 million for the same period in 2007. Interest expense for the quarter ended December 31, 2008, was $2.8 million, compared to $4.1 million for the same period in 2007.
- Income tax benefit for the quarter ended December 31, 2008, was $0.3 million, compared to an income tax expense of $3.2 million for the same period in 2007.

At December 31, 2008, Alkermes had cash and total investments of $423.6 million, compared to $425.8 million at September 30, 2008.

Recent Highlights

Highlights of Alkermes' third quarter and recent activities include the following:

- **Clinical development initiated for a four-week long-acting injectable formulation of risperidone:** In January, Johnson & Johnson Pharmaceutical Research & Development, L.L.C. (J&JPRD) initiated a phase 1 study for a four-week long-acting injectable formulation of risperidone for the treatment of schizophrenia. The single-dose, open-label study is designed to assess the pharmacokinetics, safety and tolerability of a gluteal injection of this risperidone formulation in approximately 26 patients diagnosed with chronic, stable schizophrenia.
- **Proprietary pipeline progress:** In December, Alkermes initiated a phase 1 study in healthy volunteers of ALKS 33, an oral opioid modulator for the potential treatment of addiction and other central nervous system (CNS) disorders. ALKS 33 is the company's first novel, small molecule drug candidate to enter the clinic. Also in December, the company initiated a pharmacokinetic study of ALKS 29, a potential treatment for alcohol dependence. Alkermes expects to report topline results from these two studies in the second half of calendar 2009.
- **Continued progress with the DURATION studies for exenatide once weekly:** In December**,** Amylin Pharmaceuticals, Inc., Eli Lilly and Company and Alkermes announced the initiation of DURATION-4, a superiority study designed to

evaluate exenatide once weekly as a monotherapy treatment compared to either metformin, a thiazolidinedione (TZD) or a dipeptidyl peptidase-4 (DPP-4) inhibitor. The double-blind study is expected to include approximately 800 type 2 diabetes patients. The companies also announced completion of enrollment in DURATION-3, an open-label, superiority study designed to compare exenatide once weekly with insulin glargine on a background of oral agent therapy in approximately 450 type 2 diabetes patients.

- **Full U.S. rights to VIVITROL regained:** On December 1, 2008, Alkermes regained from Cephalon full commercialization rights to VIVITROL in the U.S. following a portfolio review by Cephalon. Cephalon paid Alkermes $11 million as part of its obligations, and Alkermes paid Cephalon $16 million to purchase manufacturing equipment for the product.

Updated Financial Expectations for Fiscal 2009

Alkermes today updated its financial expectations for the fiscal year ending March 31, 2009. These financial expectations include the impact of 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 and in Alkermes' Form 10-K for the fiscal year ended March 31, 2008, as filed with the U.S. Securities and Exchange Commission.

- **Manufacturing Revenues:** The company expects manufacturing revenues to remain in the range of $111 to $122 million.
- **Royalty Revenues:** The company is adjusting its expectation for royalty revenues from RISPERDAL CONSTA to a range of $33 to $35 million, revised from an expectation of $34 to $36 million, due to the impact of currency fluctuations.
- **Product Sales:** The company is adjusting its expectation for net sales from VIVITROL to a range of $4 to $6 million, revised from an expectation of $5 to $8 million, due to the deferral of revenue in December. For fiscal 2009, based on the previous collaboration revenue recognition policy, the company expects gross sales of VIVITROL to remain in the range of $19 to $24 million.
- **R&D Revenues:** The company is adjusting its expectation for R&D revenues to a range of $41 to $45 million, revised from an expectation of $45 to $50 million, primarily due to the early completion of work performed on the exenatide once weekly program.
- **Net Collaborative Profit:** The company expects net collaborative profit to remain in the range of $125 to $130 million.
- **Total Revenues:** The company is adjusting its expectation for total revenues for fiscal 2009 to a range of $314 to $338 million, revised from an expectation of $320 to $346 million.
- **Cost of Goods Manufactured:** The company expects cost of goods manufactured to remain in the range of $40 to $45 million.
- **R&D Expenses:** The company expects R&D expenses to remain in the range of $92 to $97 million.
- **SG&A Expenses:** The company expects SG&A expenses to remain in the range of $53 to $58 million.
- **Operating Income:** The company is adjusting its expectation for operating income to a range of $129 to $138 million, revised from an expectation of $135 to $146 million.
- **Other Income/Expense:** The company is adjusting its expectation for other income/expense to a net expense of $3 to $5 million, revised from an expectation of net interest income/expense of $0.
- **Income Taxes:** The company continues to expect income taxes of $1 million.
- **GAAP Net Income:** The company is adjusting its expectation for GAAP net income to a range of $125 to $132 million or a basic earnings per share in the range of $1.32 to $1.39, revised from an expectation of $134 to $145 million or a basic earnings per share in the range of $1.41 to $1.53. These per share calculations are based on the current share count of 95 million shares outstanding.
- **Cash Flow from Operations:** The company expects cash flow from operations to remain in the range of $50 to $55 million.
- **SFAS 123R:** The company expects share-based compensation expense to remain in the range of $15 to $20 million.

