# Alkermes Reports Financial Results for Fiscal Year 2004

May 13, 2004

CAMBRIDGE, Mass.--(BUSINESS WIRE)--May 13, 2004--Alkermes, Inc. (NASDAQ:ALKS) today reported its financial results for the fiscal year ended March 31, 2004. The net loss on a GAAP basis for the fiscal year ended March 31, 2004 was $102.4 million or $1.25 per share as compared to a net loss of $106.9 million or $1.66 per share in the prior year. Included in the net loss for fiscal 2003 was a $94.6 million noncash charge related to the equity investment Alkermes made in Reliant Pharmaceuticals, LLC ("Reliant") in December 2001, as well as an $80.8 million noncash gain on the exchange of the Company's convertible notes in December 2002.

Pro Forma Results

Pro forma net loss for fiscal 2004 was $100.2 million or $1.22 per share compared to a pro forma net loss of $82.4 million or $1.28 per share for fiscal 2003. The increase in the pro forma net loss for fiscal 2004 compared to fiscal 2003 was the result of an increase in expenses primarily related to the manufacturing of Risperdal(R) Consta(TM) and external research costs related to the Phase III clinical trials for Vivitrex(R), the Company's proprietary product candidate for the treatment of alcohol dependence. The increase in pro forma net loss was also a result of a reduction in the research and development revenues reported in the year ended March 31, 2004 following the restructuring of the Company's collaboration with Eli Lilly and Company ("Lilly") in December 2002 to provide upfront funds for development activities in calendar 2003 and into 2004, and changes in the stage of several other collaborative agreements. This decrease in research and development revenues was offset by an increase in manufacturing and royalty revenues related to Risperdal Consta.

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 both non-recurring items (the noncash gain related to the convertible note exchange referred to above and noncash charges related to the Company's investment in Reliant) and recurring items (including restructuring charges and recoveries and noncash derivative 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. Management believes this pro forma measure helps indicate underlying trends in the Company's ongoing operations by excluding the non-recurring items as well as the potentially volatile, noncash derivative item that is unrelated to its ongoing operations.

The pro forma net loss for fiscal 2004 excludes (i) $4.5 million in noncash derivative charges associated with the provisional call structures of the Company's 6.52% convertible senior subordinated notes (the "6.52% Senior Notes") issued in December 2002 and the Company's 2 1/2% convertible subordinated notes due 2023 (the "2 1/2% Subordinated Notes") issued in August and September 2003; (ii) $2.1 million of other noncash income recognized on the net increase in the fair value of warrants of publicly traded companies held in connection with licensing arrangements and (iii) $0.2 million in restructuring recoveries. The pro forma net loss for fiscal 2003 excludes (i) the $80.8 million noncash gain related to the convertible note exchange referenced above; (ii) the $94.6 million noncash charge related to the Company's investment in Reliant, a specialty pharmaceutical company in which Alkermes holds an equity stake of approximately 12%; (iii) $6.5 million in restructuring charges and (iv) a $4.3 million noncash derivative charge associated with the provisional call structure of the Company's 6.52% Senior Notes.

Revenues

Total revenues were $39.1 million for the year ended March 31, 2004 compared with $47.3 million for the prior year.

Total manufacturing and royalty revenues were $29.5 million and $15.5 million for the fiscal years ended March 31, 2004 and 2003, respectively.

Total manufacturing revenues were $25.7 million and $14.3 million for the fiscal years ended March 31, 2004 and 2003, respectively, including $25.0 million and $13.0 million, respectively, of manufacturing revenues for Risperdal Consta. The increase in manufacturing revenues for the year ended March 31, 2004 compared to the year ended March 31, 2003 was primarily due to increased shipments of Risperdal Consta to Janssen-Cilag affiliated companies ("Janssen") for the U.S. launch of the product which occurred in December 2003 and to supply product for additional countries around the world. Risperdal Consta is marketed in more than 30 countries. Under the Company's manufacturing and supply agreement with Janssen, the Company 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%. In fiscal 2004, the Company's manufacturing revenues were based on an average of 9.8% of Janssen's net sales price for Risperdal Consta compared to 12.3% in fiscal 2003.

