

ALKERMES INC
Form 10-Q
August 14, 2006

Table of Contents

**UNITED STATES SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549**

Form 10-Q

(Mark One)

- QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the quarterly period ended June 30, 2006
- 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 1-14131

ALKERMES, INC.

(Exact name of registrant as specified in its charter)

PENNSYLVANIA

(State or other jurisdiction of incorporation or organization)

23-2472830

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

88 Sidney Street, Cambridge, MA

(Address of principal executive offices)

02139-4234

(Zip Code)

Registrant's telephone number including area code:

(617) 494-0171

(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 by check mark whether the registrant is a large accelerated filer, an accelerated filer, or a non-accelerated filer. See definition of "accelerated filer and large accelerated filer" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer Accelerated filer Non-accelerated filer

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act.): Yes No

Edgar Filing: ALKERMES INC - Form 10-Q

The number of shares outstanding of each of the issuer's classes of common stock was:

Class	As of July 31, 2006
Common Stock, \$.01 par value	100,922,394
Non-Voting Common Stock, \$.01 par value	382,632

ALKERMES, INC. AND SUBSIDIARIES

INDEX

	Page No.
<u>PART I FINANCIAL INFORMATION</u>	
<u>Item 1.</u>	<u>Unaudited Condensed Consolidated Financial Statements:</u>
	<u>Condensed Consolidated Balance Sheets June 30, 2006 and March 31, 2006</u> 3
	<u>Condensed Consolidated Statements of Operations For the Three Months Ended June 30, 2006 and 2005</u> 4
	<u>Condensed Consolidated Statements of Cash Flows For the Three Months Ended June 30, 2006 and 2005</u> 5
	<u>Notes to Unaudited Condensed Consolidated Financial Statements</u> 6
<u>Item 2.</u>	<u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u> 14
<u>Item 3.</u>	<u>Quantitative and Qualitative Disclosures about Market Risk</u> 21
<u>Item 4.</u>	<u>Controls and Procedures</u> 22
<u>PART II OTHER INFORMATION</u>	
<u>Item 1A.</u>	<u>Risk Factors</u> 24
<u>Item 2.</u>	<u>Unregistered Sales of Equity Securities and Use of Proceeds</u> 25
<u>Item 5.</u>	<u>Other Information</u> 25
<u>Item 6.</u>	<u>Exhibits</u> 25
<u>Signatures</u>	26
<u>Exhibit Index:</u>	27
<u>Ex-31.1 Certification of CEO</u>	
<u>Ex-31.2 Certification of CFO</u>	
<u>Ex-32.1 Certifications of CEO & CFO pursuant to Section 906</u>	

Table of Contents**PART 1. FINANCIAL INFORMATION****Item 1. *Unaudited Condensed Consolidated Financial Statements:*****ALKERMES, INC. AND SUBSIDIARIES****CONDENSED CONSOLIDATED BALANCE SHEETS**

	June 30, 2006	March 31, 2006
	(In thousands, except share and per share amounts)	
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	\$ 107,923	\$ 33,578
Investments short-term	260,616	264,389
Receivables	41,353	39,802
Inventory, net	11,378	7,341
Prepaid expenses and other current assets	4,802	2,782
Total current assets	426,072	347,892
PROPERTY, PLANT AND EQUIPMENT:		
Land	301	301
Building and improvements	21,186	20,966
Furniture, fixtures and equipment	63,752	61,086
Equipment under capital lease	464	464
Leasehold improvements	45,971	45,842
Construction in progress	27,158	23,555
	158,832	152,214
Less: accumulated depreciation and amortization	(42,586)	(39,297)
Property, plant and equipment net	116,246	112,917
RESTRICTED INVESTMENTS long-term	5,145	5,145
OTHER ASSETS	10,290	11,209
TOTAL ASSETS	\$ 557,753	\$ 477,163
LIABILITIES, REDEEMABLE CONVERTIBLE PREFERRED STOCK AND SHAREHOLDERS EQUITY		
CURRENT LIABILITIES:		
Accounts payable and accrued expenses	\$ 28,992	\$ 36,141

Edgar Filing: ALKERMES INC - Form 10-Q

Accrued interest	2,985	3,239
Accrued restructuring costs	855	852
Unearned milestone revenue current portion	56,320	83,338
Deferred revenue current portion	200	200
Convertible subordinated notes current portion	676	676
Long-term debt current portion	1,239	1,214
Total current liabilities	91,267	125,660
NON-RECOURSE RISPERDAL CONSTA SECURED 7% NOTES	154,427	153,653
CONVERTIBLE SUBORDINATED NOTES LONG-TERM PORTION		124,346
LONG-TERM DEBT	1,200	1,519
UNEARNED MILESTONE REVENUE LONG-TERM PORTION	124,319	16,198
DEFERRED REVENUE LONG-TERM PORTION	700	750
OTHER LONG-TERM LIABILITIES	6,677	6,821
TOTAL LIABILITIES	378,590	428,947
REDEEMABLE CONVERTIBLE PREFERRED STOCK, par value, \$0.01 per share; authorized and issued, 1,500 shares at June 30, 2006 and March 31, 2006 (at liquidation preference)	15,000	15,000
COMMITMENTS AND CONTINGENCIES		
SHAREHOLDERS EQUITY:		
Capital stock, par value, \$0.01 per share; authorized, 4,550,000 shares (includes 2,997,000 shares of preferred stock); issued, none		
Common stock, par value, \$0.01 per share; authorized, 160,000,000 shares; 101,041,464 and 91,744,680 shares issued, 100,906,834 and 91,744,680 shares outstanding at June 30, 2006 and March 31, 2006, respectively	1,010	917
Nonvoting common stock, par value, \$0.01 per share; authorized 450,000 shares; issued and outstanding, 382,632 shares at June 30, 2006 and March 31, 2006	4	4
Treasury stock, at cost (134,630 and 0 shares at June 30, 2006 and March 31, 2006, respectively)	(2,627)	
Additional paid-in capital	798,084	664,596
Deferred compensation		(374)
Accumulated other comprehensive income	1,398	1,064
Accumulated deficit	(633,706)	(632,991)
Total shareholders equity	164,163	33,216
TOTAL LIABILITIES, REDEEMABLE CONVERTIBLE PREFERRED STOCK AND SHAREHOLDERS EQUITY	\$ 557,753	\$ 477,163

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.

