Alkermes Reports Financial Results for Second Quarter of Fiscal 2005

November 4, 2004

CAMBRIDGE, Mass.--(BUSINESS WIRE)--Nov. 4, 2004--Alkermes, Inc. (NASDAQ:ALKS) today reported its financial results for the quarter ended September 30, 2004. The net loss on a GAAP basis for the quarter ended September 30, 2004 was $14.3 million or $0.16 per share as compared to a net loss of $26.2 million or $0.31 per share for the same period in 2003. The decrease in the net loss for the quarter ended September 30, 2004 as compared to the same period in 2003 was the result of an increase in revenues related to the Company's AIR(R) insulin and AIR human growth hormone ("hGH") development programs, as well as an increase in revenues related to Risperdal(R) Consta(TM).

"This was a very successful quarter for us as Risperdal Consta continued its strong growth, providing a key driver for our goal of profitability," commented Richard Pops, chief executive officer of Alkermes. "In addition, we continue to make significant progress toward achieving key milestones across our pipeline. Our diabetes franchise is advancing in the clinic, and we remain on track to file a New Drug Application with the FDA for Vivitrex(R) in the first half of the next calendar year."

Recent Highlights

In August 2004, Alkermes announced that Eli Lilly and Company ("Lilly") made a positive product decision to proceed with significant investment for the further development of an inhaled formulation of insulin. The decision followed the successful execution of several critical steps, including the completion and analysis of data from a Phase 2 study, the achievement of commercial manufacturing powder production scale-up, and the development and testing of the commercial pulmonary insulin inhaler system.

In November 2004, Alkermes, along with partners Amylin Pharmaceuticals, Inc. and Lilly, made the decision to initiate a Phase 2 multi-dose study of exenatide LAR (long-acting release) in type 2 diabetes patients using a once-a-week dosing regimen. The multi-dose study is expected to begin in the first quarter of calendar 2005. Data from the ongoing Phase 2 single-dose study have demonstrated sustained release of exenatide with no dose-limiting side effects.

Pro Forma Results

Pro forma net loss for the quarter ended September 30, 2004, was $14.9 million or $0.16 per share as compared to a pro forma net loss of $26.4 million or $0.31 per share for the same period in 2003.

Alkermes is providing pro forma 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 loss excludes certain recurring items, including noncash derivative gains and losses on the Company's outstanding convertible notes, which are likely to recur either as gains or losses depending on a number of factors, including the Company's common stock price at the end of each quarter, and noncash gains or losses recognized on the net change in the fair value of warrants of publicly traded companies held in connection with collaboration and licensing arrangements. 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 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. The pro forma net loss for the quarter ended September 30, 2003 excludes: (i) a $0.9 million noncash derivative loss associated with the provisional call structure of the Company's 2 1/2% convertible subordinated notes; and (ii) $1.1 million of other noncash income recognized on the net increase in the fair value of warrants of publicly traded companies held in connection with collaboration and licensing arrangements.

Revenues

Total revenues were $18.0 million for the quarter ended September 30, 2004 as compared to $7.5 million for the same period in 2003.

Manufacturing revenues were $7.7 million for the quarter ended September 30, 2004, all related to Risperdal Consta, as compared to $4.6 million for the same period in 2003, of which $4.5 million related to Risperdal Consta. The increase in manufacturing revenues was due to increased shipments of Risperdal Consta to Janssen-Cilag ("Janssen"), a wholly owned subsidiary of Johnson & Johnson. Risperdal Consta is marketed in more than 35 countries.

