

U.S. SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

☒ QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the quarterly period ended June 30, 2002

☐ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from _____ to _____

Commission file number 0-19267

ALKERMES, INC.

(Exact name of registrant as specified in its charter)

PENNSYLVANIA

23-2472830

(State or other jurisdiction of
incorporation or organization)

(I.R.S. Employer
Identification No.)

88 Sidney Street, Cambridge, MA

02139-4136

(Address of principal executive offices)

(Zip Code)

Registrant's telephone number including area code: (617) 494-0171

64 Sidney Street, Cambridge, MA 02139-4136

(Former name, former address, and former fiscal year, if changed since last report)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate the number of shares outstanding of each of the issuer's classes of common stock, as of the latest practicable date.

Class	Shares Outstanding as of August 7, 2002
Common Stock, par value \$.01	64,312,182
Non-Voting Common Stock, par value \$.01	382,632

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PART I. FINANCIAL INFORMATION

Item 1. Consolidated Financial Statements:

ALKERMES, INC. AND SUBSIDIARIES

CONSOLIDATED BALANCE SHEETS (Unaudited)

	June 30, 2002	March 31, 2002
ASSETS		
Current Assets:		
Cash and cash equivalents	\$ 9,488,795	\$ 16,023,074
Short-term investments	100,338,942	136,323,768
Receivables from collaborative arrangements	19,501,908	19,039,706
Prepaid expenses and other current assets	5,647,655	5,249,797
Total current assets	134,977,300	176,636,345
Property, Plant and Equipment:		
Land	235,000	235,000
Building	5,076,961	5,058,936
Furniture, fixtures and equipment	51,274,335	49,558,745
Leasehold improvements	15,108,993	15,016,553
Construction in progress	41,245,053	26,497,064
	112,940,342	96,366,298
Less accumulated depreciation and amortization	(36,745,946)	(34,530,467)
	76,194,396	61,835,831
Investments	8,823,556	9,126,093
Investment in Reliant Pharmaceuticals, LLC	70,383,636	94,596,536
Other Assets	7,224,197	8,155,472
Total Assets	\$ 297,603,085	\$ 350,350,277
LIABILITIES AND SHAREHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable and accrued expenses	\$ 22,703,760	\$ 20,764,375
Accrued interest	2,881,226	1,013,521
Deferred revenue	6,807,177	7,083,516
Long-term obligations — current portion	3,900,000	14,025,000
Total current liabilities	36,292,163	42,886,412
Long-Term Obligations	6,825,000	7,800,000
Convertible Subordinated Notes	200,000,000	200,000,000
Shareholders' Equity:		
Capital stock, par value \$.01 per share: authorized, 4,550,000 shares; none issued		
Common stock, par value \$.01 per share:		
authorized, 160,000,000 shares; issued, 64,290,178 and 64,225,395 shares at June 30, 2002 and March 31, 2002, respectively	642,902	642,254
Non-voting common stock, par value \$.01 per share:		
authorized, 450,000 shares; issued, 382,632 at June 30, 2002 and March 31, 2002	3,826	3,826
Additional paid-in capital	444,851,926	444,425,742

Deferred compensation	(2,587,460)	(3,162,448)
Accumulated other comprehensive income	692,198	1,619,541
Accumulated deficit	(389,117,470)	(343,865,050)
	<u>54,485,922</u>	<u>99,663,865</u>
Total shareholders' equity		
	<u>54,485,922</u>	<u>99,663,865</u>
Total Liabilities and Shareholders' Equity	\$ 297,603,085	\$ 350,350,277
	<u>\$ 297,603,085</u>	<u>\$ 350,350,277</u>

See notes to consolidated financial statements.

ALKERMES, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF OPERATIONS
(Unaudited)

	Three Months Ended June 30, 2002	Three Months Ended June 30, 2001
Revenues:		
Research and development revenue under collaborative arrangements	\$ 10,291,391	\$ 15,526,675
Expenses:		
Research and development	24,599,673	20,710,031
General and administrative	6,016,040	5,374,278
Total expenses	30,615,713	26,084,309
Net operating loss	(20,324,322)	(10,557,634)
Other income (expense):		
Interest income	1,365,936	4,525,015
Interest expense	(2,081,134)	(2,309,927)
Total other (expense) income	(715,198)	2,215,088
Equity in losses of Reliant Pharmaceuticals, LLC	24,212,900	—
Net loss	(\$45,252,420)	(\$8,342,546)
Basic and diluted loss per common share	(\$0.70)	(\$0.13)
Weighted average number of common shares outstanding	64,260,903	63,236,893

See notes to consolidated financial statements.