Table of Contents**ALKERMES, INC. AND SUBSIDIARIES****CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS**

	Three Months Ended June 30, 2006	Three Months Ended June 30, 2005
	(In thousands, except per share amounts)	
REVENUES:		
Manufacturing revenues	\$ 22,193	\$ 13,983
Royalty revenues	5,139	3,604
Research and development revenue under collaborative arrangements	14,464	7,251
Net collaborative profit	9,742	
Total revenues	51,538	24,838
EXPENSES:		
Cost of goods manufactured	9,338	4,517
Research and development	25,863	21,622
Selling, general and administrative	16,530	8,952
Total expenses	51,731	35,091
OPERATING LOSS	(193)	(10,253)
OTHER INCOME (EXPENSE):		
Interest income	4,335	1,631
Interest expense	(5,473)	(5,169)
Derivative loss related to convertible subordinated notes		(266)
Other income (expense), net	787	320
Total other income (expense)	(351)	(3,484)
LOSS BEFORE INCOME TAXES	(544)	(13,737)
INCOME TAXES	171	
NET LOSS	\$ (715)	\$ (13,737)
LOSS PER COMMON SHARE, BASIC AND DILUTED	\$ (0.01)	\$ (0.15)
WEIGHTED AVERAGE NUMBER OF COMMON SHARES OUTSTANDING, BASIC AND DILUTED	93,784	90,410

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.

Table of Contents**ALKERMES, INC. AND SUBSIDIARIES****CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS**

	Three Months Ended June 30, 2006	Three Months Ended June 30, 2005
	(In thousands)	
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	\$ (715)	\$ (13,737)
Adjustments to reconcile net loss to net cash provided by operating activities:		
Depreciation and amortization	2,826	2,578
Stock-based compensation	8,347	58
Other non-cash charges	1,215	1,303
Derivative loss related to convertible subordinated notes		266
Gain on investments	(846)	(308)
Loss on sale of equipment	5	
Changes in assets and liabilities:		
Receivables	(1,551)	(9,004)
Inventory, prepaid expenses and other current assets	(5,401)	(776)
Accounts payable, accrued expenses and accrued interest	(7,370)	1,006
Accrued restructuring costs	(159)	(322)
Unearned milestone revenue	81,103	160,000
Deferred revenue	(50)	100
Other long-term liabilities	18	108
Net cash provided by operating activities	77,422	141,272
CASH FLOWS FROM INVESTING ACTIVITIES:		
Additions to property, plant and equipment	(6,160)	(5,301)
Proceeds from the sale of equipment		1
Purchases of short and long-term investments	(63,374)	(326,173)
Sales and maturities of short and long-term investments	67,096	165,431
Decrease in other assets	14	18
Net cash used in investing activities	(2,424)	(166,024)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from issuance of common stock	2,268	351
Payment of debt	(294)	(273)
Purchase of treasury stock	(2,627)	
Net cash (used in) provided by financing activities	(653)	78
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	74,345	(24,674)

Edgar Filing: ALKERMES INC - Form 10-Q

CASH AND CASH EQUIVALENTS	Beginning of period	33,578	47,485
CASH AND CASH EQUIVALENTS	End of period	\$ 107,923	\$ 22,811
SUPPLEMENTARY INFORMATION:			
Cash paid for interest		\$ 4,511	\$ 2,057
Noncash activities:			
Conversion of 2.5% convertible subordinated notes into common stock		\$ 125,000	\$

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.

Table of Contents

ALKERMES, INC. AND SUBSIDIARIES

NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

1. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Basis of Presentation

The accompanying condensed consolidated financial statements of Alkermes, Inc. (the Company or Alkermes) for the three months ended June 30, 2006 and 2005 are unaudited and have been prepared on a basis substantially consistent with the audited financial statements for the year ended March 31, 2006. In the opinion of management, the condensed consolidated financial statements include all adjustments that are necessary to present fairly the results of operations for the reported periods. The Company s condensed consolidated financial statements are prepared in conformity with accounting principles generally accepted in the United States of America (commonly referred to as GAAP).

These financial statements should be read in conjunction with the Company s audited consolidated financial statements and notes thereto which are contained in the Company s Annual Report on Form 10-K/A for the year ended March 31, 2006, filed with the Securities and Exchange Commission (SEC).

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.

Principles of Consolidation The unaudited condensed consolidated financial statements include the accounts of Alkermes, Inc. and its wholly-owned subsidiaries: Alkermes Controlled Therapeutics, Inc. (ACT I); Alkermes Controlled Therapeutics, Inc. II (ACT II); Alkermes Acquisition Corp.; Alkermes Europe, Ltd.; Advanced Inhalation Research, Inc. (AIR); and RC Royalty Sub LLC (Royalty Sub). Intercompany accounts and transactions have been eliminated. The assets of Royalty Sub are not available to satisfy obligations of Alkermes and its subsidiaries, other than the obligations of Royalty Sub including Royalty Sub s non-recourse RISPERDAL CONSTA secured 7% notes (the Non-Recourse 7% Notes).

Use of Estimates The preparation of the Company s unaudited condensed consolidated financial statements in conformity with GAAP necessarily requires management to make estimates and assumptions that affect the following: (1) reported amounts of assets and liabilities; (2) disclosure of contingent assets and liabilities at the date of the unaudited condensed consolidated financial statements; and (3) the reported amounts of revenues and expenses during the reporting period. Actual results could differ from these estimates.

New Accounting Pronouncements

Effective April 1, 2006, the Company adopted the provisions of Statement of Financial Accounting Standards (SFAS) No. 151, *Inventory Costs* (SFAS 151), which amends Accounting Research Bulletin (ARB) No. 43, Chapter 4, *Inventory Pricing*, to clarify the accounting for idle facility expense, freight, handling costs and waste (spoilage). Adoption of SFAS 151 did not have a material impact on the unaudited condensed consolidated financial statements.

Effective April 1, 2006, the Company adopted the provisions of SFAS No. 123(R), *Share-Based Payment* (SFAS 123R). See Note 8.

In July 2006, the Financial Accounting Standards Board (FASB) issued FASB Interpretation (FIN) No. 48, *Accounting for Uncertainty in Income Taxes* (FIN No. 48), an interpretation of SFAS No. 109, *Accounting for Income Taxes* . FIN No. 48 clarifies the accounting for uncertainty in income taxes recognized in a company s financial

statements and prescribes a recognition threshold and measurement process for financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. FIN No. 48 also provides guidance on derecognition, classification, interest and penalties, accounting in interim periods, disclosure and transition and will become effective for the Company on April 1, 2007. The Company is in the process of evaluating the impact of adoption of FIN No. 48.