Conference Call

Alkermes will host a conference call at 4:30 p.m. EST on Thursday, February 5, 2009, to discuss these financial results and provide an update on the company. The conference call may be accessed by dialing 1-866-219-5260 for domestic callers and 1-703-639-1117 for international callers. The conference call ID number is 1328237. In addition, a replay of the conference call will be available from 7:30 p.m. EST on Thursday, February 5, 2009, through 5:00 p.m. EST on Thursday, February 12, 2009, and may be accessed by visiting Alkermes' website or by dialing 1-888-266-2081 for domestic callers and 1-703-925-2533 for international callers. The replay access code is 1328237. Alkermes is also providing a podcast MP3 file available for download on the Alkermes website, which will be available shortly following the conference call and will be available until Thursday, February 12, 2009.

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. 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 Cambridge, Massachusetts, Alkermes has research facilities 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, cash flow and profitability; the continued growth of RISPERDAL CONSTA sales; and the successful continuation of development activities for proprietary and partnered programs, including RISPERDAL CONSTA and exenatide once weekly. 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: the current credit and financial climate; any changes to the reimbursement of pharmaceutical products by public and private payors; actions or decisions by the company's partners with regard to development, regulatory strategy, timing and funding of the company's partnered product candidates, which are out of the company's control; the outcome of clinical and preclinical work the company is pursuing, both on its own and with partners; decisions by the U.S. Food and Drug Administration (FDA) or foreign regulatory authorities regarding the company's product candidates; potential changes in cost, scope and duration of clinical trials; the occurrence of unintended side effects, adverse reactions or incidents of misuse related to the company's products and product candidates that could cause the FDA or other foreign regulatory authorities to require post approval studies, new labeling, or removal of such products from the market; and the company's ability to build its own commercial infrastructure necessary to successfully market and sell its proprietary products. 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 Income (In thousands, except per share data)	Three Months Ended December 31, 2008	Three Months Ended December 31, 2007
Revenues:		
Manufacturing revenues	$20,533	$14,275
Royalty revenues	7,970	7,384
Research and development revenue under collaborative arrangements	3,736	23,985
Net collaborative profit	123,422	5,127
Total Revenues	155,661	50,771
Expenses:		
Cost of goods sold	5,536	7,499
Research and development	22,669	30,395
Selling, general and administrative	14,568	15,249
Total Expenses	42,773	53,143
Operating Income (Loss)	112,888	(2,372)
Other (Expense) Income:		
Gain on sale of investment in Reliant Pharmaceuticals, Inc.	-	174,631
Interest income	2,574	4,292
Interest expense	(2,829)	(4,088)
Other (expense) income, net	(641)	(393)
Total Other (Expense) Income	(896)	174,442
Income before Income Taxes	111,992	172,070
Income tax (benefit) provision	(330)	3,189
Net Income	$112,322	$168,881
Earnings per Common Share:		
Basic	$1.18	$1.66
Diluted	$1.17	$1.63
Weighted Average Number of Common Shares Outstanding (GAAP and Pro Forma):		
Basic	95,316	101,703
Diluted	95,818	103,914
Pro Forma Reconciliation:		
Net Income - GAAP	$112,322	$168,881
Share-based compensation expense	3,281	5,182
Impact of the termination of the collaboration agreements with Cephalon, Inc. for VIVITROL	(120,582)	-
Gain on sale of investment in Reliant Pharmaceuticals, Inc. (net of income taxes)	-	(171,294)
Net increase in the fair value of warrants	-	2
Net (Loss) Income - Pro Forma	($4,979)	$2,771
Pro Forma (Loss) Earnings per Common Share:		

