Alkermes Reports Financial Results for First Quarter of Fiscal 2005

August 5, 2004

CAMBRIDGE, Mass.--(BUSINESS WIRE)--Aug. 5, 2004--Alkermes, Inc. (NASDAQ:ALKS) today reported its financial results for the three-month period ended June 30, 2004. The net loss on a GAAP basis for the quarter ended June 30, 2004 was $36.1 million or $0.40 per share as compared to a net loss of $30.6 million or $0.47 per share for the three months ended June 30, 2003. Included in the net loss for the three months ended June 30, 2004 were restructuring charges of $11.9 million, related to the decision by Alkermes and Genentech to discontinue commercialization of Nutropin Depot(R).

Pro Forma Results

Pro forma net loss for the three months ended June 30, 2004, was $25.5 million or $0.29 per share as compared to a pro forma net loss of $28.2 million or $0.44 per share for the quarter ended June 30, 2003. The decrease in the pro forma net loss for the three months ended June 30, 2004 as compared to the corresponding period in 2003, was the result of an increase in revenues, related primarily to Risperdal(R) Consta(TM), partially offset by higher operating expenses.

Alkermes is providing pro forma net loss as a complement to results provided in accordance with accounting principles generally accepted in the U.S. (known as "GAAP"). The pro forma net loss excludes certain recurring items, including restructuring charges, 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 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. Management believes this pro forma measure helps indicate underlying trends in the Company's ongoing operations by excluding the restructuring and the potentially volatile noncash derivative and warrant items that are unrelated to its ongoing operations.

The pro forma net loss for the three months ended June 30, 2004 excludes (i) $11.9 million of restructuring charges related to the decision by Alkermes and Genentech to discontinue commercialization of Nutropin Depot; (ii) $1.5 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 (iii) $0.3 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 three months ended June 30, 2003 excludes (i) a $3.8 million noncash derivative loss associated with the provisional call structure of the Company's 6.52% Senior Notes; and (ii) $1.4 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 $11.5 million for the quarter ended June 30, 2004 as compared to $4.3 million for the three months ended June 30, 2003.

Total manufacturing and royalty revenues were $8.0 million and $1.5 million for the three months ended June 30, 2004 and 2003, respectively.

Total manufacturing revenues were $6.2 million and $1.0 million for the three months ended June 30, 2004 and 2003, respectively, including $6.2 million and $0.7 million, respectively, of manufacturing revenues for 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, following launch of the product in the U.S. in December 2003, as well as to supply product for additional countries around the world. Risperdal Consta is marketed in more than 35 countries. Under the Company's manufacturing and supply agreement with Janssen, Alkermes records manufacturing revenues upon shipment of product by Alkermes to Janssen based on a percentage of Janssen's net selling price. These percentages are based on the volume of units shipped to Janssen in any given calendar year, with a minimum manufacturing fee of 7.5%. The Company expects to earn manufacturing revenues at an average of 8.2% in the fiscal year ending March 31, 2005, as compared to 9.8% in the fiscal year ended March 31, 2004. As discussed below, in the quarter ended June 30, 2004, we ceased commercial production of Nutropin Depot and there were, therefore, no manufacturing revenues earned during the three months ended June 30, 2004 related to Nutropin Depot.

Total royalty revenues were $1.8 million and $0.6 million for the three months ended June 30, 2004 and 2003, respectively, including $1.7 million and $0.4 million, respectively, of royalty revenues for Risperdal Consta. The increase in royalty revenues for the three months ended June 30, 2004 as compared to the same period in 2003 was due to an increase in global sales of Risperdal Consta by Janssen. Under the Company's license agreements with Janssen, Alkermes records royalty revenues equal to 2.5% of Janssen's net sales of Risperdal Consta in the quarter in which the product is sold by Janssen.