ALKERMES, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF CASH FLOWS

(Unaudited)

	Three Months Ended June 30, 2002	Three Months Ended June 30, 2001
Cash flows from operating activities:		
Net loss	(\$45,252,420)	(\$8,342,546)
Adjustments to reconcile net loss to net cash used by operating activities:		
Depreciation, amortization and other noncash expenses	3,071,035	2,313,341
Equity in losses of Reliant Pharmaceuticals, LLC	24,212,900	—
Noncash interest expense	—	138,730
Adjustments to other assets	—	250,447
Changes in assets and liabilities:		
Receivables from collaborative arrangements	(462,201)	(6,132,254)
Prepaid expenses and other current assets	(400,779)	1,011,462
Accounts payable and accrued expenses	3,823,187	1,818,670
Deferred revenue	(276,341)	(579,472)
Net cash used by operating activities	<u>(15,284,619)</u>	<u>(9,521,622)</u>
Cash flows from investing activities:		
Additions to property, plant and equipment	(16,626,892)	(2,441,554)
Purchases of available-for-sale short-term investments	(35,290,276)	(69,221,396)
Sales of available-for-sale short-term investments	71,241,888	66,764,763
Purchases of held-to-maturity short-term investments, net	—	(19,309,847)
Maturities of long-term investments, net	—	38,739,459
Increase in other assets	—	(300,000)
Net cash provided by investing activities	<u>19,324,720</u>	<u>14,231,425</u>
Cash flows from financing activities:		
Proceeds from issuance of common stock	480,681	1,402,349
Repayment of loan	(10,000,000)	—
Payment of long-term obligations	(1,100,000)	(1,350,000)
Net cash (used by) provided by financing activities	<u>(10,619,319)</u>	<u>52,349</u>
Effect of exchange rate changes on cash	<u>44,939</u>	<u>(10,948)</u>
Net (decrease) increase in cash and cash equivalents	(6,534,279)	4,751,204
Cash and cash equivalents, beginning of period	<u>16,023,074</u>	<u>5,923,282</u>
Cash and cash equivalents, end of period	<u>\$ 9,488,795</u>	<u>\$ 10,674,486</u>
Supplementary information:		
Cash paid for interest	<u>\$ 213,428</u>	<u>\$ 301,123</u>

See notes to consolidated financial statements.

ALKERMES, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

1. BASIS OF PRESENTATION

The consolidated financial statements of Alkermes, Inc. (the “Company”) for the three months ended June 30, 2002 and 2001 are unaudited and include all adjustments which are normal and recurring and, in the opinion of management, are necessary to present fairly the results of operations for the periods then ended. All such adjustments are of a normal recurring nature. These financial statements should be read in conjunction with the Company’s Annual Report on Form 10-K for the year ended March 31, 2002, which includes consolidated financial statements and notes thereto for the years ended March 31, 2002, 2001 and 2000. In addition, the financial statements include the accounts of Alkermes Controlled Therapeutics, Inc., Alkermes Controlled Therapeutics Inc. II, Advanced Inhalation Research, Inc. (“AIR”), Alkermes Investments, Inc., Alkermes Europe, Ltd. and Alkermes Development Corporation II (“ADC II”), wholly owned subsidiaries of the Company.

The results of the Company’s operations for any interim period are not necessarily indicative of the results of the Company’s operations for any other interim period or for a full fiscal year.

The preparation of the Company’s consolidated financial statements in conformity with accounting principles generally accepted in the United States of America necessarily requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the consolidated financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

2. COMPREHENSIVE INCOME (LOSS)

Comprehensive income (loss) is comprised of net income (loss) and other comprehensive income (loss). Other comprehensive income (loss) includes certain changes in the shareholders’ equity of the Company that are excluded from net income (loss). Specifically, other comprehensive income (loss) includes unrealized holding gains and losses on the Company’s “available-for-sale” securities and changes in cumulative foreign currency translation adjustments.