Total royalty revenues were $3.8 million and $1.2 million for the fiscal years ended March 31, 2004 and 2003, respectively, including $3.1 million and $0.4 million, respectively, of royalty revenues for Risperdal Consta. The increase in royalty revenues for fiscal 2004 compared to fiscal 2003 was due to an increase in global sales of Risperdal Consta by Janssen. Under the Company's license agreements with Janssen, the Company records royalty revenues equal to 2.5% of Janssen's net sales of Risperdal Consta in the quarter when the product is sold by Janssen.

Research and development revenue under collaborative arrangements for the year ended March 31, 2004 was $9.5 million compared to $31.8 million for the prior year. The decrease was primarily the result of the restructuring of the Company's AIR(R) insulin and AIR human growth hormone ("hGH") programs with Lilly, changes in the Company's partners, as well as changes in the stage of several other collaborative programs. Beginning January 1, 2003, Alkermes no longer records research and development revenue for work performed on the Lilly programs but instead uses the proceeds from Lilly's purchase of $30.0 million of the Company's convertible preferred stock in December 2002 to pay for development costs into calendar year 2004. Also, in December 2002, the royalty payable by Lilly to the Company based on revenues of potential inhaled insulin products was increased. Lilly has the right to return the convertible preferred stock to the Company in exchange for a reduction in this royalty rate. At March 31, 2004, approximately

$24.6 million of the proceeds from the sale of $30.0 million of the Company's convertible preferred stock had been 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 the Company's development programs with Lilly. This funding has been recorded as deferred revenue in the consolidated balance sheets and the Company expects to recognize the $7.0 million as revenue after the proceeds from the sale of $30.0 million of the Company's convertible preferred stock have been spent.

Cost of Goods Manufactured

Cost of goods manufactured was $19.0 million in fiscal 2004, consisting of approximately $13.0 million for Risperdal Consta and $6.0 million for Nutropin Depot(R). Cost of goods manufactured was $10.9 million in fiscal 2003, consisting of approximately $5.5 million for Risperdal Consta and $5.4 million for Nutropin Depot. The increase in cost of goods manufactured in fiscal 2004 compared to fiscal 2003 was primarily the result of an increase in production of Risperdal Consta for shipment to the Company's partner, Janssen.

Research and Development/General and Administrative Expenses

Research and development expenses were $91.1 million for the year ended ended March 31, 2004 compared to $85.4 million in the prior year. Research and development expenses were higher in the year ended March 31, 2004 primarily because of an increase in external research expenses related to both the continuing development of the Company's proprietary product candidates, primarily Vivitrex, and also its collaborator product candidates, as well as 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 were $26.0 million in fiscal 2004, compared to $26.7 million for fiscal 2003. Excluding the write off of $2.7 million in deferred merger costs in connection with the termination of the Company's proposed merger with Reliant in the year ended March 31, 2003, general and administrative expenses for the year ended March 31, 2004 were higher than in fiscal 2003 primarily as a result of an increase in personnel, consulting and insurance costs.

Interest Income/Expense

Interest income for the year ended March 31, 2004 was $3.4 million as compared with $3.8 million for the prior year. The decrease in interest income was primarily the result of a decline in interest rates on investments held during the year, partially offset by higher cash and investment balances held during the year ended March 31, 2004 compared to the year ended March 31, 2003. Interest expense was $6.5 million for the fiscal year ended March 31, 2004 compared to $10.4 million for the prior year. The decrease in interest expense was primarily the result of a decrease in the outstanding average debt balance as well as a lower interest rate payable on the convertible debt outstanding during fiscal 2004 as compared to fiscal 2003.

Cash and Investments

At March 31, 2004, Alkermes had total cash and investments of $148.9 million, as compared to $145.0 million at March 31, 2003.

Financial Expectations for Fiscal 2005

The following outlines the Company's financial expectations for the 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 our expectations, please see risk factors at the end of this press release and reports filed by Alkermes with the Securities and Exchange Commission under the Securities Exchange Act of 1934, as amended.

