



Alkermes Reports Financial Results for Fiscal 2009 and Provides Financial Expectations for Fiscal 2010

May 21, 2009

- Reports Fourth Consecutive Year of Positive Cash Flow from Operations -

- Expects Increased Revenues from RISPERDAL® CONSTA®, Positive Cash Flow from Operations with Increased Investment in Proprietary Pipeline in Fiscal 2010 -

CAMBRIDGE, Mass.--(BUSINESS WIRE)--May. 21, 2009-- Alkermes, Inc. (NASDAQ: ALKS) today reported financial results for its fiscal year ended March 31, 2009, and provided financial expectations for fiscal 2010.

Financial highlights:

- GAAP net income of \$130.5 million for fiscal 2009.
- Fourth consecutive year of positive cash flow from operations. The business generated \$34.6 million in cash from operations during fiscal 2009.
- Record manufacturing and royalty revenues from RISPERDAL® CONSTA® of \$145.5 million. Worldwide sales of RISPERDAL CONSTA by Janssen, Division of Ortho-McNeil-Janssen Pharmaceuticals, Inc. and Janssen-Cilag (Janssen) were over \$1.3 billion in fiscal 2009, a 12.6 percent increase over sales of RISPERDAL CONSTA in fiscal 2008, and are based on product sales in approximately 60 countries.
- Strong financial position, with cash and total investments of \$404.5 million.
- Expected annual cost savings in the range of \$10 to \$15 million in fiscal 2011 and beyond, resulting from plans to move its corporate headquarters to Waltham, Massachusetts.

Other recent highlights:

- RISPERDAL CONSTA approved by the U.S. Food and Drug Administration (FDA) as both a monotherapy and adjunctive therapy in the maintenance treatment of bipolar I disorder.
- RISPERDAL CONSTA approved in Japan for the treatment of schizophrenia.
- Submission of a New Drug Application (NDA) for exenatide once weekly by Amylin Pharmaceuticals, Inc.
- Launch of VIVITROL® for the treatment of alcohol dependence in Russia by Cilag GmbH International (Cilag GmbH) and completion of enrollment in the registration study of VIVITROL for opioid dependence.
- Continued pipeline progress, with positive data reported from clinical studies of both ALKS 33 and ALKS 29, as well as new clinical studies initiated for VIVITROL and ALKS 33.

"We enter fiscal 2010 in a strong financial position, with RISPERDAL CONSTA sales continuing to grow. We are also focused on positioning the company for long-term growth. The NDA for exenatide once weekly was recently submitted, and we announced positive data for several proprietary product candidates," commented James Frates, chief financial officer of Alkermes. "In fiscal 2010, we expect to continue to generate cash while making investments in our advancing pipeline and commercial infrastructure."

Key operating results for fiscal 2009 include the following:

- Net income was \$130.5 million or a basic earnings per share of \$1.37 and diluted earnings per share of \$1.36, compared to a net income of \$167.0 million or a basic earnings per share of \$1.66 and diluted earnings per share of \$1.62 for fiscal 2008.
- Pro forma net income was \$24 thousand or a basic and diluted earnings per share of \$0.00, compared to a pro forma net income of \$31.8 million or a basic earnings per share of \$0.32 and diluted earnings per share of \$0.31 for fiscal 2008.

Alkermes is providing pro forma results as a complement to reported results. The pro forma net income excludes certain non-cash or non-recurring 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 earnings per share for fiscal 2009 and fiscal 2008 is provided in the following table:

	Pro Forma Diluted Earnings	Impact of the Termination of the Collaborative Agreements with Cephalon, Inc.	Impact of the Termination of the Collaborative Agreements with Eli Lilly and Company, Net of Taxes	Income from Sale of Stake in Reliant Pharmaceuticals, Inc., Net of Taxes	Restructuring and Impairment Charges	Share-Based Compensation Expense	Reported GAAP Diluted Earnings
FY 2009	\$0.00	\$1.25	\$0.26	--	--	(\$0.15)	\$1.36
FY 2008	\$0.31	--	--	\$1.66	(\$0.18)	(\$0.19)	\$1.62

Note: Amounts do not sum due to rounding.