Basic	($0.05)	$0.03
Diluted	($0.05)	$0.03

Condensed Consolidated Balance Sheets (In thousands)	December 31, 2008	March 31, 2008
Cash, cash equivalents and total investments	$423,593	$460,361
Receivables	26,713	47,249
Inventory	21,113	18,884
Prepaid expenses and other current assets	15,448	5,720
Property, plant and equipment, net	107,299	112,539
Other assets	3,029	11,558
Total Assets	$597,195	$656,311
Unearned milestone revenue - current portion	-	$5,927
Non-recourse RISPERDAL CONSTA secured 7% notes - current portion	23,750	-
Other current liabilities	42,015	36,093
Non-recourse RISPERDAL CONSTA secured 7% notes - long-term portion	69,613	160,324
Unearned milestone revenue - long-term portion	-	111,730
Deferred revenue - long-term portion	5,369	27,837
Other long-term liabilities	7,272	9,086
Total shareholders' equity	449,176	305,314
Total Liabilities and Shareholders' Equity	$597,195	$656,311

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, 2008, and the company's report on Form 10-Q for the three months ended December 31, 2008, which the company intends to file in February 2009.

VIVITROL Selected Financial Information (Unaudited, in thousands)	Three Months Ended December 31, 2008	Three Months Ended December 31, 2007
VIVITROL Income Statement (1)		
Alkermes' expenses within the collaboration	$ 2,653	$ 3,815
Cephalon's net losses	1,257	3,105
Collaboration net losses	3,910	6,920
Alkermes' net losses outside the collaboration (month of December 2008)	2,316	-
VIVITROL net losses	$ 6,226	$ 6,920
Net Collaborative Profit		
Milestone revenue recognized with respect to the license (2)	$ 875	$ 1,312
Net flow of funds from Cephalon (3)	737	3,815
Remaining milestone revenue and deferred revenue recognized upon termination of collaboration (4)	120,652	-
Milestone revenue recognized to offset Cephalon's prepaid share of the net product losses (5)	1,158	-
Net collaborative profit	$ 123,422	$ 5,127

Notes

(1) The collaboration agreements with Cephalon, Inc. ("Cephalon") with respect to VIVITROL terminated effective December 1, 2008. The results provided above, reflect two months (October and November) of collaboration activity and one month (December) during which Alkermes was solely responsible for VIVITROL.

(2) Milestone revenue related to the license commenced upon approval of VIVITROL, by the FDA, on April 13, 2006 and was being recognized on a straight line basis over 10 years, at the rate of approximately $1.3 million per quarter. The recognition of this milestone revenue ceased on December 1, 2008.

(3) Alkermes was responsible for net losses up to $124.6 million and reimbursed Cephalon for their net losses during this period. Once the $124.6 million was reached in April 2007, Cephalon reimbursed Alkermes for its VIVITROL expenses through December 31, 2007. Between January 1, 2008 and December 1, 2008, the two companies shared net losses on the product.

(4) Upon termination of the collaboration agreements, Alkermes recognized the remaining unearned milestone revenue ($113.8 million) and deferred revenue ($6.9 million), received from Cephalon during the collaboration. The deferred revenue was net of $16.0 million that Alkermes paid to Cephalon upon termination, for title to two partially completed VIVITROL manufacturing lines.

(5) Upon termination of the collaboration agreements, Cephalon paid Alkermes $11.0 million to cover Cephalon's share of the estimated net losses over the ensuing 12 months. This revenue was deferred and is being recognized using a proportional performance methodology based on net product losses.

Upon termination of the collaboration agreements, Alkermes reversed $0.8 million of manufacturing revenue and $0.7 million of associated cost of goods sold, related to VIVITROL inventory that had previously been sold to Cephalon under the collaboration agreements, and which Alkermes will now be selling in the end-market. These transactions were reported through the Alkermes income statement and do not impact the numbers provided above.

Source: Alkermes, Inc.

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