Revenues. The total revenue projections for Alkermes for the upcoming fiscal year range from $95 to $125 million.

Total manufacturing and royalty revenues are projected to range from $50 to $60 million for fiscal 2005.

The Company expects manufacturing revenues to range from $42 to $50 million. The projected increase in manufacturing revenues is mainly the result of an expected increase in shipments of Risperdal Consta. The revenues for Risperdal Consta are based on the Company's ability to manufacture sufficient quantities of Risperdal Consta to meet the estimates from our partner, who has the right to change the timing and amount of their purchases. In addition, the Company is renegotiating its manufacturing and supply agreement with Genentech, Inc. ("Genentech") with respect to Nutropin Depot to address recurring manufacturing losses associated with current volume levels. This expectation assumes a successful conclusion to these negotiations, although there can be no assurance that such negotiations will be successful.

The Company expects royalty revenues to range from $8 to $10 million. These targets assume continued revenue growth of Risperdal Consta in the U.S. following launch in December 2003 and also assume that further approvals and launches of Risperdal Consta continue as anticipated in the rest of the world. The Company relies on sales projections received from its partners to determine royalty revenue expectations and such projections may not turn out to be accurate.

The Company projects that research and development revenues will range from $45 to $65 million. This estimate includes anticipated revenue of between $15 and $30 million for a partnering deal with respect to Vivitrex. The Company is currently in discussions with interested parties and there can be no assurances of the outcome of these discussions at this time. The Company is also including research and development revenue for work performed on the Lilly programs after the proceeds from Lilly's purchase of $30 million of the Company's preferred stock in December 2002 to pay for development costs are fully used in fiscal 2005. This assumes a positive product decision on pulmonary insulin and the continued collaborative development of the Company's pulmonary hGH program. In addition, the estimate of research and development revenues assumes that certain milestones and other assumptions related to partnered programs will be achieved. Research and development revenues, which are received from our corporate partners, can fluctuate as our partners can terminate or change the scope or timing of the programs at any time.

Cost of Goods Manufactured. The Company's projections for cost of goods manufactured for fiscal 2005 range from $23 to $27 million. These costs are estimated based on projected orders from our partners for Risperdal Consta and Nutropin Depot and based on our historical yields. Orders from our partners are subject to change at any time.

Research and Development Expenses. The Company's projections for research and development expenses for fiscal 2005 range from $85 to $95 million. This expectation reflects our continuing efforts to advance our pipeline, notably our Vivitrex program, toward commercialization and our collaborations with Lilly for pulmonary insulin and hGH.

General and Administrative Expenses. The Company's projections for general and administrative expenses for fiscal 2005 range from $29 to $33

million. This increase is mainly a result of planned expenditures on sales and marketing infrastructure as the Vivitrex program advances toward commercialization, as well as expected increases in personnel and associated costs, insurance, legal and consulting costs in fiscal 2005.

Projected Net Loss. The Company anticipates recording a net loss of $35 to $45 million for the fiscal year ended March 31, 2005 or approximately $0.39 to $0.50 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, which excludes the potential conversion of the 2 1/2% Subordinated Notes. If the price of Alkermes' common stock closes at or above $20.78 for any 20 trading days out of a 30 trading day period, Alkermes has the right to automatically convert the outstanding $125 million of the 2 1/2% Subordinated Notes into its common stock. The projected net loss excludes any noncash gain or loss relating to the derivative associated with the 2 1/2% Subordinated Notes which cannot be estimated as it will fluctuate based on a number of factors, including Alkermes' common stock price at the end of each quarter, and the net loss also excludes noncash gains or losses on the fair value of warrants of publicly traded companies held in connection with licensing arrangements.

Capital. The Company anticipates that its capital expenditures for fiscal 2005 will be approximately $25 million, an increase from the $15 million spent during fiscal 2004. This increase reflects the Company's investment to expand its manufacturing infrastructure for Risperdal Consta, Exenatide LAR and Vivitrex in addition to continued improvements to its manufacturing and development facilities in Massachusetts and Ohio.