Table of Contents**ALKERMES, INC. AND SUBSIDIARIES****NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)****2. COMPREHENSIVE LOSS**

Comprehensive loss for the three months ended June 30, 2006 and 2005 is as follows:

(In thousands)	Three Months Ended June 30, 2006	Three Months Ended June 30, 2005
Net loss	\$ (715)	\$ (13,737)
Unrealized gain on marketable securities	334	136
Comprehensive loss	\$ (381)	\$ (13,601)

3. LOSS PER COMMON SHARE

Basic loss per common share was calculated using the weighted average number of shares outstanding for the reporting periods. For the three months ended June 30, 2006 and 2005, the Company reported net losses and, therefore, basic and diluted loss per common share were the same amount. Basic and diluted loss per common share excludes the dilutive effect of stock options, stock awards, convertible preferred stock and convertible debt.

The following table sets forth common stock equivalents which were excluded from the computation of diluted loss per common share for the three months ended June 30, 2006 and 2005, because they had an anti-dilutive effect due to net losses for such periods:

	Three Months Ended June 30, 2006	Three Months Ended June 30, 2005
Stock options and awards	19,546,023	17,780,394
Shares issuable on conversion of 2.5% convertible subordinated notes	7,438,413	9,025,275
Shares issuable on conversion of 3.75% convertible subordinated notes	9,978	9,978
Shares issuable on conversion of convertible preferred stock	630,385	2,285,714
Total	27,624,799	29,101,361

4. INVENTORY

Inventory, net was stated at the lower of cost or market. Cost was determined using the first-in, first-out method. Inventory, net consisted of the following:

(In thousands)	June 30, 2006	March 31, 2006
Raw materials	\$ 3,321	\$ 3,757
Work in process	3,667	2,083
Finished goods	4,390	1,501
Total(1)	\$ 11,378	\$ 7,341

(1) Net of allowances for inventory losses of \$0.8 million as of June 30, 2006 and March 31, 2006.

5. CONVERTIBLE SUBORDINATED NOTES

2.5% Convertible Subordinated Notes On June 15, 2006, the Company converted all of the outstanding \$125.0 million principal amount of the 2.5% convertible subordinated notes due 2023 (2.5% Subordinated

Table of Contents**ALKERMES, INC. AND SUBSIDIARIES****NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

Notes) into 9,025,271 shares of the Company's common stock. In connection with the conversion, the Company paid approximately \$0.6 million in cash to satisfy a three-year interest make-whole provision in the note indenture. None of the 2.5% Subordinated Notes were outstanding as of June 30, 2006, and no gain or loss was recorded on the conversion of the 2.5% Subordinated Notes, which was executed in accordance with the underlying indenture.

6. RESTRUCTURING

In connection with the 2004 restructuring program, in which the Company and Genentech, Inc. announced the decision to discontinue commercialization of NUTROPIN DEPOT® (the 2004 Restructuring), the Company recorded net restructuring charges of approximately \$11.5 million in the year ended March 31, 2005. As of June 30, 2006, the Company had paid in cash or written off an aggregate of approximately \$9.2 million in facility closure costs and \$0.1 million in employee separation costs in connection with the 2004 Restructuring. The amounts remaining in the restructuring accrual as of June 30, 2006 are expected to be paid out through fiscal 2009 and relate primarily to estimates of lease costs associated with the exited facility.

The following table displays the restructuring activity during the three months ended June 30, 2006:

Type of Liability (In thousands)	Balance March 31, 2006	Payments	Balance June 30, 2006
2004 Restructuring:			
Employee separation	\$ 9	\$	\$ 9
Facility closure	2,359	(159)	2,200
Total	\$ 2,368	\$ (159)	\$ 2,209

7. SHAREHOLDERS EQUITY

On June 15, 2006, the Company converted all of its outstanding 2.5% Subordinated Notes into 9,025,271 shares of the Company's common stock (see Note 5).

In September 2005, the Company's Board of Directors authorized a share repurchase program up to \$15.0 million of common stock to be repurchased in the open market or through privately negotiated transactions. The repurchase program has no set expiration date and may be suspended or discontinued at any time. During the three months ended June 30, 2006 and since September 2005, the Company repurchased 134,630 shares at a cost of approximately \$2.6 million under the program.

8. SHARE-BASED PAYMENTS

Effective April 1, 2006, the Company adopted the provisions of SFAS 123R which is a revision to SFAS No. 123 *Accounting for Stock-Based Compensation* (SFAS 123) and supersedes accounting principles board (APB) Opinion No. 25, *Accounting for Stock Issued to Employees* (APB 25). Under the provisions of SFAS 123R, share-based compensation cost is measured at the grant date based on the fair value of the award and is recognized as an expense over the employee s requisite service period (generally the vesting period of the equity grant).

Prior to April 1, 2006, the Company accounted for share-based compensation to employees in accordance with APB 25 and related interpretations, and the Company also followed the disclosure requirements of SFAS 123.

The Company has elected to adopt the provisions of SFAS 123R using the modified prospective transition method, and recognizes share-based compensation cost on a straight-line basis over the requisite service

Table of Contents**ALKERMES, INC. AND SUBSIDIARIES**

NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

periods of awards. Under the modified prospective transition method, share-based compensation expense is recognized for the portion of outstanding stock options and stock awards granted prior to the adoption of SFAS 123R for which service has not been rendered, and for any future grants of stock options and stock awards. The Company recognizes share-based compensation cost for awards that have graded vesting on a straight-line basis over the requisite service period of each separately vesting portion.

The following table presents share-based compensation expense for continuing operations included in the Company's unaudited condensed consolidated statements of operations:

	Three Months Ended June 30, 2006
(In thousands)	
Cost of goods manufactured	\$ 260
Research and development	2,836
Selling, general and administrative	5,251
Share-based compensation expense	\$ 8,347

During the three months ended June 30, 2006, \$0.7 million of share-based compensation cost was capitalized and recorded under the caption, Inventory, net in the unaudited condensed consolidated balance sheet.