Total royalty revenues were $2.2 million for the quarter ended September 30, 2004 as compared to $0.7 million for the same period in 2003, including $2.1 million and $0.5 million, respectively, of royalty revenues for Risperdal Consta. The increase in royalty revenues for the quarter ended September 30, 2004 as compared to the same period in 2003 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, 2004 was $8.1 million as compared to $2.1 million for the same period in 2003. The increase was primarily due to an increase in revenues related to work performed on the AIR insulin and AIR hGH programs, in addition to the work performed on several other collaborative programs. As of September 30, 2004, Alkermes had spent the full $30 million in funding received in connection with the purchase of the Company's Convertible

Preferred Stock by Lilly in December 2002, relating to the AIR insulin and AIR hGH development programs. Therefore, beginning in the quarter ended

June 30, 2004 for the AIR hGH program and beginning in the quarter ended September 30, 2004 for the AIR insulin program, the Company recorded revenue for work performed on these programs.

Cost of Goods Manufactured

For the quarter ended September 30, 2004, the cost of goods manufactured was $2.4 million, all of which related to Risperdal Consta, as compared to $4.6 million in the same period in 2003, consisting of approximately $3.5 million for Risperdal Consta and $1.1 million for Nutropin Depot(R). The decrease in cost of goods manufactured for the quarter ended September 30, 2004 as compared to the same period last year was primarily the result of manufacturing efficiencies and increased volumes that resulted in a lower per unit cost for Risperdal Consta, as well as the June 2004 decision to discontinue commercialization of Nutropin Depot. The Company's per unit cost for Risperdal Consta will fluctuate from quarter to quarter.

Research and Development Expenses

Research and development expenses were $22.6 million for the quarter ended September 30, 2004 as compared to $23.4 million for the same period in 2003. The decrease was primarily due to a decrease in external research costs related to the clinical trials of Vivitrex, partially offset by increases in personnel costs related to the Company's proprietary and collaborator product candidates and increases in occupancy costs.

Sales, General and Administrative Expenses

Sales, general and administrative expenses were $7.4 million for the quarter ended September 30, 2004 as compared to $5.9 million for the same period in 2003, reflecting an increase in personnel-related costs, especially within sales and marketing as the Company prepares for commercialization of Vivitrex, as well as legal costs associated with the pending securities litigation, as described in the Company's condensed consolidated financial statements on Form 10-Q for the quarter ended June 30, 2004.

Cash and Investments

At September 30, 2004, Alkermes had cash and total investments of $102.8 million as compared to $126.9 million at June 30, 2004. The decrease in cash and total investments during the quarter ended September 30, 2004 was primarily a result of cash used to fund Alkermes' operations and to acquire fixed assets.

Guidance

The following outlines the Company's financial expectations for the fiscal year ending March 31, 2005. 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 actual results to differ 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.

In October 2004, Alkermes and Serono discontinued the development of a sustained-release version of recombinant human follicle stimulating hormone ("r-hFSH") for the treatment of infertility. As a result of this decision, Alkermes is reducing its guidance for research and development revenues by $5 million.

Revenues: Alkermes' expectations for manufacturing revenues for fiscal 2005 remain in the range of $38 to $46 million and the expectations for royalty revenues remain in the range of $7 to $9 million. Alkermes is reducing its guidance for research and development revenues from a range of $45 to $65 million to a range of $40 to $60 million as a result of the decision to discontinue development of r-hFSH. This guidance for research and development revenues includes anticipated revenue of between $15 and $30 million for a partnering transaction with respect to Vivitrex. With this adjustment, Alkermes' total revenues are now expected to range from $85 to $115 million, revised from earlier expectations of $90 to $120 million.

Cost of Goods Manufactured: Alkermes' expectations for cost of goods manufactured for fiscal 2005 remain in the range of $19 to $23 million.

Research and Development Expenses: The Company's expectations for research and development expenses for fiscal 2005 remain in the range of $84 to $94 million.

Sales, General and Administrative Expenses: The Company's expectations for sales, general and administrative expenses for fiscal 2005 remain in the range of $29 to $33 million.

Net Loss: Alkermes' net loss for fiscal 2005 on a pro forma basis, excluding any restructuring charges and noncash derivative items, is expected to be in the range of $40 to $50 million or approximately $0.44 to $0.56 per share. The net loss per share calculation is based on an estimated 90 million shares of the Company's common stock outstanding on a weighted average basis.