Revenues

- Total revenues for fiscal 2009 were \$326.8 million, compared to \$240.7 million for fiscal 2008.
- Total manufacturing revenues for fiscal 2009 were \$116.8 million, consisting of \$112.4 million for RISPERDAL CONSTA and \$4.4 million for VIVITROL, compared to \$101.7 million for fiscal 2008, consisting of \$95.2 million for RISPERDAL CONSTA and \$6.5 million for VIVITROL.
- Royalty revenues for fiscal 2009 were \$33.2 million, of which \$33.1 million related to RISPERDAL CONSTA, based on sales of \$1.3 billion, compared to \$29.5 million, based on RISPERDAL CONSTA sales of \$1.2 billion for fiscal 2008.
- Net sales from VIVITROL were \$4.5 million in the fourth quarter of fiscal 2009. Alkermes started to record net sales effective December 1, 2008. Alkermes deferred sales in the month of December as it changed its revenue recognition policy for the product to a sales-out model due to the introduction of a return policy. Under the previous policy, which recognized sales upon shipment into the distribution channel, gross sales of VIVITROL would have been \$18.8 million in fiscal 2009, compared to \$18.0 million in fiscal 2008.
- Research and development (R&D) revenue under collaborative arrangements for fiscal 2009 was \$42.1 million, compared to \$89.5 million for fiscal 2008.
- Net collaborative profit for fiscal 2009 was \$130.2 million, compared to \$20.0 million for fiscal 2008.

Costs and Expenses

- Cost of goods manufactured for fiscal 2009 was \$43.4 million, of which \$31.4 million related to RISPERDAL CONSTA and \$11.8 million related to VIVITROL, compared to \$40.7 million for fiscal 2008, of which \$34.8 million related to RISPERDAL CONSTA and \$5.9 million related to VIVITROL.
- R&D expenses for fiscal 2009 were \$89.5 million, compared to \$125.3 million for fiscal 2008.
- Selling, general and administrative (SG&A) expenses for fiscal 2009 were \$59.0 million, compared to \$59.5 million for fiscal 2008.
- Share-based compensation expense (included in the expenses above) for fiscal 2009 was \$14.8 million, of which \$1.4 million related to cost of goods manufactured, \$4.4 million related to R&D expenses and \$9.0 million related to SG&A expenses. Share-based compensation expense for fiscal 2008 was \$19.4 million, of which \$1.8 million related to cost of goods manufactured, \$7.0 million related to R&D expenses and \$10.6 million related to SG&A expenses.
- Interest income for fiscal 2009 was \$11.4 million, compared to \$17.8 million for fiscal 2008. Interest expense for fiscal 2009 was \$13.8 million, compared to \$16.4 million for fiscal 2008.
- Income tax expense for fiscal 2009 was \$0.5 million, compared to \$5.9 million for fiscal 2008.

At March 31, 2009, Alkermes had cash and total investments of \$404.5 million, compared to \$423.6 million at December 31, 2008, and \$460.4 million at March 31, 2008. During the fiscal year, Alkermes repurchased a principal amount of \$93.0 million of its non-recourse RISPERDAL CONSTA secured 7% notes for \$89.4 million. The company also used cash during the fiscal year to repurchase 1.6 million shares of common stock for \$18.0 million as part of an ongoing stock repurchase program.

Financial Expectations for Fiscal 2010

The following outlines Alkermes' financial expectations for the fiscal year ending March 31, 2010. 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.