Comprehensive income (loss) for the three months ended June 30, 2002 and 2001 is as follows:

	Three Months Ended June 30, 2002	Three Months Ended June 30, 2001
Net loss	(\$45,252,420)	(\$8,342,546)
Foreign currency translation adjustments	49,908	(10,575)
Unrealized (loss) gain on marketable securities	(977,251)	9,182
Comprehensive loss	(\$46,179,763)	(\$8,343,939)

3. NET LOSS PER SHARE

Basic and diluted net loss per share are computed using the weighted average number of common shares outstanding during the period. Basic net loss per share excludes any dilutive effect from stock options and the 3 3/4% Convertible Subordinated Notes due 2007 (the “3 3/4% Notes”). The Company continues to be in a net loss position and, therefore, diluted net loss per share is the same amount as basic net loss per share. Certain securities were not included in the computations of diluted net loss per share for the three months ended June 30, 2002 and 2001 because they would have an antidilutive effect due to net losses for such periods. These securities include (i) outstanding stock options and awards with respect to 11,368,201 and 9,455,725 shares of common stock in the three months ended June 30, 2002 and 2001 and (ii) 2,952,030 shares of common stock issuable upon conversion of the 3 3/4% Notes in the three months ended June 30, 2002 and 2001.

4. INVESTMENT IN RELIANT PHARMACEUTICALS, LLC

In December 2001, the Company announced a strategic alliance with Reliant Pharmaceuticals, LLC, a privately held pharmaceutical company marketing branded, prescription pharmaceutical products to primary care physicians in the U.S.

As part of the alliance, in December 2001, the Company purchased approximately 63% of an offering by Reliant of its Series C Convertible Preferred Units, representing approximately 19% of the equity interest in Reliant, for a purchase price of \$100 million. The investment is being accounted for under the equity method of accounting because Reliant is organized as a limited liability company which is treated in a manner similar to a partnership. Because, at the time of the Company’s investment, Reliant had an accumulated deficit from operations and a deficit in members capital, under applicable accounting rules, the Company’s share of Reliant’s losses from the date of the investment will be recognized in proportion to the Company’s percentage participation in the Series C financing, and not in proportion to its percentage ownership interest in Reliant. The Company records its equity in the income or losses of Reliant three months in arrears. Reliant is a privately held company over which the Company does not exercise control and it relies on the unaudited financial statements prepared by Reliant and provided to the Company to calculate its share of Reliant’s losses in the Company’s consolidated statements of operations. The Company anticipates that Reliant will have substantial net losses through 2003, and accordingly, recorded its 63% share of such losses in its consolidated financial statements beginning in the quarter ended March 31, 2002.

In connection with the Company’s \$100 million equity investment in Reliant, the Company is in the process of allocating its proportionate share of the assets acquired and liabilities assumed in accordance with the guidance set forth in Statement of Financial Accounting Standards (“SFAS”) No. 141. The Company took a \$2.7 million noncash charge for in-process research and development through the income statement under the caption “Equity in losses of Reliant Pharmaceuticals, LLC” in fiscal 2002. The \$2.7 million noncash charge is related to management’s current estimate of the amount of the purchase price to be allocated to in-process research and development. This analysis of the purchase price allocation is preliminary and the amount of in-process research and development is subject to future adjustment.

Termination of Proposed Merger Transaction with Reliant

On March 20, 2002, we entered into an Agreement and Plan of Merger (the “Merger Agreement”) with Reliant. On August 14, 2002, the Company and Reliant announced the mutual termination of the Merger Agreement. The companies agreed to terminate due to general market conditions. There will be no payments triggered by the mutual termination and each company will bear its own legal and transaction fees.

5. RECENT ACCOUNTING PRONOUNCEMENTS

In August 2002, the Financial Accounting Standards Board (“FASB”) issued Statement of Financial Accounting Standards (“SFAS”) No. 146, “Accounting for Costs Associated with Exit or Disposal Activities.” SFAS No. 146 addresses financial accounting and reporting for costs associated with exit or disposal activities and nullifies Emerging Issues Task Force Issue No. 94-3, “Liability Recognition for Certain Employee Termination Benefits and Other Costs to Exit an Activity (including Certain Costs Incurred in a Restructuring).” SFAS No. 146 requires that a liability for a cost associated with an exit or disposal activity be recognized when the liability is incurred. The provisions of SFAS No. 146 are effective for exit or disposal activities that are initiated after December 31, 2002. The Company does not believe that the adoption of SFAS No. 146 will have a material impact on its financial statements and result of operations.

6. SUBSEQUENT EVENT

In August, the Company announced the regulatory approval and expected commercial launch of Risperdal Consta™ in Germany and the United Kingdom. Under the Company’s agreements with Janssen and based on the foregoing, certain minimum revenues are to be paid to the Company in minimum annual amounts for up to ten years beginning in calendar 2003. The actual amount of such minimum revenues will be determined by a formula and are currently estimated to aggregate approximately \$150 million. The minimum revenue obligation will be satisfied upon receipt by the Company of revenues equalling such aggregate amount of minimum revenues.