Research and development revenue under collaborative arrangements for the three months ended June 30, 2004 was $3.5 million as compared to $2.8 million for the quarter ended June 30, 2003. The increase was primarily due to an increase in revenues earned related to work performed on the Eli Lilly and Company ("Lilly") AIR(R) human growth hormone ("hGH") program and to the work performed on several other collaborative programs. In December 2002, Alkermes and Lilly expanded the collaboration for the development of inhaled formulations of insulin and hGH based on the Company's AIR pulmonary drug delivery technology. At that time, Lilly purchased $30.0 million of Alkermes' convertible preferred stock, the proceeds from which represented $25.0 million and $5.0 million in funding for the Lilly insulin and Lilly hGH development programs, respectively, for the period starting January 1, 2003 and into calendar 2004. As a result of this transaction, the Company did not recognize research and development revenue related to work performed on the Lilly development programs while the proceeds from the sale of the convertible preferred stock were being spent. In December 2003, Lilly made additional payments to the Company totaling approximately $7.0 million in order to fund an increase in the scope of our joint development programs, $3.0 million of which represented funding for the Lilly insulin development program and the remaining $4.0 million represented funding for the Lilly hGH development program. The $7.0 million payment was recorded as deferred revenue in the consolidated balance

sheets in the quarter ended December 31, 2003. When the funding for a program provided for by the proceeds from the sale of convertible preferred stock has been spent, the Company will begin to recognize revenue on that program as work is performed. As of June 30, 2004, approximately $24.9 million of the $25.0 million of funding from the convertible preferred stock related to the Lilly insulin program had been spent and the entire $5.0 million of funding from the convertible preferred stock related to the Lilly hGH program had been spent. Thus, in the quarter ended June 30, 2004, the Company recognized revenue of approximately $0.9 million related to work performed on the hGH development program.

Cost of Goods Manufactured

For the three months ended June 30, 2004, the cost of goods manufactured was $5.2 million, consisting of approximately $2.9 million for Risperdal Consta and approximately $2.3 million for Nutropin Depot. Cost of goods manufactured was $2.6 million in the three months ended June 30, 2003, consisting of approximately $1.4 million for Risperdal Consta and $1.2 million for Nutropin Depot. The increase in cost of goods manufactured in the three months ended June 30, 2004 as compared to the corresponding period in 2003 was primarily the result of an increase in the production of Risperdal Consta for shipment to our partner, Janssen. In addition, on June 1, 2004, Alkermes and Genentech announced the decision to discontinue commercialization of Nutropin Depot. In connection with this decision, Alkermes ceased commercial manufacturing of Nutropin Depot and recorded a one time write-off of Nutropin Depot inventory of $1.3 million under the caption "cost of goods manufactured" in the consolidated statement of operations in the quarter ended June 30, 2004.

Research and Development Expenses

Research and development expenses were $24.1 million for the three months ended June 30, 2004 as compared to $21.7 million for the three months ended June 30, 2003. The increase was due primarily to an increase in personnel costs related to the Company's proprietary and collaborator product candidates, as well as to an increase in occupancy costs and depreciation expense related to the expansion of the Company's facilities in both Massachusetts and Ohio.

General and Administrative Expenses

General and administrative expenses were $7.0 million for the three months ended June 30, 2004 as compared to $5.8 million for the same period in 2003, reflecting an increase in personnel-related costs, notably 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 Note 16 to the consolidated financial statements on Form 10-K for the fiscal year ended March 31, 2004.

Restructuring

In June 2004, the Company announced a restructuring program in connection with the decision by Alkermes and Genentech to discontinue commercialization of Nutropin Depot. The decision was based on the significant resources required by both companies to continue manufacturing and commercializing the product. In connection with this decision, Alkermes ceased commercial manufacturing of Nutropin Depot in June 2004 and recorded restructuring charges in the quarter ended June 30, 2004 of approximately $11.9 million. The restructuring charges related primarily to facility closure costs, including fixed asset write-offs and estimates of future lease costs relating to the Company's ability to sublease the exited facility through the end of its lease term in August 2008.