Alkermes will host a conference call at 4:30 pm EST on November 4, 2004 to discuss these financial results and provide an update on the Company. The call will be webcast on the investor relations section of Alkermes' website at www.alkermes.com and will be archived until Tuesday, November 9, 2004 at 5:00 pm EST.

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(R) Consta(TM) ((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 subsidiary 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 operating results; the successful completion of development activities for the Company's programs, including clinical, regulatory and manufacturing development of AIR insulin, exenatide LAR and Vivitrex; and the potential

commercial launch of Vivitrex. 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: whether manufacturing and royalty revenues for Risperdal Consta will generate significant revenues, particularly because the Company relies on its partner to market this product; whether additional regulatory approvals will be received or whether additional commercial launches of Risperdal Consta in countries where it has been or may be approved occur in a timely and successful manner; whether or not regulatory authorities will accept the Company's Vivitrex submission and approve the product for sale; whether the Company enters into any collaboration with a third party to market or fund Vivitrex or its other proprietary product candidates and whether the terms of such a collaboration meet expectations; whether the Company is able to file an NDA for Vivitrex in the first half of 2005 and whether the FDA accepts the filing; whether the Company and/or its collaborator will be able to successfully launch and commercialize Vivitrex; whether the Company is able to successfully and efficiently manufacture its commercial products and scale-up its product candidates; whether the securities litigation brought against the Company will result in financial losses or require the dedication of significant management resources; and whether advancement of the Company's product pipeline 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 is 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 its interpretations; and potential changes in cost, scope and duration of clinical trials. For further information with respect to factors that could cause the Company's actual results to differ 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 guidance contained in this release.

Alkermes, Inc. and Subsidiaries
Selected Financial Information
(In thousands, except per share data)

Condensed Consolidated Statements of Operations (Unaudited)	Three Months Ended September 30, 2004	Three Months Ended September 30, 2003
Revenues:		
Manufacturing and royalty revenues	$9,938	$5,310
Research and development revenue under collaborative arrangements	8,097	2,140
Total Revenues	18,035	7,450
Expenses:		
Cost of goods manufactured	2,390	4,567
Research and development	22,590	23,404
Sales, general and administrative	7,379	5,918
Total Expenses	32,359	33,889
Net Operating Loss	(14,324)	(26,439)
Other Income (Expense):		
Interest income	660	668
Other (expense) income, net	(585)	1,098
Derivative income (losses) related to convertible notes	1,172	(900)
Interest expense	(1,187)	(647)
Total Other Income (Expense)	60	219
Net Loss	($14,264)	($26,220)
Net Loss Per Common Share, Basic and Diluted	($0.16)	($0.31)
Weighted Average Number of Common Shares Outstanding, Basic and Diluted	90,067	84,984

Pro Forma Reconciliation:

Net Loss-GAAP	($14,264)	($26,220)
Other expense (income), net	585	(1,098)
Derivative (income) losses related to convertible notes	(1,172)	900
Net Loss-Pro Forma	($14,851)	($26,418)
Net Loss Per Common Share, Basic and Diluted -Pro Forma	($0.16)	($0.31)
Weighted Average Number of Common Shares Outstanding, Basic and Diluted	90,067	84,984

Condensed Consolidated Balance Sheets (Unaudited)	September 30, 2004	March 31, 2004
Cash, cash equivalents and total investments	$102,757	$148,948
Receivables, prepaid expenses and other current assets	11,241	13,682
Inventory	2,919	2,605
Property, plant and equipment, net	90,300	95,743
Other assets	7,055	9,052
Total Assets	$214,272	$270,030
Total current liabilities	$32,195	$41,516
Accrued restructuring costs	2,444	-
Obligation under capital lease	294	338
Convertible subordinated notes	122,634	122,246
Convertible preferred stock	30,000	30,000
Total shareholders' equity	26,705	75,930
Total Liabilities and Shareholders' Equity	$214,272	$270,030

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, 2004 and the Company's Form 10-Q for the three months ended September 30, 2004.

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