- **Revenues:** The company expects total revenues for fiscal 2010 to range from \$182 to \$197 million.
- The company expects total manufacturing revenues to range from \$116 to \$122 million. The expected manufacturing revenues for RISPERDAL CONSTA range from \$115 to \$120 million and are based on a purchase forecast from Janssen and assume no significant changes in exchange rates. The expected manufacturing revenues for VIVITROL related to the Russian market range from \$1 to \$2 million and are based on a purchase forecast from Cilag GmbH. Both Janssen and Cilag GmbH have the right to change the timing and amount of their purchases. Alkermes' revenue estimates are also dependent upon its ability to manufacture sufficient quantities of RISPERDAL CONSTA and VIVITROL to meet its partners' estimates.
- The company expects royalty revenues from RISPERDAL CONSTA to range from \$36 to \$38 million. This expectation assumes continued sales growth in the U.S. and around the world and no significant changes in exchange rates. Alkermes relies on sales projections received from Janssen to determine royalty revenue expectations and such projections are subject to change. RISPERDAL CONSTA sales are dependent on Janssen.
- The company expects net product sales from VIVITROL to range from \$23 to \$28 million.
- The company expects R&D revenues to range from \$2 to \$4 million.
- The company expects net collaborative profit to be approximately \$5 million.
- **Cost of Goods Manufactured:** The company expects total cost of goods manufactured to range from \$50 to \$60 million. The expected cost of goods manufactured related to RISPERDAL CONSTA range from \$40 to \$44 million. The expected cost of goods manufactured related to VIVITROL range from \$10 to \$16 million. These cost estimates are based on expected sales by Alkermes in the U.S., projected orders from Janssen and Cilag GmbH and the company's historical manufacturing yields. Margins on RISPERDAL CONSTA and VIVITROL are dependent on many factors and may fluctuate. Orders from Janssen and Cilag GmbH are subject to change at any time.
- **R&D Expenses:** The company expects R&D expenses to range from \$93 to \$100 million. These expectations reflect \$77 to \$82 million to support the company's continuing efforts to advance its product candidates toward commercialization, as well as \$16 to \$18 million of non-cash charges associated with the relocation of the company's headquarters, primarily related to the accelerated depreciation of certain assets. These non-cash charges will be incurred during fiscal 2010 and are non-recurring.
- **SG&A Expenses:** The company expects SG&A expenses to range from \$69 to \$77 million. These expectations include the company's continuing efforts to commercialize VIVITROL, as well as \$2 to \$5 million of non-cash charges associated with the relocation of the company's headquarters, primarily related to the accelerated depreciation of certain assets. These non-cash charges will be incurred during fiscal 2010 and are non-recurring.
- **Operating Loss:** The company expects operating loss to range from \$30 to \$40 million.
- **Net Interest and Income Taxes:** The company expects interest income and interest expense to offset, and does not expect to incur any income taxes in fiscal 2010.
- **Net Loss:** The company expects net loss to range from \$30 to \$40 million, or a basic and diluted loss per share of approximately \$0.32 to \$0.42 per share. The basic loss per share is based on the current basic share count of 95 million shares outstanding.
- **Cash Flow from Operations:** The company expects positive cash flow from operations to range from \$1 to \$5 million in fiscal 2010.
- **SFAS 123R:** The company has included share-based compensation expense in the expense expectations provided. The company expects to recognize this expense within cost of goods manufactured, R&D expenses and SG&A expenses in the approximate ratio of 10 percent, 30 percent and 60 percent, respectively. Based on the company's expectation with respect to fiscal 2010 stock grants and the estimates used to value such grants, the company expects share-based compensation expense to be in the range of \$10 to \$15 million or \$0.11 to \$0.16 per share for fiscal 2010.

Conference Call

Alkermes will host a conference call at 4:30 p.m. ET on Thursday, May 21, 2009, to discuss these financial results and provide an update on the company. The conference call may be accessed by dialing 1-866-256-9239 for domestic callers and 1-703-639-1213 for international callers. The conference call ID number is 1360066. In addition, a replay of the conference call will be available from 7:30 p.m. ET on Thursday, May 21, 2009, through 5:00 p.m. ET on Thursday, May 28, 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 1360066.

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 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 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; the successful manufacture and commercialization of VIVITROL and RISPERDAL CONSTA; continued revenue growth from RISPERDAL CONSTA; 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 in Russia; whether RISPERDAL CONSTA will continue to be commercialized successfully by its partner Janssen; whether the company is able to successfully and efficiently scale up and manufacture its product candidates; 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 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.

(tables follow)

VIVITROL[®] is a registered trademark of Alkermes, Inc. and RISPERDAL[®] CONSTA[®] is a registered trademark of Janssen-Cilag group of companies.

Alkermes, Inc. and Subsidiaries

Selected Financial Information (Unaudited)

	Year Ended March 31, 2009	Year Ended March 31, 2008
Condensed Consolidated Statements of Income		
(In thousands, except per share data)		
Revenues:		
Manufacturing revenues	\$116,844	\$101,700
Royalty revenues	33,247	29,457
Product sales, net	4,467	-
Research and development revenue under collaborative arrangements	42,087	89,510
Net collaborative profit	130,194	20,050
Total Revenues	326,839	240,717
Expenses:		
Cost of goods manufactured and sold	43,396	40,677
Research and development	89,478	125,268
Selling, general and administrative	59,008	59,508
Impairment of long-lived assets	-	11,630
Restructuring	-	6,423
Total Expenses	191,882	243,506
Operating Income (Loss)	134,957	(2,789)
Other (Expense) Income:		
Interest income	11,400	17,834
Interest expense	(13,756)	(16,370)
Gain on sale of investment in Reliant Pharmaceuticals, Inc.	-	174,631
Other expense, net	(1,589)	(476)
Total Other (Expense) Income	(3,945)	175,619
Income Before Income Taxes	131,012	172,830
Provision for Income Taxes	507	5,851
Net Income	\$130,505	\$166,979
Earnings per Common Share:		
Basic	\$1.37	\$1.66

Diluted	\$1.36	\$1.62
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Weighted Average Number of Common Shares Outstanding (GAAP and Pro Forma):

Basic	95,161	100,742
Diluted	96,252	102,923

Pro Forma Reconciliation:

Net Income - GAAP	\$130,505	\$166,979
Share-based compensation expense	14,810	19,445
Impact of the termination of the collaboration agreements with Cephalon, Inc. for VIVITROL®	(120,582)	-
Income from Eli Lilly and Company related to termination of the AIR® Insulin program (net of income taxes)	(24,709)	-
Impairment of long-lived assets	-	11,630
Restructuring	-	6,423
Gain on sale of investment in Reliant Pharmaceuticals, Inc. (net of income taxes)	-	(171,294)
Net increase in the fair value of warrants	-	(1,423)
Net Income - Pro Forma	\$24	\$31,760

Pro Forma Earnings per Common Share:

Basic	\$0.00	\$0.32
Diluted	\$0.00	\$0.31

**Condensed Consolidated Balance Sheets
(In thousands)**

	March 31, 2009	March 31, 2008
Cash, cash equivalents and total investments	\$ 404,482	\$ 460,361
Receivables	24,588	47,249
Inventory	20,297	18,884
Prepaid expenses and other current assets	7,500	5,720
Property, plant and equipment, net	106,461	112,539
Other assets	3,158	11,558
Total Assets	\$ 566,486	\$ 656,311
Unearned milestone revenue - current portion	\$ -	\$ 5,927
Non-recourse RISPERDAL CONSTA secured 7% notes - current	25,667	-
Other current liabilities	43,323	36,093
Non-recourse RISPERDAL CONSTA secured 7% notes - long-term	50,221	160,324
Unearned milestone revenue - long-term	-	111,730
Deferred revenue - long-term	5,238	27,837
Other long-term liabilities	7,149	9,086
Total shareholders' equity	434,888	305,314
Total Liabilities and Shareholders' Equity	\$ 566,486	\$ 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, 2009, which the company intends to file in May 2009.

Alkermes, Inc. and Subsidiaries

Quarterly Financial Data Fiscal Year 2009

	Three Months Ended				Year Ended March 31, 2009
	June 30, 2008	September 30, 2008	December 31, 2008	March 31, 2009	
(Unaudited)					
(In thousands, except per share data)					
Revenues:					
Manufacturing revenues	\$ 38,610	\$ 33,039	\$ 20,533	\$ 24,662	\$ 116,844
Royalty revenues	8,581	8,439	7,970	8,257	33,247
Product sales, net	-	-	-	4,467	4,467
Research and development revenue under collaborative arrangements	31,450	5,252	3,736	1,649	42,087
Net collaborative profit	1,351	581	123,422	4,840	130,194
Total Revenues	<u>79,992</u>	<u>47,311</u>	<u>155,661</u>	<u>43,875</u>	<u>326,839</u>
Expenses:					

Cost of goods sold	14,314	12,071	5,536	11,475	43,396
Research and development	22,261	19,710	22,669	24,838	89,478
Selling, general and administrative	11,926	11,679	14,568	20,835	59,008
Total Expenses	<u>48,501</u>	<u>43,460</u>	<u>42,773</u>	<u>57,148</u>	<u>191,882</u>
Operating Income (Loss)	31,491	3,851	112,888	(13,273)	134,957
Other Expense:					
Interest income	3,616	2,693	2,574	2,517	11,400
Interest expense	(4,226)	(4,243)	(2,436)	(2,851)	(13,756)
Other expense, net	(164)	(666)	(641)	(118)	(1,589)
Total Other Expense	<u>(774)</u>	<u>(2,216)</u>	<u>(503)</u>	<u>(452)</u>	<u>(3,945)</u>
Income (Loss) Before Income Taxes	30,717	1,635	112,385	(13,725)	131,012
Income Tax Provision (Benefit)	1,030	(63)	(330)	(130)	507
Net Income (Loss)	<u>\$ 29,687</u>	<u>\$ 1,698</u>	<u>\$ 112,715</u>	<u>\$ (13,595)</u>	<u>\$ 130,505</u>

Earnings (Loss) Per Common Share:

Basic	<u>\$ 0.31</u>	<u>\$ 0.02</u>	<u>\$ 1.18</u>	<u>\$ (0.14)</u>	<u>\$ 1.37</u>
Diluted	<u>\$ 0.31</u>	<u>\$ 0.02</u>	<u>\$ 1.18</u>	<u>\$ (0.14)</u>	<u>\$ 1.36</u>

Weighted Average Number of Common Shares Outstanding:

Basic	<u>95,361</u>	<u>95,637</u>	<u>95,316</u>	<u>94,898</u>	<u>95,161</u>
Diluted	<u>96,631</u>	<u>97,356</u>	<u>95,818</u>	<u>94,898</u>	<u>96,252</u>

Source: Alkermes, Inc.

Alkermes, Inc.

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