The Company estimates the fair value of stock options on the grant date using the Black-Scholes option-pricing model. Assumptions used to estimate the fair value of stock options are the expected option term, expected volatility of the Company's common stock over the option's expected term, the risk-free interest rate over the option's expected term and the Company's expected annual dividend yield. The Company believes that the valuation technique and the approach utilized to develop the underlying assumptions are appropriate in calculating the fair values of the Company's stock options granted in the three months ended June 30, 2006. Estimates of fair value are not intended to predict actual future events or the value to be ultimately realized by persons who receive equity awards.

The Company used historical data as the basis for estimating option terms and forfeitures. Separate groups of employees that have similar historical stock option exercise and forfeiture behavior were considered separately for valuation purposes. The ranges of expected terms disclosed below reflect different expected behavior among certain groups of employees. Expected stock volatility factors were based on a weighted average of implied volatilities from traded options on the Company's common stock and historical stock price volatility of the Company's common stock, which was determined based on a review of the weighted average of historical weekly price changes of the Company's common stock. The risk-free interest rate for periods commensurate with the expected term of the share option was based on the United States (U.S.) treasury yield curve in effect at the time of grant. The dividend yield on the Company's common stock was estimated to be zero as the Company does not issue dividends. The exercise price of option grants equaled the average of the high and low of the Company's common stock traded on the NASDAQ National Market on the date of grant.

In addition, amounts previously presented as stock-based compensation in our results for the quarter ended June 30, 2005 of \$58,000 have been reclassified to the captions to which they relate in these unaudited consolidated financial statements to be consistent with the current year presentation.

Table of Contents**ALKERMES, INC. AND SUBSIDIARIES****NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

During the quarter ended June 30, 2006, the fair value of each stock option grant was estimated on the grant date with the following assumptions:

	Three Months Ended June 30, 2006
Expected option term	4-5 years
Expected stock volatility	50%
Risk-free interest rate	4.98%
Expected annual dividend yield	

Upon adoption of SFAS 123R, the Company recognized a benefit of \$0.02 million as a cumulative effect of a change in accounting principle resulting from the requirement to estimate forfeitures on the Company's restricted stock awards at the date of grant under SFAS 123R rather than recognizing forfeitures as incurred under APB 25. An estimated forfeiture rate was applied to previously recorded compensation expense for the Company's unvested restricted stock awards to determine the cumulative effect of a change in accounting principle. The cumulative benefit, net of tax, was immaterial for separate presentation in the unaudited condensed consolidated statement of operations and was included in operating loss.

The Company had previously adopted the provisions of SFAS 123, as amended by SFAS No. 148, *Accounting for Stock-Based Compensation Transition and Disclosure* through disclosure only. The following table illustrates the effects on net loss and loss per common share, basic and diluted, for the three months ended June 30, 2005 as if the Company had applied the fair value recognition provisions of SFAS 123 to share-based employee awards.

	Three Months Ended June 30, 2005
(In thousands, except per share amounts)	
Net loss as reported	\$ (13,737)
Add: employee share-based compensation expense as reported in the unaudited condensed consolidated statement of operations	58
Deduct: employee share-based compensation expense determined under the fair-value method for all options and awards	(5,813)
Net loss pro-forma	\$ (19,492)
Basic and diluted loss per common share:	
Basic and diluted as reported	\$ (0.15)
Basic and diluted pro-forma	\$ (0.22)

The fair value of each option grant was estimated on the grant date using the Black-Scholes option pricing model with the following assumptions:

	Three Months Ended June 30, 2005
Expected option term	4 years
Expected stock volatility	54%
Risk-free interest rate	3.72%
Expected annual dividend yield	

Table of Contents

ALKERMES, INC. AND SUBSIDIARIES

NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Stock Options And Award Plans

The Company's stock option plans (the "Plans") provide for issuance of nonqualified and incentive stock options to employees, officers and directors of, and consultants to, the Company. Stock options generally expire ten years from the grant date and generally vest ratably over a four-year period, except for grants to the non-employee directors, which vest over six months. The exercise price of stock options granted under the Plans may not be less than 100% of the fair market value of the common stock on the date of grant. The measurement date for accounting purposes is generally the date of the grant. Under the terms of one plan, the option exercise price may be below the fair market value, but not below par value, of the underlying stock at the time the option is granted.

The Compensation Committee of the Board of Directors is responsible for administering the Company's equity plans. The Limited Compensation Sub-Committee has the authority to make individual grants of options under certain of the Company's stock option plans to purchase shares of common stock to employees of the Company who are not subject to the reporting requirements of the Securities Exchange Act. The Limited Compensation Sub-Committee has generally approved new hire employee stock option grants of up to the limit of its authority. Until July 2006, such authority was limited to 5,000 shares per individual grant. In July 2006, this limit was raised by the Compensation Committee to 25,000 shares per individual grant and limited to employees who are not subject to the reporting requirements of the Securities Exchange Act and below the level of Vice President of the Company.

The Compensation Committee has established procedures for the grant of options to new employees. The Limited Compensation Sub-Committee will grant options to new hires, within the limits of its authority, on the first Wednesday following the first Monday of each month (or the first business day thereafter if such day is a holiday) (the "New Hire Grant Date") for all new hires beginning their employment the prior month. New hire grants that exceed the authority of the Limited Compensation Sub-Committee will be granted on the New Hire Grant Date by the Compensation Committee as a whole.

The Compensation Committee has also established procedures for regular grants of stock options to Company employees. The Compensation Committee will consider the grant of stock options twice a year at meetings held in conjunction with Board meetings regularly scheduled around May and December; however, no grant of options will be made effective in May until forty-eight hours after the announcement of the Company's fiscal year end results.

The Board of Directors administers the stock option plan for Directors.

Under the 1990 Omnibus Stock Option Plan, (the "1990 Plan") limited stock appreciation rights ("LSARs") may be granted to all or any portion of shares covered by stock options granted to Directors and executive officers. LSARs may be granted with the grant of a nonqualified stock option or at any time during the term of such option but could only be granted at the time of the grant in the case of an incentive stock option. The grants of LSARs are not effective until six months after their date of grant. Upon the occurrence of certain triggering events, including a change of control, the options with respect to which LSARs have been granted shall become immediately exercisable and the persons who have received LSARs will automatically receive a cash payment in lieu of shares. As of June 30, 2006, there were no LSARs outstanding under the 1990 Plan. No LSARs were granted during the quarters ended June 30, 2006 and 2005.