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

Introduction

Alkermes, Inc. (together with its subsidiaries, referred to as “we”, “us”, “our” or the “Registrant”), a Pennsylvania corporation organized in 1987, is an emerging pharmaceutical company developing products based on applying its sophisticated drug delivery technologies to enhance therapeutic outcomes. Our areas of focus include: controlled, extended-release of injectable drugs using our ProLease® and Medisorb® delivery systems, and the development of inhaled pharmaceuticals based on our proprietary Advanced Inhalation Research, Inc. (“AIR™”) pulmonary delivery system. Our business strategy is twofold. We partner our proprietary technology systems and drug delivery expertise with many of the world's finest pharmaceutical companies and we also develop novel, proprietary drug candidates for our own account. We have a pipeline of products in various stages of development. In addition to our Cambridge, Massachusetts headquarters, research and manufacturing facilities, we operate research and manufacturing facilities in Ohio and a medical affairs office in Cambridge, England. Since our inception in 1987, we have devoted substantially all of our resources to research and development programs. At June 30, 2002, we had an accumulated deficit of \$389.1 million. We expect to incur substantial additional operating losses over the next few years.

We have funded our operations primarily through public offerings and private placements of debt and equity securities, bank loans and payments under research and development agreements with collaborators. We historically have developed our product candidates in collaboration with others on whom we rely for funding, development, manufacturing and/or marketing. While we continue to develop product candidates in collaboration with others, we also develop proprietary product candidates for our own account that we fund on our own.

Forward-Looking Statements

Any statements herein or otherwise made in writing or orally by us with regard to our expectations as to financial results and other aspects of our business may constitute forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. These statements relate to our future plans, objectives, expectations and intentions and may be identified by words like “believe,” “expect,” “may,” “will,” “should,” “seek,” or “anticipate,” and similar expressions.

Although we believe that our expectations are based on reasonable assumptions within the bounds of our knowledge of our business and operations, our business is subject to significant risks and there can be no assurance that actual results of our development and manufacturing activities and our results of operations will not differ materially from our expectations. Factors which could cause actual results to differ from expectations include, among others: (i) Johnson & Johnson Pharmaceutical Research and Development, LLC received a non-approvable letter for Risperdal Consta from the FDA and there can be no assurance that the issues raised in the letter will be resolved in a timely basis, if at all; (ii) Nutropin Depot™, Risperdal Consta and our product candidates (including Vivitrex™), if approved for marketing, may not produce significant revenues and, in commercial use, may have unintended

side effects, adverse reactions or incidents of misuse; (iii) our delivery technologies or product development efforts may not produce safe, efficacious or commercially viable products; (iv) our collaborators could elect to terminate or delay programs at any time and disputes with collaborators or failure to negotiate acceptable new collaborative arrangements for our technologies could occur; (v) we may be unable to manufacture our first products, Nutropin Depot and Risperdal Consta, or to manufacture future products, on a commercial scale or economically; (vi) after the completion of clinical trials and the submission to the FDA of an NDA for marketing approval and to other health authorities as a marketing authorization application, the FDA or other health authorities could refuse to accept such filings or could request additional preclinical or clinical studies be conducted, each of which could result in significant delays, or such authorities could refuse to approve the product at all; (vii) clinical trials are a time-consuming and expensive process; (viii) our product candidates could be ineffective or unsafe during preclinical studies and clinical trials and we and our collaborators may not be permitted by regulatory authorities to undertake new or additional clinical trials for product candidates incorporating our technologies, or clinical trials could be delayed; (ix) we could lose our entire investment in Reliant Pharmaceuticals, LLC ("Reliant"); (x) we depend on others to market and sell our products and product candidates; (xi) even if our product candidates appear promising at an early stage of development, product candidates could fail to receive necessary regulatory approvals, be difficult to manufacture on a large scale, be uneconomical, fail to achieve market acceptance, be precluded from commercialization by proprietary rights of third parties or experience substantial competition in the marketplace; (xii) technological change in the biotechnology or pharmaceutical industries could render our product candidates obsolete or noncompetitive; (xiii) difficulties or set-backs in obtaining and enforcing our patents and difficulties with the patent rights of others could occur; (xiv) we will need to spend substantial funds to become profitable and will, therefore, continue to incur losses for the foreseeable future; and (xv) we could incur difficulties or set-backs in obtaining the substantial additional funding required to continue research and development programs and clinical trials.