Interest Income/Expense

Interest income for the three months ended June 30, 2004 was $0.6 million as compared to $1.0 million for the three months ended June 30, 2003. The decrease in interest income was primarily the result of lower average cash and investment balances held during the three months ended June 30, 2004 as compared to the corresponding period in 2003. Interest expense was $1.2 million for the three months ended June 30, 2004 as compared to $3.5 million for the same period in the prior year. The decrease in interest expense was primarily the result of a decrease in the average outstanding debt balance and a lower interest rate payable on the convertible debt outstanding during the respective periods.

Other (Expense) Income, Net

Other (expense) income, net was an expense of $0.3 million in the three months ended June 30, 2004 as compared to an income of $1.4 million for the three months ended June 30, 2003. This amount represents the expense or income recognized on the net changes in the fair value of warrants of public companies, held by the Company in connection with collaboration and licensing arrangements, which are recorded as derivatives in the consolidated balance sheets. The recorded value of such warrants can fluctuate significantly based on fluctuations in the market value of the underlying securities of the issuer of the warrants.

Cash and Investments

At June 30, 2004, Alkermes had total cash and investments of $126.9 million as compared to $148.9 million at March 31, 2004. The decrease in cash and total investments during the three months ended June 30, 2004 was primarily a result of cash used to fund Alkermes' operations and to acquire fixed assets.

Alkermes will host a conference call at 4:30 pm EDT on August 5, 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, August 10, 2004 at 5:00 pm EDT.

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 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 and pulmonary drug products based on its proprietary technology and expertise, ProLease and Medisorb for extended-release of injectable drug products, and AIR for inhaled drug products. 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 and estimates relating to restructuring charges. 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 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 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 June 30, 2004	Three Months Ended June 30, 2003
Revenues:		
Manufacturing and royalty revenues	$7,965	$1,545
Research and development revenue under collaborative arrangements	3,509	2,757
Total Revenues	11,474	4,302
Expenses:		
Cost of goods manufactured	5,241	2,560
Research and development	24,132	21,673
General and administrative	7,039	5,781
Restructuring	11,896	-
Total Expenses	48,308	30,014
Net Operating Loss	(36,834)	(25,712)
Other Income (Expense):		
Interest income	630	975
Other (expense) income, net	(274)	1,409
Derivative income (losses) related to convertible notes	1,518	(3,764)
Interest expense	(1,188)	(3,480)
Total Other Income (Expense)	686	(4,860)
Net Loss	($36,148)	($30,572)
Basic and Diluted Loss Per Common Share	($0.40)	($0.47)
Weighted Average Number of Common Shares Outstanding	89,409	64,736
Pro Forma Reconciliation:		
Net Loss-GAAP	($36,148)	($30,572)

Restructuring	11,896	-
Other expense (income), net	274	(1,409)
Derivative (income) losses related to convertible notes	(1,518)	3,764
Net Loss-Pro Forma	($25,496)	($28,217)
Basic and Diluted Loss Per Common Share	($0.29)	($0.44)
Weighted Average Number of Common Shares Outstanding	89,409	64,736

Condensed Consolidated Balance Sheets (Unaudited)	Three Months Ended June 30, 2004	Three Months Ended March 31, 2004
Cash, cash equivalents and total investments	$126,913	$148,948
Receivables, prepaid expenses and other current assets	9,367	13,682
Inventory	2,043	2,605
Property, plant and equipment, net	88,826	95,743
Other assets	8,102	9,052
Total Assets	$235,251	$270,030
Total current liabilities	$41,938	$41,516
Obligation under capital lease	316	338
Convertible subordinated notes	122,440	122,246
Convertible preferred stock	30,000	30,000
Total shareholders' equity	40,557	75,930
Total Liabilities and Shareholders' Equity	$235,251	$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 report on Form 10-Q for the three months ended June 30, 2004.

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SOURCE: Alkermes, Inc.