The Company has also adopted restricted stock award plans (the Award Plans) which provide for awards to certain eligible employees, officers and directors of, and consultants to, the Company of up to a maximum of 1,000,000 shares of common stock. Awards may vest based on cliff vesting or grading vesting and vest over various periods. At June 30, 2006, the Company has reserved a total of 371,774 shares of common stock for issuance upon release of awards that have been or may be granted under the Award Plans.

Table of Contents**ALKERMES, INC. AND SUBSIDIARIES****NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

The Company generally issues common stock from previously authorized but unissued shares to satisfy option exercises and restricted stock awards.

The following table sets forth the stock option and restricted stock award activity during the three months ended June 30, 2006:

	Options Outstanding			Restricted Stock Awards Outstanding	
	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term	Number of Shares	Weighted Average Grant Date Fair Value
Outstanding at March 31, 2006	18,733,823	\$ 16.09	6.71	91,000	\$ 8.15
Granted	875,430	20.79		297,500	18.99
Exercised	(220,703)	10.27			
Vesting of restricted stock				(74,375)	18.99
Cancelled	(155,652)	16.31		(1,000)	11.45
Outstanding at June 30, 2006	19,232,898	\$ 16.37	6.62	313,125	\$ 15.86
Exercisable at June 30, 2006	11,497,341	\$ 17.07	5.37		\$

Outstanding and exercisable stock options under the Plans as of June 30, 2006 are summarized below:

Range of Exercise Prices	Options Outstanding			Options Exercisable	
	Number Outstanding	Weighted-Average Remaining Contractual Life (In years)	Weighted-Average Exercise Price	Number Exercisable	Weighted-Average Exercise Price
\$ 0.30 - \$ 7.69	2,664,774	5.65	\$ 6.56	2,064,839	\$ 6.56
7.72 - 12.16	2,881,899	6.36	10.73	1,941,618	10.44
12.19 - 14.57	2,089,023	7.63	13.38	878,262	13.67
14.76 - 16.33	2,847,628	8.31	15.01	810,086	15.06
16.69 - 18.60	3,551,322	6.79	17.65	1,730,214	16.76

Edgar Filing: ALKERMES INC - Form 10-Q

18.61 - 28.25	2,881,652	6.96	21.16	1,755,722	21.14
28.30 - 96.88	2,316,600	4.40	31.15	2,316,600	31.15
\$ 0.30 - \$96.88	19,232,898	6.62	\$ 16.37	11,497,341	\$ 17.07

As of June 30, 2006, the Company has reserved a total of 21,367,578 shares of common stock for issuance upon exercise of stock options that have been or may be granted under the Plans.

Table of Contents**ALKERMES, INC. AND SUBSIDIARIES****NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

The following table sets forth the activity for unvested stock options and restricted stock awards for the three months ended June 30, 2006:

	Unvested Stock Options		Unvested Restricted Stock Awards	
	Number of Shares	Weighted Average Fair Value	Number of Shares	Weighted Average Grant Date Fair Value
Unvested at March 31, 2006	7,373,398	\$ 16.97	91,000	\$ 8.15
Granted	875,430	20.79	297,500	18.99
Vested	(389,809)	16.88	(74,375)	18.99
Cancelled	(123,462)	13.56	(1,000)	11.45
Unvested at June 30, 2006	7,735,557	\$ 16.91	313,125	\$ 15.86

The weighted average grant date fair value of stock options granted during the three months ended June 30, 2006 and 2005 was \$10.16 and \$4.65, respectively. The intrinsic value of stock options exercised during the three months ended June 30, 2006 and 2005 was \$2.2 million and \$0.3 million, respectively. At June 30, 2006, the aggregate intrinsic value of stock options outstanding and exercisable was \$82.8 million and \$52.9 million, respectively. The intrinsic value of a stock option is the amount by which the market value of the underlying stock exceeds the exercise price of the stock option.

As of June 30, 2006, there was \$28.8 million and \$4.1 million total unrecognized compensation cost related to unvested share-based compensation arrangements granted under the Company's Plans and Award Plans, respectively. This cost is expected to be recognized over a weighted-average period of approximately 2.5 years and 2.6 years for the Company's Plans and Award Plans, respectively.

Cash received from option exercises under the Company's Plans during the three months ended June 30, 2006 was \$2.3 million.

Due to the Company's full valuation allowance on its deferred tax assets and carryforwards, the Company did not realize any tax benefits from option exercises under the share-based payment arrangements during the three months ended June 30, 2006 and 2005.

9. INCOME TAXES

The Company records a deferred tax asset or liability based on the difference between the financial statement and tax bases of assets and liabilities, as measured by enacted tax rates assumed to be in effect when these differences reverse.

As of June 30, 2006, the Company determined that the deferred tax assets may not be realized and a full valuation allowance has been recorded.

The provision for income taxes in the amount of approximately \$0.2 million for the three months ended June 30, 2006 relates to the U.S. alternative minimum tax. Tax recognition of a portion of the nonrefundable payment received from Cephalon, Inc. (Cephalon) during fiscal 2006 was deferred to fiscal 2007 when it will be recognized in full. Utilization of tax loss carryforwards is limited for use against the U.S. alternative minimum tax resulting in federal tax obligations in fiscal 2007.

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

Alkermes, Inc. (as used in this section, together with our subsidiaries, us, we or our), a Pennsylvania corporation organized in 1987, is a biotechnology company that develops products based on sophisticated drug delivery technologies to enhance therapeutic outcomes in major diseases. We have two commercial products. RISPERDAL® CONSTA® [(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, a subsidiary of Johnson & Johnson, together with other affiliates (Janssen). VIVITROL® (naltrexone for extended-release injectable suspension) is the first and only once-monthly injection approved for the treatment of alcohol dependence, and is marketed in the United States (U.S.) primarily by Cephalon, Inc. (Cephalon). We have a pipeline of extended-release injectable products and pulmonary products based on our proprietary technology and expertise. Our product development strategy is twofold: we partner our proprietary technology systems and drug delivery expertise with several of the world's finest pharmaceutical companies; and we also develop novel, proprietary drug candidates for our own account. Our headquarters are located in Cambridge, Massachusetts, and we operate research and manufacturing facilities in Massachusetts and Ohio.