Critical Accounting Policies

In December 2001, the Securities and Exchange Commission ("SEC") requested that all registrants discuss their most "critical accounting policies" in management's discussion and analysis of financial condition and results of operations. The SEC indicated that a "critical accounting policy" is one which is both important to the portrayal of our financial condition and results and requires management's most difficult, subjective or complex judgments, often as a result of the need to make estimates about the effect of matters that are inherently uncertain. While our significant accounting policies are more fully described in Note 2 to our consolidated financial statements, we believe the following accounting policies to be important to the portrayal of our financial condition and can require estimates from time to time. For the three months ended June 30, 2002, there were estimates made in connection with upfront fees paid under license agreements that were immaterial to the overall revenues earned and there were immaterial estimates made for research and development expenses. In connection with the \$100 million equity investment in Reliant in December 2001, we recorded a \$2.7 million noncash charge for in-process research and development based on management's estimate at the time of the investment, which is subject to adjustment (see "Results of Operations" below).

Revenue Recognition – Research and development revenue consists of non-refundable research and development funding under collaborative arrangements with various corporate partners. Research and development funding generally compensates us for formulation, preclinical and clinical testing related to the collaborative research programs, and is recognized as revenue at the time the research and development activities are performed under the terms of the related agreements, when the corporate partner is obligated to pay and when no future performance obligations exist.

Fees for the licensing of product rights on initiation of collaborative arrangements are recorded as deferred revenue upon receipt and recognized as income on a systematic basis (based upon the timing and level of work performed or on a straight-line basis if not otherwise determinable) over the period that the related products or services are delivered or obligations as defined in the agreement are performed. Revenue from milestone or other upfront payments is recognized as earned in accordance with the terms of the related agreements. These agreements may require deferral of revenue recognition to future periods.

Research and Development Expenses – Our research and development expenses include salaries and related benefits, laboratory supplies, temporary help costs, external research costs, consulting costs, occupancy costs, depreciation expense and other allocable costs directly related to its research and development activities. Research and development expenses are incurred in conjunction with the development of our technologies, proprietary product candidates, collaborators' product candidates and in-licensing arrangements. External research costs relate to toxicology studies, pharmacokinetic studies and clinical trials that are performed under contract by external companies, hospitals or medical centers for us. All such costs are charged to research and development expenses as incurred.

Results of Operations

The net loss for the three months ended June 30, 2002 in accordance with generally accepted accounting principles was \$45.3 million or \$0.70 basic and diluted loss per common share. The net loss in accordance with generally accepted accounting principles for the three months ended June 30, 2001 was \$8.3 million or \$0.13 basic and diluted loss per common share. The net loss for the three months ended June 30, 2002 excluding the \$24.2 million noncash charge related to the equity in losses of our investment in Reliant Pharmaceuticals, LLC was \$21.0 million or \$0.33 basic and diluted loss per common share. The increase in the net loss excluding our loss in Reliant, increased primarily as a result of an increase in research and development and general and administrative expenses as we continue to advance our proprietary product candidates and our collaborators' product candidates through development and clinical trials and prepare for commercialization. This was coupled with a decrease in revenues as our Risperdal Consta™ program evolves from a development stage project into a commercial program.

Our research and development revenue under collaborative arrangements for the three months ended June 30, 2002 was \$10.3 million compared to \$15.5 million for the corresponding period of the prior year. The decrease for the three months ended June 30, 2002 was the result of a milestone payment received during the three months ended June 30, 2001 as well as decreased funding from Janssen Pharmaceutica, Inc. ("Janssen") during the three months ended June 30, 2002 as the Risperdal Consta project evolves from a development stage project into a commercial program. See the Risperdal Consta discussion below for the status of Risperdal Consta. The decrease in research and development funding was partially offset by an increase in research and development funding earned under other collaborative agreements.

Total operating expenses increased to \$30.6 million for the three months ended June 30, 2002 from \$26.1 million for the three months ended June 30, 2001. The increase was due to increases in

research and development expenses and general and administrative expenses, which are discussed below.

Research and development expenses for the three months ended June 30, 2002 were \$24.6 million as compared to \$20.7 million for the corresponding period of the prior year. The increase in research and development expenses for the three months ended June 30, 2002 as compared to the three months ended June 30, 2001 was mainly the result of increases in personnel and external research expenses as we advance our proprietary product candidates and our collaborators' product candidates through development and clinical trials and prepare for commercialization. There was also an increase in occupancy costs as we continue to expand our facilities in both Massachusetts and Ohio. We expect an increase in research and development expenses during fiscal 2003 resulting from the continuing development of our proprietary product candidates and collaborators' product candidates.

Below is a summary of our proprietary and collaborators' product candidates and their respective stages of clinical development.