Finally, as Alkermes pipeline continues to mature and with the anticipated demand for Risperdal Consta, the Company continues to target profitability in late calendar year 2005.

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 Jannsen, 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. Alkermes has a pipeline of extended-release injectable and pulmonary drug products based on its proprietary technology and expertise. The company's headquarters are in Cambridge, Massachusetts, and it operates research and manufacturing facilities in Massachusetts and Ohio.

Certain statements set forth above are forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, including, but not limited to, statements concerning the achievement of certain business and operating milestones, future operating results, revenue projections, projections of costs of goods manufactured, projections of research and development expenses, projections of general and administrative expenses, projections of net loss and projections of capital expenditures. 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 are subject to significant risk and uncertainties that could cause our actual results to differ materially from our expectations. These include: whether manufacturing and royalty revenues for Risperdal Consta or the Company's other product will continue to grow, particularly because the Company relies on its partners to forecast and market these products; 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 we meet our timeline for filing an NDA for Vivitrex and whether or not regulatory authorities will accept our 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 its expectations; whether the Company is able to renegotiate the manufacturing and supply agreement with Genentech to cover manufacturing costs associated with current volume levels of Nutropin Depot and whether the terms of such renegotiation meet the Company's current expectations; whether the Company is successful in continuing the collaborative development of pulmonary insulin and hGH programs with Lilly and whether the terms of such continued collaborative development meet the Company's current expectations; whether the Company is able to successfully and efficiently manufacture its commercial products, add new production lines and scale-up its product candidates; whether the Company will get a return on its investment in Reliant; 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 pipeline will be delayed due to: actions or decisions by the Company's partners with regard to development and regulatory strategy, timing and funding which are out of the Company's 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 actual results to differ from expectations, reference is made to the reports filed by the Company with the Securities and Exchange Commission under the Securities Exchange Act of 1934, as amended, including the Company's Annual Report on Form 10-K. The forward-looking statements made in this release are made only as of the date hereof and Alkermes disclaims any intention or responsibility for updating predictions or financial expectations contained in this release.

Note: Alkermes will host a conference call at 4:30pm EDT on May 13, 2004. The call will be webcast on the investor relations section of Alkermes' website at www.alkermes.com and will be archived until Tuesday, May 18 at 5:00 pm EDT.

Alkermes, Inc. and Subsidiaries

| | Three Months Ended | | | | Year Ended |
|---|---|---|---|---|---|
| Quarterly Financial Data Fiscal 2004 (In thousands, except per share data) | June 30, 2003 | September 30, 2003 | December 31, 2003 | March 31, 2004 | March 31, 2004 |
| Revenues: | | | | | |
| Manufacturing | | | | | |

| | | | | | |
|---|---|---|---|---|---|
| and royalty revenues | $ 1,545 | $ 5,310 | $ 8,636 | $ 14,035 | $ 29,526 |
| Research and development revenue under collaborative arrangements | 2,757 | 2,140 | 2,585 | 2,046 | 9,528 |
| Total Revenues | 4,302 | 7,450 | 11,221 | 16,081 | 39,054 |
| Expenses: | | | | | |
| Cost of goods manufactured | 2,560 | 4,567 | 4,069 | 7,841 | 19,037 |
| Research and development | 21,673 | 23,404 | 21,148 | 24,872 | 91,097 |
| General and administrative | 5,781 | 5,918 | 6,538 | 7,792 | 26,029 |
| Restructuring | - | - | - | (208) | (208) |
| Total Expenses | 30,014 | 33,889 | 31,755 | 40,297 | 135,955 |
| Net Operating Loss | (25,712) | (26,439) | (20,534) | (24,216) | (96,901) |
| Other Income (Expense): | | | | | |
| Interest income | 975 | 668 | 957 | 809 | 3,409 |
| Other income, net | 1,409 | 1,098 | (746) | 357 | 2,118 |
| Derivative loss related to convertible subordinated notes | (3,764) | (900) | 650 | (500) | (4,514) |
| Interest expense | (3,480) | (647) | (1,190) | (1,180) | (6,497) |
| Total Other Income (Expense) | (4,860) | 219 | (329) | (514) | (5,484) |
| Net Loss | ($30,572) | ($26,220) | ($20,863) | ($24,730) | ($102,385) |
| Basic and Diluted Loss per Common Share | ($0.47) | ($0.31) | ($0.23) | ($0.28) | ($1.25) |
| Weighted Average Number of Common Shares Outstanding | 64,736 | 84,984 | 89,014 | 89,224 | 82,083 |