We have funded our operations primarily through public offerings and private placements of debt and equity securities, bank loans, term loans, equipment financing arrangements and payments received under research and development agreements and other 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. Our costs, including research and development costs for our product candidates and sales, marketing and promotion expenses for any future products to be marketed by us or our collaborators, if any, may exceed revenues in the future, which may result in losses from operations.

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, including, but not limited to, statements concerning future operating results, the achievement of certain business and operating goals, manufacturing revenues, research and development spending, plans for clinical trials and regulatory approvals, spending relating to selling and marketing and clinical development activities, financial goals and projections of capital expenditures, recognition of revenues, and future financings. These statements relate to our future plans, objectives, expectations and intentions and may be identified by words like believe, expect, designed, 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, the forward-looking statements contained in this document, including but not limited to statements concerning: the achievement of certain business and operating milestones and future operating results and profitability; continued revenue growth from RISPERDAL CONSTA; the successful launch and commercialization of VIVITROL; recognition of milestone payments from our partner Cephalon related to the future sales of VIVITROL; the successful continuation of development activities for our programs, including long-acting release (LAR) formulation of exenatide (exenatide LAR)®, AIRled Insulin (AIR Insulin) and AIRparathyroid hormone (AIR PTH); the successful manufacture of our products and product candidates, including RISPERDAL CONSTA and VIVITROL, and the successful manufacture of exenatide LAR by Amylin Pharmaceuticals, Inc. (Amylin); the building of a selling and marketing infrastructure for VIVITROL by ourselves or our partner Cephalon; whether we can successfully manufacture VIVITROL at a commercial scale; and the successful scale-up,

establishment and expansion of manufacturing capacity, are neither promises nor guarantees; and our business is subject to significant risk and uncertainties and there can be no assurance that our actual results will not differ materially from our expectations. Factors which could cause actual results to differ materially from our expectations set forth in our forward-looking statements include, among others: (i) manufacturing and royalty revenues for RISPERDAL CONSTA may not continue to grow, particularly because we rely on our partner,

Table of Contents

Janssen, to forecast and market this product; (ii) we may be unable to manufacture RISPERDAL CONSTA in sufficient quantities and with sufficient yields to meet Janssen's requirements or to add additional production capacity for RISPERDAL CONSTA, or unexpected events could interrupt manufacturing operations at our RISPERDAL CONSTA facility, which is the sole source of supply for that product; (iii) we may be unable to manufacture VIVITROL economically or in sufficient quantities and with sufficient yields to meet our own or our partner Cephalon's requirements or add additional production capacity for VIVITROL, or unexpected events could interrupt manufacturing operations at our VIVITROL facility, which is the sole source of supply for that product; (iv) we and our partner Cephalon may be unable to develop the selling and marketing capabilities, and/or infrastructure necessary to jointly support the commercialization of VIVITROL; (v) we and our partner Cephalon may be unable to launch VIVITROL successfully; (vi) VIVITROL may not produce significant revenues; (vii) because we have limited selling, marketing and distribution experience, we depend significantly on our partner Cephalon to successfully commercialize VIVITROL; (viii) third party payors may not cover or reimburse VIVITROL; (ix) we may be unable to scale-up and manufacture our other product candidates, including exenatide LAR and AIR Insulin and AIR PTH, commercially or economically; (x) we may not be able to source raw materials for our production processes from third parties; (xi) we may not be able to successfully transfer manufacturing technology for exenatide LAR to Amylin and Amylin may not be able to successfully operate the manufacturing facility for exenatide LAR; (xii) our other product candidates, if approved for marketing, may not be launched successfully in one or all indications for which marketing is approved and, if launched, may not produce significant revenues; (xiii) we rely on our partners to determine the regulatory and marketing strategies for RISPERDAL CONSTA and our other partnered, non-proprietary programs; (xiv) we rely on our partner Cephalon to commercialize VIVITROL in the U.S.; (xv) RISPERDAL CONSTA, VIVITROL and our product candidates in commercial use may have unintended side effects, adverse reactions or incidents of misuse and the U.S. Food and Drug Administration (FDA) or other health authorities could require post approval studies or require removal of our products from the market; (xvi) 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; (xvii) clinical trials may take more time or consume more resources than initially envisioned; (xviii) results of earlier clinical trials are not necessarily predictive of the safety and efficacy results in larger clinical trials; (xix) 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; (xx) after the completion of clinical trials for our product candidates and the submission for marketing approval, 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 the failure of such product to receive marketing approval; (xxi) 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; (xxii) technological change in the biotechnology or pharmaceutical industries could render our product candidates obsolete or non-competitive; (xxiii) difficulties or set-backs in obtaining and enforcing our patents and difficulties with the patent rights of others could occur; (xxiv) we may continue to incur losses in the future; (xxv) the effect of our adoption of Statement of Financial Accounting Standard No. 123R, *Share-Based Payment* (SFAS 123R) on our results of operations depends on a number of factors, many of which are out of our control, including estimates of stock price volatility, option terms, interest rates, the number and type of stock options and stock awards granted during the reporting period, as well as other factors; (xxvi) we face potential liabilities and diversion of management's attention as a result of a pending informal SEC investigation and any private litigation regarding our past practices with respect to equity incentives; (xxvii) we may not recoup any of our \$100.0 million investment in Reliant Pharmaceuticals, LLC (Reliant); and (xxviii) we may need to raise substantial additional funding to continue research and development programs and clinical trials and could incur difficulties or setbacks in raising such funds.

Table of Contents

The forward-looking statements made in this document are made only as of the date hereof and we do not intend to update any of these factors or to publicly announce the results of any revisions to any of our forward-looking statements other than as required under the federal securities laws.

Product Developments

VIVITROL

On June 13, 2006, VIVITROL became commercially available in the U.S.

AIR Insulin

On June 10, 2006, we and Eli Lilly and Company (Lilly) reported new study results of the companies' investigational AIR Inhaled Insulin System (AIR Insulin System), including the first published analysis of the effect of chronic obstructive pulmonary disease (COPD) on inhaled insulin absorption and action; the importance to patients of simple, patient-directed training of an inhaled insulin system; and dosing flexibility with the AIR Insulin System. These study findings were presented at the American Diabetes Association's (ADA) 66th Annual Scientific Sessions in Washington, D.C. This Phase I study is the first published analysis of the effect of COPD on inhaled insulin absorption and action and was designed to evaluate the impact that compromised lung function has on inhaled insulin dose delivery. As expected in a patient population with compromised lung function, the absorption and action of AIR Insulin was reduced by a consistent amount in the presence of COPD. The results also demonstrated that AIR Insulin was able to deliver similar results on different days in patients with or without COPD and was generally well-tolerated.