Product Candidate	Indication	Phase of Clinical Development (1)
Nutropin Depot	Pediatric growth hormone deficiency	Marketed
Risperdal Consta	Schizophrenia	(2)
Vivitrex	Alcohol dependence	Phase III
Vivitrex	Opioid dependence	Phase II
Nutropin Depot	Adult growth hormone deficiency	Phase III
AIR Albuterol	Asthma	Phase II completed
Cereport and Carboplatin	Pediatric brain tumor	Phase I/II
ProLease r-hFSH	Infertility	Phase I completed
Medisorb AC2993 (Exendin-4)	Diabetes	Phase II
AIR Insulin	Diabetes	Undisclosed
AIR hGH	Growth hormone deficiency	Phase I completed
AIR small molecule products	Respiratory disease	Phase I completed/Preclinical

- (1) "Phase I/II" clinical trials indicates that the compound is being tested in humans for safety and preliminary indications of biological activity in a limited patient population. "Phase II" clinical trials indicates that the trial is being conducted in patients and is to provide information on dosing and is testing for safety and preliminary evidence of efficacy. "Phase III" clinical trials indicates that the trial is being conducted in patients and is testing the safety and efficacy of the compound. "Preclinical" indicates that we or our partners are conducting formulation, efficacy, pharmacology and/or toxicology testing of a compound in animal models or biochemical assays.
- (2) Approved in the United Kingdom and Germany. Received a non-approvable letter from the FDA. See "Results of Operations-Risperdal Consta" for further information on the status of Risperdal Consta.

General and administrative expenses for the three months ended June 30, 2002 were \$6.0 million as compared to \$5.4 million for the corresponding period of the prior year. The increase in the three months ended June 30, 2002 as compared to the three months ended June 30, 2001 was primarily a result of an increase in personnel, as well as increased professional fees and consulting costs.

Interest income for the three months ended June 30, 2002 was \$1.4 million compared to \$4.5 million for the corresponding period of the prior year. The decrease in such income for the three months ended June 30, 2002 as compared to the three months ended June 30, 2001 was primarily the result of a lower average cash and investment balance as compared to the prior year period as discussed below. Interest income also decreased as a result of a decline in interest rates as compared to the same periods in the prior year.

Interest expense for the three months ended June 30, 2002 was \$2.1 million as compared to \$2.3 million for the corresponding period of the prior year. The decrease in interest expense for the three months ended June 30, 2002 as compared to the three months ended June 30, 2001 was primarily the result of a decrease in the average outstanding debt balance as compared to the prior year period.

In December 2001, we announced a strategic alliance with Reliant Pharmaceuticals, LLC. As part of the alliance, in December 2001, we purchased approximately 63% of an offering by Reliant of its Series C Convertible Preferred Units, representing approximately 19% of the equity interest in Reliant, for a purchase price of \$100 million. The investment is being accounted for under the equity method of accounting because Reliant is organized as a limited liability company which is under applicable accounting rules, treated in a manner similar to a partnership. Because, at the time of our investment, Reliant had an accumulated deficit from operations and deficit in members capital, under applicable accounting rules, our share of Reliant's losses from the date of our investment will be recognized in proportion to our percentage participation in the Series C financing, and not in proportion to our percentage ownership interest in Reliant. Alkermes records its equity in the income or losses of Reliant three months in arrears. For the three months ended June 30, 2002, this noncash charge amounted to \$24.2 million. Reliant is a privately held company over which we do not exercise control and we rely on the unaudited financial statements prepared by Reliant and provided to us to calculate our share of Reliant's losses in our consolidated statements of operations. We anticipate that Reliant will have substantial net losses through 2003, and accordingly, recorded our 63% share of such losses in our consolidated financial statements beginning in the quarter ended March 31, 2002.

In connection with our \$100 million equity investment in Reliant, we are in the process of allocating our proportionate share of the assets acquired and liabilities assumed in accordance with the guidance set forth in SFAS No. 141. We have taken a \$2.7 million noncash charge for in-process research and development through the income statement under the caption "Equity in losses of Reliant Pharmaceuticals, LLC." The \$2.7 million noncash charge is related to management's current estimate of the amount of the purchase price to be allocated to in-process research and development. This analysis of the purchase price allocation is preliminary and the amount of in-process research and development is subject to future adjustment.

Termination of Proposed Merger Transaction with Reliant

On March 20, 2002, we entered into an Agreement and Plan of Merger (the "Merger Agreement") with Reliant. On August 14, 2002, we and Reliant announced the mutual termination of the Merger Agreement. The companies agreed to terminate due to general market conditions. There will be no payments triggered by the mutual termination and each company will bear its own legal and transaction fees.

