Alkermes Reports Second Quarter Fiscal 2006 Financial Results; Company Reports Profitable Quarter; Financial Expectations for Fiscal 2006 Improve

November 3, 2005

CAMBRIDGE, Mass.--(BUSINESS WIRE)--Nov. 3, 2005--Alkermes, Inc. (Nasdaq: ALKS) today announced financial results for the second fiscal quarter ended September 30, 2005. The net income on a GAAP basis for the quarter was $11.8 million or $0.13 per share as compared to a net loss of $14.3 million or $0.16 per share for the quarter ended September 30, 2004.

Alkermes reported a profitable quarter, driven by an increase in total revenues, which included the recognition of net collaborative profit related to work performed on the VIVITREX(R) (naltrexone long-acting injection) program, the receipt of a milestone payment of $9 million from Eli Lilly and Company (Lilly) in conjunction with the initiation of the Phase III clinical program for the Lilly/Alkermes inhaled insulin system (AIR(R) insulin) and royalty and manufacturing revenue related to RISPERDAL CONSTA(R).

"The Company's financial performance this quarter demonstrates that the fundamental elements are in place to build Alkermes into a profitable growth company," stated James Frates, chief financial officer of Alkermes.

Recent highlights for the Company include the following:

- Alkermes and Amylin Pharmaceuticals, Inc. (Amylin) entered into an agreement for the construction of a manufacturing facility, and related technology transfer, to enable Amylin to manufacture exenatide LAR. Under the terms of the agreement, Amylin will own the manufacturing facility, will be responsible for all costs associated with the manufacturing facility and will manufacture the once weekly formulation of exenatide LAR for commercial sale, if approved. Alkermes will oversee the design, construction and validation of the manufacturing facility and will receive royalty payments based on net product sales. In August 2005, Alkermes, Amylin and Lilly announced positive results from the ongoing Phase II multi-dose study of exenatide LAR. The study showed that exenatide LAR was well tolerated and improved glucose levels in patients with type 2 diabetes.
- Pursuant to a 2002 agreement under which Lilly purchased $30 million of Alkermes convertible preferred stock, Alkermes exercised its option to convert $15 million of the convertible preferred stock owned by Lilly into 823,677 shares of Alkermes common stock, which represents less than 1% of the Company's 90.6 million shares outstanding at September 30, 2005. This conversion secures an incremental increase in royalty payable to Alkermes on potential future revenues from AIR insulin, currently being developed by Alkermes with Lilly.
- Alkermes' Board of Directors has authorized a share repurchase program of up to $15 million dollars of common stock in the open market or through privately negotiated transactions to offset any dilutive impact of the Lilly preferred stock conversion. The repurchase plan may commence immediately and has no set expiration date. The Company expects to make the repurchases at the discretion of management from time to time depending on market conditions. The repurchase authorization may be suspended or discontinued at any time.
- The United States Food and Drug Administration (FDA) extended the action date for its priority review of the New Drug Application (NDA) for VIVITREX to December 30, 2005. Alkermes and Cephalon continue to anticipate the launch of VIVITREX in the first half of 2006.

"We have focused on key strategic initiatives that we believe can create long-term value for the Company and its shareholders. We recently entered into an agreement related to the manufacture of exenatide LAR by Amylin, and we secured a higher royalty rate for AIR insulin," stated Richard Pops, chief executive officer of Alkermes. "As we move into the last part of the calendar year, we look forward to a response from the FDA on VIVITREX, continued revenue growth from RISPERDAL CONSTA and continued progress in our development programs for AIR insulin and exenatide LAR."

Pro Forma Results

Pro forma net income for the quarter ended September 30, 2005 was $11.7 million or $0.13 per share as compared to a pro forma net loss of $14.9 million or $0.16 per share for the same period in 2004.

Alkermes is providing pro forma net income and net loss as a complement to results provided in accordance with generally accepted accounting principles in the U.S. (known as GAAP). The pro forma net income and net loss exclude certain recurring items including: noncash derivative income and loss on the Company's outstanding convertible notes, which are likely to recur either as income or loss depending on a number of factors, including the Company's common stock price at the end of each quarter; and noncash income or expense recognized on the net change in the fair value of warrants of publicly traded companies held in connection with collaboration and licensing arrangements. Alkermes' management believes this pro forma measure helps indicate underlying trends in the Company's ongoing operations by excluding the potentially volatile noncash derivative and warrant items that are unrelated to its ongoing operations.