On June 5, 2006, we and Lilly announced the completion of patient enrollment in a pivotal safety study required for registration for the AIR Insulin System. The goal of the study is to more fully define the safety and efficacy of the AIR Insulin System in patients with type one diabetes. This study is part of a comprehensive Phase III clinical program that began in July 2005 which includes pivotal efficacy studies and additional long-term safety studies in both type one and type two diabetes patients.

Exenatide LAR

On June 10, 2006, we, Amylin Pharmaceuticals, Inc. and Lilly announced detailed results from a safety and efficacy study of the LAR formulation of BYETTA® (exenatide) injection. Data from the study demonstrated that 86 percent of patients using the higher of two doses of the once-weekly formulation of exenatide were able to achieve recommended levels of glucose control, as measured by hemoglobin A1C (A1C), with an average improvement of approximately two percent compared to placebo. These study findings were presented at the ADA's 66th Annual Scientific Sessions in Washington, D.C. The study was conducted in 45 patients with type-two diabetes unable to achieve adequate glucose control with metformin or a diet and exercise regimen. The patients received a once-weekly subcutaneous injection of exenatide LAR (either 0.8 mg or 2.0 mg) or placebo. After 15 weeks of treatment there was a 12-week safety monitoring period during which no study medication was administered. Dose-dependent improvements in A1C and weight loss were observed at 15 weeks.

Critical Accounting Policies

As fully described in the Management's Discussion and Analysis of Financial Condition and Results of Operations section of our Annual Report on Form 10-K/A for the year ended March 31, 2006, we consider our critical accounting policies to be as follows. We refer the reader to our Annual Report on Form 10-K/A for more information on these policies.

Revenue recognition;

Derivatives embedded in certain debt securities;

Warrant valuation;

Cost of goods manufactured;

Research and development expenses;

Restructuring charges;

Table of Contents

Accrued expenses;

Income taxes; and

Share-based compensation.

Results of Operations

The net loss in accordance with accounting principles generally accepted in the United States of America (commonly referred to as GAAP) for the three months ended June 30, 2006 was \$0.7 million, or \$0.01 per basic and diluted loss per common share, as compared to a net loss of \$13.7 million, or \$0.15 per basic and diluted loss per common share, for the same period in 2005.

Total revenues were \$51.5 million for the three months ended June 30, 2006, as compared to \$24.8 million for the three months ended June 30, 2005.

Total manufacturing revenues were \$22.2 million for the three months ended June 30, 2006, as compared to \$14.0 million for the three months ended June 30, 2005. The increase in manufacturing revenues for the three months ended June 30, 2006, as compared to the same period in 2005, was due to increased shipments of RISPERDAL CONSTA to Janssen, first time shipments of VIVITROL to our partner Cephalon and recognition of milestone revenue related to the manufacture of VIVITROL.

RISPERDAL CONSTA manufacturing revenue was \$19.1 million for the three months ended June 30, 2006, as compared to \$14.0 million for the three months ended June 30, 2005. The increase in RISPERDAL CONSTA revenues in the three months ended June 30, 2006, as compared to the same period in 2005, was due to our increased shipments of the product to satisfy demand. Under our manufacturing and supply agreement with Janssen, we earn manufacturing revenues upon shipment of product by us to Janssen based on a percentage of Janssen's net selling price. These percentages are based on the anticipated volume of units shipped to Janssen in any given calendar year, with a minimum manufacturing fee of 7.5%. We anticipate that we will earn manufacturing revenues at 7.5% of Janssen's net sales price for RISPERDAL CONSTA in the fiscal year ending March 31, 2007 and beyond. We earned manufacturing revenues at an average of 7.5% of Janssen's net sales price in the fiscal year ended March 31, 2006.

VIVITROL manufacturing revenue was \$3.1 million for the three months ended June 30, 2006. We did not record any manufacturing revenue related to VIVITROL for the three months ending June 30, 2005. We began shipping VIVITROL to our partner Cephalon for the first time during the three months ended June 30, 2006. Under our agreements with Cephalon, we bill Cephalon at cost for finished commercial product shipped to them. VIVITROL manufacturing revenue for the three months ended June 30, 2006 included \$0.3 million of milestone revenue related to manufacturing profit on VIVITROL. This equates to 10% profit on sales of VIVITROL to Cephalon. We recognized this revenue for the first time during the three months ended June 30, 2006 as we began shipping VIVITROL to Cephalon.

Total royalty revenues were \$5.1 million for the three months ended June 30, 2006, based on RISPERDAL CONSTA sales of \$205 million, as compared to \$3.6 million for the three months ended June 30, 2005, based on RISPERDAL CONSTA sales of \$144 million. The increase in royalty revenues for the three months ended June 30, 2006, as compared to the same period in 2005, was due to an increase in global sales of RISPERDAL CONSTA by Janssen. Under our license agreements with Janssen, we record royalty revenues equal to 2.5% of Janssen's net sales of RISPERDAL CONSTA in the quarter when the product is sold by Janssen, based upon net sales reports furnished by Janssen.

Research and development revenue under collaborative arrangements was \$14.5 million for the three months ended June 30, 2006, as compared to \$7.3 million for the three months ended June 30, 2005. The increase in research and development revenue for the three months ended June 30, 2006, as compared to the same period in 2005, was primarily due to increases in revenues related to work performed on the AIR Insulin and exenatide LAR programs.

Net collaborative profit was \$9.7 million for the three months ended June 30, 2006. We did not record any net collaborative profit for the three months ending June 30, 2005. For the three months ended June 30,

Table of Contents

2006, we recognized \$27.4 million of milestone revenue cost recovery to offset losses incurred on VIVITROL by both us and Cephalon. This consisted of approximately \$8.3 million of expenses that we incurred on behalf of the collaboration, \$18.9 million of net losses incurred by Cephalon on behalf of the collaboration and \$0.2 million of expenses that we incurred with respect to our efforts to obtain FDA approval of VIVITROL, for which we were solely responsible. In addition, following FDA approval of VIVITROL, we recognized \$1.2 million of milestone revenue related to the licenses provided to Cephalon to commercialize VIVITROL. During the three months ended June 30, 2006, we made payments of \$18.9 million to Cephalon to reimburse their net losses on VIVITROL. In the aggregate, net collaborative profit of \$9.7 million for the three months ended June 30, 2006 consisted of \$28.6 million of milestone revenue, partially offset by the \$18.9 million of payments we made to Cephalon to reimburse their losses on VIVITROL.