Risperdal Consta

In August 2001, Janssen Pharmaceutica, L.P. filed a new drug application (“NDA”) for Risperdal Consta™ with the U.S. Food and Drug Administration (“FDA”) and similar regulatory filings have been submitted to other drug regulatory agencies worldwide. Risperdal Consta is a Medisorb long-acting formulation of Janssen’s antipsychotic drug Risperdal®. On June 28, 2002, Johnson & Johnson Pharmaceutical Research and Development, LLC (“J&J PRD”), an affiliate of our collaborative partner Janssen, received a non-approvable letter for Risperdal Consta from the FDA. Johnson & Johnson has met with the FDA and is working to answer the agency’s questions. There can be no assurance that the issues raised in the FDA’s letter will be resolved on a timely basis, if at all. On August 1, 2002 and August 9, 2002, we announced that J&J PRD received approval to market Risperdal Consta in Germany and the United Kingdom, respectively. We also announced that Risperdal Consta is in late-stage regulatory review in a number of other countries. However, the impact of the FDA’s non-approvable letter on the other regulatory filings made worldwide is not known at this time. There can be no assurance that Risperdal Consta will be approved by the FDA or other regulatory agencies, on a timely basis, if at all. See our Annual Report on Form 10-K, “Risk Factors –J&J PRD received a non-approvable letter for Risperdal Consta from the FDA and the future of Risperdal Consta is uncertain.”

We do not believe that inflation and changing prices have had a material impact on our results of operations.

Liquidity and Capital Resources

Cash and cash equivalents and short-term investments were approximately \$109.8 million at June 30, 2002 as compared to \$152.3 million at March 31, 2002. The decrease in cash and short-term investments is a result of cash used to fund our operations, to acquire fixed assets and to make interest and principal payments on our indebtedness.

We invest in cash equivalents, U.S. Government obligations, high-grade corporate notes and commercial paper, with the exception of our \$100 million investment in Reliant. Our investment objectives for such investments taken as a whole are, first, to assure liquidity and conservation of capital, and second, to obtain investment income. Investments classified as long-term at June 30, 2002 consist of U.S. Government obligations held as collateral under certain letters of credit, lease and loan agreements.

All of our investments in debt securities are classified as “available-for-sale” and are recorded at fair value. Fair value was determined based on quoted market prices.

In August, we announced the regulatory approval and expected commercial launch of Risperdal Consta in Germany and the United Kingdom. Under our agreements with Janssen and based on the foregoing, certain minimum revenues are to be paid to us in minimum annual amounts for up to ten years beginning in calendar 2003. The actual amount of such minimum revenues will be determined by a formula and are currently estimated to aggregate approximately \$150 million. The minimum revenue obligation will be satisfied upon receipt by us of revenues equaling such aggregate amount of minimum revenues.

We have funded our operations primarily through public offerings and private placements of debt and equity securities, bank loans and payments under research and development agreements with collaborators. We expect to incur significant additional research and development and other

costs in connection with collaborative arrangements and as we expand the development of our proprietary product candidates, including costs related to preclinical studies, clinical trials and facilities expansion. We expect that our costs, including research and development costs for our product candidates, will exceed our revenues significantly for the next few years, which will result in continuing losses from operations.

Capital expenditures were approximately \$16.6 million for the three months ended June 30, 2002, principally reflecting equipment purchases and building expansion and improvements. We expect our capital expenditures to increase significantly during fiscal year 2003, primarily as a result of the expansions of our facilities in both Massachusetts and Ohio. The estimated total expenditures related to these projects and other capital expenditures are expected to be approximately \$42 million in fiscal 2003. Our capital expenditures for equipment, facilities and building improvements have been financed to date primarily with proceeds from bank loans and the sales of debt and equity securities. Under the provisions of our existing loans, Fleet National Bank has a security interest in certain of our assets. See our Annual Report on Form 10-K for our material contractual cash obligations.

We will continue to pursue opportunities to obtain additional financing in the future. Such financing may be sought through various sources, including debt and equity offerings, corporate collaborations, bank borrowings, lease arrangements relating to fixed assets or other financing methods. The source, timing and availability of any financings will depend on market conditions, interest rates and other factors. Our future capital requirements will also depend on many factors, including continued scientific progress in our research and development programs (including our proprietary product candidates), the magnitude of these programs, progress with preclinical testing and clinical trials, the time and costs involved in obtaining regulatory approvals, the costs involved in filing, prosecuting and enforcing patent claims, competing technological and market developments, the establishment of additional collaborative arrangements, the cost of manufacturing facilities and of commercialization activities and arrangements and the cost of product in-licensing and any possible acquisitions.