The pro forma net income for the quarter ended September 30, 2005 excludes: (i) $0.5 million of noncash derivative loss associated with the provisional call structure of the Company's 2 1/2% convertible subordinated notes due 2023 issued in August and September 2003; and (ii) $0.6

million of other noncash income recognized on the net increase in the fair value of warrants of publicly traded companies held in connection with certain collaboration and licensing arrangements. The pro forma net loss for the quarter ended September 30, 2004 excludes: (i) $1.2 million of noncash derivative income associated with the provisional call structure of the Company's 2 1/2% convertible subordinated notes due 2023 issued in August and September 2003; and (ii) $0.6 million of other noncash expense recognized on the net decrease in the fair value of warrants of publicly traded companies held in connection with collaboration and licensing arrangements.

Revenues

Total revenues were $46.7 million for the quarter ended September 30, 2005 as compared to $18.0 million for the same period in 2004.

Manufacturing revenues were $13.6 million for the quarter ended September 30, 2005 as compared to $7.7 million for the same period in 2004, all of which related to RISPERDAL CONSTA. The increase in manufacturing revenues was due to increased shipments of RISPERDAL CONSTA to Janssen-Cilag (Janssen), a wholly-owned division of Johnson & Johnson. Total royalty revenues were $4.0 million for the quarter ended September 30, 2005 as compared to $2.2 million for the same period in 2004, of which $4.0 million and $2.1 million, respectively, were related to RISPERDAL CONSTA. The increase in royalty revenues for the quarter ended September 30, 2005 as compared to the same period in 2004 was due to an increase in global sales of RISPERDAL CONSTA by Janssen.

Research and development revenue under collaborative arrangements for the quarter ended September 30, 2005 was $16.7 million as compared to $8.1 million for the same period in 2004. The increase was primarily due to a $9.0 million milestone payment paid by Lilly in conjunction with the start of the Phase III clinical development program for AIR insulin.

Net collaborative profit related to the VIVITREX collaboration with Cephalon was $12.4 million for the quarter ended September 30, 2005. This consists of $13.6 million of milestone revenue recognized to offset expenses incurred on the product by both Alkermes and Cephalon, less $1.2 million of payments made to Cephalon to reimburse its expenses relating to the product. Alkermes did not record any net collaborative profit in the quarter ended September 30, 2004.

Cost of Goods Manufactured

For the quarter ended September 30, 2005, the cost of goods manufactured was $4.4 million as compared to $2.4 million for the same period in 2004, all of which related to RISPERDAL CONSTA. The increase in cost of goods manufactured was due to increased manufacturing volumes of RISPERDAL CONSTA to meet increased demand for the product.

Research and Development Expenses

Research and development expenses were $19.4 million for the quarter ended September 30, 2005 as compared to $22.6 million for the same period in 2004, reflecting the completion of certain VIVITREX clinical trials in the previous fiscal year, and the fact that certain VIVITREX raw materials to be used in commercial manufacturing are now being capitalized to inventory, rather than being expensed to R&D.

Selling, General and Administrative Expenses

Selling, general and administrative expenses were $9.1 million for the quarter ended September 30, 2005 as compared to $7.4 million for the same period in 2004, reflecting an increase in selling and marketing costs as the Company prepares for the potential future commercialization of VIVITREX.

Interest Income/Expense

Interest income for the quarter ended September 30, 2005 was $3.0 million, as compared to $0.7 million for the same period in 2004. The increase in interest income was primarily the result of higher average cash and investment balances held during the quarter ended September 30, 2005 as compared to the same period in 2004. Interest expense was $5.2 million for the quarter ended September 30, 2005 as compared to $1.2 million for the same period in 2004. The increase in interest expense was primarily the result of interest expense related to the issuance in February 2005 of the Non-recourse Risperdal Consta Secured 7% Notes.

Cash and Investments

At September 30, 2005, Alkermes had cash and total investments of $341.3 million as compared to $343.5 million at June 30, 2005.