This quarterly financial data 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 which will be filed in June 2004.

Certain reclassifications have been made to the quarterly numbers to

reflect the presentation used for the year ended March 31, 2004.

Alkermes, Inc. and Subsidiaries
Selected Financial Information

| Condensed Consolidated Statements of Operations (Unaudited) (In thousands, except per share data) | Year Ended March 31, 2004 | Year Ended March 31, 2003 |
|---|---|---|
| Revenues: | | |
| Manufacturing and royalty revenues | $ 29,526 | $ 15,482 |
| Research and development revenue under collaborative arrangements | 9,528 | 31,784 |
| Total Revenues | 39,054 | 47,266 |
| Expenses: | | |
| Cost of goods manufactured | 19,037 | 10,910 |
| Research and development | 91,097 | 85,388 |
| General and administrative | 26,029 | 26,694 |
| Restructuring | (208) | 6,497 |
| Total Expenses | 135,955 | 129,489 |
| Net Operating Loss | (96,901) | (82,223) |
| Other Income (Expense): | | |
| Interest income | 3,409 | 3,776 |
| Other income, net | 2,118 | - |
| Gain on exchange of notes | - | 80,849 |
| Derivative loss related to convertible subordinated notes | (4,514) | (4,300) |
| Interest expense | (6,497) | (10,403) |
| Total Other Income (Expense) | (5,484) | 69,922 |
| Equity in Losses of Reliant Pharmaceuticals, LLC | - | (94,597) |
| Net Loss | ($102,385) | ($106,898) |
| Basic and Diluted Loss Per Common Share | ($1.25) | ($1.66) |
| Weighted Average Number of Common Shares Outstanding | 82,083 | 64,368 |
| | | |
| Pro Forma Reconciliation: | | |
| Net Loss-GAAP | ($102,385) | ($106,898) |
| Restructuring | (208) | 6,497 |
| Other income, net | (2,118) | - |
| Gain on exchange of notes | - | (80,849) |
| Derivative loss related to our convertible subordinated notes | 4,514 | 4,300 |
| Equity in Losses of Reliant Pharmaceuticals, LLC | - | 94,597 |
| Net Loss-Pro Forma | ($100,197) | ($82,353) |
| Basic and Diluted Loss Per Common Share | ($1.22) | ($1.28) |
| Weighted Average Number of Common Shares | | |

| | | |
|---|---|---|
| Outstanding | 82,083 | 64,368 |

Condensed Consolidated Balance Sheets
(Unaudited)

| | March 31, 2004 | March 31, 2003 |
|---|---|---|
| Cash, cash equivalents and total investments | $ 148,948 | $ 145,040 |
| Receivables, prepaid expenses and other current assets | 13,682 | 9,467 |
| Inventory | 2,605 | 2,576 |
| Property, plant and equipment, net | 95,743 | 91,474 |
| Other assets | 9,052 | 7,142 |
| Total Assets | $ 270,030 | $ 255,699 |
| Total current liabilities | $ 41,516 | $ 54,044 |
| Deferred revenue | - | 10,114 |
| Obligation under capital lease | 338 | - |
| Convertible subordinated notes | 122,246 | 166,587 |
| Convertible preferred stock | 30,000 | 30,000 |
| Total shareholders' equity (deficit) | 75,930 | (5,046) |
| Total Liabilities and Shareholders' Equity (Deficit) | $ 270,030 | $ 255,699 |

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 which will be filed in June 2004.

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SOURCE: Alkermes, Inc.