We may need to raise substantial additional funds for longer-term product development, including development of our proprietary product candidates, regulatory approvals and manufacturing and marketing activities that we might undertake in the future. There can be no assurance that additional funds will be available on favorable terms, if at all. If adequate funds are not available, we may be required to curtail significantly one or more of our research and development programs and/or obtain funds through arrangements with collaborative partners or others that may require us to relinquish rights to certain of our technologies, product candidates or future products.

Recent Accounting Pronouncements

In August 2002, the Financial Accounting Standards Board ("FASB") issued Statement of Financial Accounting Standards ("SFAS") No. 146, "Accounting for Costs Associated with Exit or Disposal Activities. SFAS No. 146 addresses financial accounting and reporting for costs associated with exit or disposal activities and nullifies Emerging Issues Task Force Issue No. 94-3, "Liability Recognition for Certain Employee Termination Benefits and Other Costs to Exit on Activity (including Certain Costs Incurred in Restructuring)." SFAS No. 146 requires that a liability for a cost associated with an exit or disposal activity be recognized when the liability is incurred. The provisions of SFAS No. 146 are effective for exit or disposal activities that are initiated after December 31, 2002. We do not believe that the adoption of SFAS No. 146 will have a material impact on our financial statements and result of operations.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

As part of our investment portfolio we own financial instruments that are sensitive to market risks. The investment portfolio, excluding our December 2001 \$100 million investment in Reliant, is used to preserve our capital until it is required to fund operations, including our research and development activities. Our short-term investments and investments consist of U.S. Government obligations, high-grade corporate notes and commercial paper. All of our investments in debt securities are classified as “available-for-sale” and are recorded at fair value. Our investments, excluding our investment in Reliant, are subject to interest rate risk, and could decline in value if interest rates increase. Due to the conservative nature of our short-term investments and investments we do not believe that we have a material exposure to interest rate risk. Although our investments (excluding our investment in Reliant) are subject to credit risk, our investment policies specify credit quality standards for our investments and limit the amount of credit exposure from any single issue, issuer or type of investment.

Our “available-for-sale” marketable securities are sensitive to changes in interest rates. Interest rate changes would result in a change in the fair value of these financial instruments due to the difference between the market interest rate and the rate at the date of purchase of the financial instrument. A 10% decrease in quarter-end market interest rates would result in no material impact on the net fair value of such interest-sensitive financial instruments.

The interest rate on our 3 3/4% Notes is fixed and, therefore, is not subject to interest rate risk.

PART II. OTHER INFORMATION

Item 6. Exhibits and Reports on Form 8-K

(a) Exhibits:

Number	Exhibit
3.1	Third Amended and Restated Articles of Incorporation as filed with the Pennsylvania Secretary of State on June 7, 2001. (Incorporated by reference to Exhibit 3.1 to the Company's Report on Form 10-K for the fiscal year ended March 31, 2001).
3.2	Amended and Restated By-Laws of Alkermes, Inc., effective as of February 11, 2001. (Incorporated by reference to Exhibit 3.2 to the Company's Report on Form 10-K for the fiscal year ended March 31, 2001).
4.1	Specimen of Common Stock Certificate of Alkermes, Inc. (Incorporated by reference to Exhibit 4 to the Company's Registration Statement on Form S-1, as amended (File No. 33-40250)).
4.2	Specimen of Non-Voting Common Stock Certificate of Alkermes, Inc. (Incorporated by reference to Exhibit 4.4 to the Company's Report on Form 10-K for the fiscal year ended March 31, 1999).
4.3	Indenture, dated as of February 18, 2000, between Alkermes, Inc. and State Street Bank and Trust Company, as Trustee. (Incorporated by reference to Exhibit 4.6 to the Company's Registration Statement on Form S-3, as amended (File No. 333-31354)).
99.1	Certification pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, 18 U.S.C. Section 1350 by Chief Executive Officer.
99.2	Certification pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, 18 U.S.C. Section 1350 by Chief Financial Officer.

- (b) During the quarter ended June 30, 2002, the Company filed a Current Report on Form 8-K, dated April 2, 2002, under Items 7 and 9 and a Current Report on Form 8-K, dated June 28, 2002, under Item 5.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

ALKERMES, INC.
(Registrant)

Date: August 14, 2002

By: /s/ Richard F. Pops

Richard F. Pops
Chief Executive Officer and
Director
(Principal Executive Officer)

Date: August 14, 2002

By: /s/ James M. Frates

James M. Frates
Vice President, Chief
Financial Officer and Treasurer
(Principal Financial and
Accounting Officer)

Exhibit Index

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