Financial Expectations

The following outlines the Company's financial expectations for the fiscal year ending March 31, 2006. 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 our actual results to differ materially from the Company's expectations, please see risk factors provided at the end of this press release and within reports filed by Alkermes with the Securities and Exchange Commission under the Securities Exchange Act of 1934, as amended, including the annual report on Form 10-K for the year ended March 31, 2005.

Alkermes today revised its financial expectations for the fiscal year 2006 due to an expected increase in net collaborative profit related to the collaboration with Cephalon for the commercialization of VIVITREX and additional interest income related to higher average cash and investment balances and higher interest rates.

Revenues: The Company is increasing its expectation for total revenue for fiscal 2006 to a range of $150 to $170 million, revised from earlier expectations of $140 to $165 million. The Company expects manufacturing and royalty revenue related to RISPERDAL CONSTA and VIVITREX to remain in the range of $85 to $95 million. The Company expects R&D revenues to remain in the range of $35 to $40 million. The Company is raising its expectation for net collaborative profit from a range of $20 to $30 million to a range of $30 to $35 million due to an increase in milestone revenue to offset expenses for work performed by Alkermes on the VIVITREX program.

Cost of Goods Manufactured: The Company's expectation for cost of goods manufactured for fiscal 2006 remains in the range of $33 to $38 million.

Research and Development Expenses: The Company's expectation for research and development expenses for fiscal 2006 remains in the range of $80 to $90 million.

Selling, General and Administrative Expenses: The Company's expectation for selling, general and administrative expenses for fiscal 2006 remains in the range of $45 to $50 million.

Operating Loss: The Company is improving its expectation for operating loss (loss before net interest expense, other income (expense) and derivative (loss) income related to convertible subordinated notes) for fiscal 2006 from a range of $13 to $18 million to a range of $3 to $8 million.

Net Interest Expense: The Company is reducing its expectation for net interest expense for fiscal 2006 from a range of $12 to $17 million to a range of $10 to $15 million based on additional interest income that it expects to generate from higher cash and investment balances and higher interest rates.

Pro forma Net Loss: Alkermes is improving its expectation for pro forma net loss for fiscal year 2006 from a range of $25 to $35 million, or approximately $0.27 to $0.38 per share, to a range of $13 to $23 million, or approximately $0.14 to $0.25 per share. The basic pro forma net loss per share calculation is based on an estimated 92 million shares of the Company's common stock outstanding on a weighted average basis for fiscal 2006.

Capital Expenditures: The Company continues to expect capital expenditures to be approximately $35 million.

Conference Call

Alkermes will host a conference call at 4:30 pm ET on November 3, 2005 to discuss these financial results and provide an update on the Company. The conference call may be accessed by dialing 1-866-814-8476 (domestic callers) and 1-703-639-1370 (international callers). The conference call ID number is 799078. In addition, the call will be webcast on the investor relations section of Alkermes' website at www.alkermes.com and archived on the site until Tuesday, November 8, 2005 at 5:00 pm ET. A replay of the conference call will be available from 7:30 p.m. ET on November 3, 2005 through 5:00 p.m. ET on November 8, 2005, and may be accessed by visiting Alkermes' website or by dialing 1-888-266-2081 (domestic callers) and 1-703-925-2533 (international callers). The replay access code is 799078.

About Alkermes

Alkermes, Inc. is a pharmaceutical company that develops products based on sophisticated drug delivery technologies to enhance therapeutic outcomes in major diseases. The Company's lead commercial product, RISPERDAL CONSTA(R) ((risperidone) long-acting injection), is the first and only long-acting atypical antipsychotic medication approved for use in schizophrenia, and is marketed worldwide by Janssen-Cilag (Janssen), a wholly-owned division of Johnson & Johnson. The Company's lead proprietary product candidate, VIVITREX(R) (naltrexone long-acting injection), is a once-a-month injection for the treatment of alcohol dependence. The Company has a pipeline of extended-release injectable products and pulmonary drug products based on its proprietary technology and expertise. Alkermes' product development strategy is twofold: the Company partners its proprietary technology systems and drug delivery expertise with several of the world's finest pharmaceutical companies; and it also develops novel, proprietary drug candidates for its own account. The Company's headquarters are in Cambridge, Massachusetts, and it operates research and manufacturing facilities in Massachusetts and 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 and profitability; the successful registration, launch and commercialization of VIVITREX; recognition of milestone payments from Cephalon related to the approval and future manufacture and sale of VIVITREX; continued revenue growth from RISPERDAL CONSTA; the successful continuation of development activities for our programs, including exenatide LAR and AIR insulin; the manufacture of exenatide LAR by Amylin; and the intent of management to repurchase Alkermes common shares in the open market. 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 can continue to manufacture RISPERDAL CONSTA on a commercial scale or economically or in sufficient quantities to supply the market; whether RISPERDAL CONSTA will continue to be commercialized successfully by our partner Janssen; whether the Company can successfully scale up and manufacture VIVITREX at a commercial scale; whether VIVITREX will ultimately receive marketing approval, and, if approved, whether it will be launched and commercialized successfully by Alkermes and its partner, Cephalon; whether the Company is able to successfully and efficiently manufacture its other commercial products and scale-up its product candidates; whether advancement of the Company's product pipeline, including exenatide LAR and AIR insulin, 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, including the results of clinical trials; decisions by the FDA or foreign regulatory authorities regarding the Company's product candidates, which may be based on interpretations of data that differ from our own interpretations; the Company's ability to transfer manufacturing technology to Amylin and Amylin's ability to successfully operate the manufacturing facility for exenatide LAR; potential changes in cost, scope and duration of clinical trials; and whether RISPERDAL CONSTA, VIVITREX and our 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 our products from the market; and whether the Company will actually purchase all shares for which it has authorization, or the timing or prices of such purchases. 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.

(table follows)

Alkermes, Inc. and Subsidiaries
Selected Financial Information

Condensed Consolidated Statements of Operations (Unaudited) (In thousands, except per share data)	Three Months Ended Sept. 30, 2005	Three Months Ended Sept. 30, 2004

Revenues:		
Manufacturing and royalty revenues	$17,561	$9,938
Research and development revenue under collaborative arrangements	16,733	8,096
Net collaborative profit	12,394	-
Total Revenues	46,688	18,034
Expenses:		
Cost of goods manufactured	4,360	2,390
Research and development	19,370	22,589
Selling, general and administrative	9,109	7,379
Total Expenses	32,839	32,358
Operating Income (Loss)	13,849	(14,324)
Other Income (Expense):		
Interest income	3,019	660
Other income (expense), net	599	(585)
Derivative (loss) income related to convertible subordinated notes	(503)	1,172
Interest expense	(5,212)	(1,187)
Total Other Income (Expense)	(2,097)	60
Net Income (Loss)	$11,752	($14,264)
Earnings (Loss) per Common Share:		
Basic	$0.13	($0.16)
Diluted	$0.12	($0.16)
Weighted Average Number of Common Shares Outstanding (GAAP and Pro Forma):		
Basic	90,558	90,067
Diluted	96,559	90,067
Pro Forma Reconciliation:		
Net Income (Loss)-GAAP	$11,752	($14,264)
Other (income) expense, net	(560)	585
Derivative (income) loss related to convertible subordinated notes	503	(1,172)
Net Income (Loss)-Pro Forma	$11,695	($14,851)
Pro Forma Earnings (Loss) per Common Share:		
Basic	$0.13	($0.16)
Diluted	$0.12	($0.16)

Condensed Consolidated Balance Sheets

(Unaudited) (In thousands)	Sept. 30, 2005	March 31, 2005
Cash, cash equivalents and total investments	$341,262	$207,470
Receivables, prepaid expenses and other		

current assets	27,581	21,395
Inventory	7,711	3,766
Property, plant and equipment, net	100,890	95,188
Other assets	11,100	11,055
Total Assets	$488,544	$338,874
Unearned milestone revenue - current portion	$100,132	$-
Other current liabilities	25,721	23,668
Non-recourse Risperdal Consta Secured 7% Notes	152,157	150,730
Other long-term debt	125,548	125,755
Unearned milestone revenue - long-term portion	46,280	-
Other long-term liabilities	4,535	4,609
Convertible preferred stock	30,000	30,000
Total shareholders' equity	4,171	4,112
Total Liabilities and Shareholders' Equity	$488,544	$338,874

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, 2005 and the Company's report on Form 10-Q for the three months ended September 30, 2005.

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SOURCE: Alkermes, Inc.