A summary of net collaborative profit for the three months ended June 30, 2006 follows:

	June 30, 2006
(In thousands)	
Milestone revenue cost recovery:	
Alkermes expenses incurred on behalf of the collaboration	\$ 8,355
Cephalon net losses incurred on behalf of the collaboration	18,873
Alkermes expenses for which Alkermes was solely responsible	196
Total milestone revenue cost recovery	27,424
Milestone revenue licenses	1,191
Total milestone revenue cost recovery and licenses	28,615
Payments made to Cephalon to reimburse their net losses	(18,873)
Net collaborative profit	\$ 9,742

On April 27, 2006, we received a nonrefundable milestone payment of \$110.0 million from Cephalon following approval of VIVITROL by the FDA. The payment was deemed to be arrangement consideration in accordance with Emerging Issues Task Force 00-21, *Revenue Arrangements with Multiple Deliverables* (EITF 00-21). The payment was recorded in our unaudited condensed consolidated balance sheets under the caption Unearned milestone revenue long-term portion . The classification between the current and long-term portions of unearned milestone revenue was based on our estimate of whether the related milestone revenue was expected to be recognized during or beyond the 12-month period following June 30, 2006, respectively.

We are responsible for the first \$120.0 million of net losses incurred on VIVITROL through December 31, 2007. Through June 30, 2006, the cumulative net losses incurred by us and Cephalon on VIVITROL, against this \$120.0 million, were \$68.2 million, of which approximately \$28.1 million was incurred by us on behalf of the collaboration and \$40.1 million was incurred by Cephalon on behalf of the collaboration.

Our estimates of the fair value of deliverables under our agreements with Cephalon, upon which arrangement consideration was allocated, was unchanged from our March 31, 2006 estimates.

Cost of goods manufactured was \$9.3 million for the three months ended June 30, 2006, as compared to \$4.5 million for the three months ended June 30, 2005. The increase in cost of goods manufactured for the three months ended June 30, 2006, as compared to the same period in 2005, was due to increased shipments of RISPERDAL CONSTA to Janssen and first time shipments of VIVITROL to Cephalon. Cost of goods manufactured included share-based compensation expense in the amount of \$0.3 million resulting from the adoption of SFAS 123R beginning April 1, 2006.

Cost of goods manufactured for RISPERDAL CONSTA was \$6.5 million for the three months ended June 30, 2006, as compared to \$4.5 million for the three months ended June 30, 2005. The increase in cost of goods manufactured for RISPERDAL CONSTA in the three months ended June 30, 2006, as compared to the same period in 2005, was due to increased shipments of the product to satisfy demand.

Table of Contents

Cost of goods manufactured for VIVITROL was \$2.8 million for the three months ended June 30, 2006. We did not record any cost of goods manufactured for VIVITROL for the three months ending June 30, 2005. We began shipping VIVITROL to our partner Cephalon for the first time during the three months ended June 30, 2006.

Research and development expenses were \$25.9 million for the three months ended June 30, 2006, as compared to \$21.6 million for the three months ended June 30, 2005. The increase for the three months ended June 30, 2006, as compared to the same period in 2005, was due to increased personnel-related costs on work performed on our product candidates, and to share-based compensation expense in the amount of \$2.8 million resulting from the adoption of SFAS 123R beginning April 1, 2006.

A significant portion of our research and development expenses (including laboratory supplies, travel, dues and subscriptions, recruiting costs, temporary help costs, consulting costs and allocable costs such as occupancy and depreciation) are not tracked by project as they benefit multiple projects or our drug delivery technologies in general. Expenses incurred to purchase specific services from third parties to support our collaborative research and development activities are tracked by project and are reimbursed to us by our partners. We generally bill our partners under collaborative arrangements using a single full-time equivalent or hourly rate. This rate has been established by us based on our annual budget of employee compensation, employee benefits and the billable non-project-specific costs mentioned above and is generally increased annually based on increases in the consumer price index. Each collaborative partner is billed using a full-time equivalent or hourly rate for the hours worked by our employees on a particular project, plus any direct external research costs, if any. We account for our research and development expenses on a departmental and functional basis in accordance with our budget and management practices.

Selling, general and administrative expenses were \$16.5 million for the three months ended June 30, 2006, as compared to \$9.0 million for the three months ended June 30, 2005. The increase for the three months ended June 30, 2006, as compared to the same period in 2005, was primarily due to share-based compensation expense in the amount of \$5.2 million resulting from the adoption of SFAS 123R beginning April 1, 2006, and increases in selling and marketing costs related to VIVITROL.

Interest income was \$4.3 million for the three months ended June 30, 2006, as compared to \$1.6 million for the three months ended June 30, 2005. The increase for the three months ended June 30, 2006, as compared to the same period in 2005, was primarily due to higher interest rates earned during the period and higher average cash and investment balances held due to the non-refundable payments we received from Cephalon in the amounts of \$160.0 million and \$110.0 million in June 2005 and April 2006, respectively.

Interest expense was \$5.5 million for the three months ended June 30, 2006, as compared to \$5.2 million for the three months ended June 30, 2005. Interest expense for the quarter ended June 30, 2006 included a one-time interest charge in the amount of \$0.6 million in connection with the conversion of our 2.5% convertible subordinated notes due 2023 (the 2.5% Subordinated Notes) to satisfy the three-year interest make-whole provision in the note indenture. We incur approximately \$4.0 million of interest expense each quarter on the non-recourse RISPERDAL CONSTA secured 7% notes (the Non-Recourse 7% Notes) through the period until principal repayment starts on April 1, 2009.

Derivative loss related to convertible subordinated notes for the three months ended June 30, 2006 was \$0, as compared to a loss of \$0.3 million for the three months ended June 30, 2005. Beginning January 1, 2006, we no longer record changes in the estimated fair value of the embedded derivatives in our results of operations in accordance with Financial Accounting Standards Board DIG Issue B39, *Embedded Derivatives: Application of Paragraph 13(b) to Call Options That Are Exercisable Only by the Debtor* . Derivative loss represented changes in the fair value of the three-year interest make-whole provision included in the 2.5% Subordinated Notes.

Other income (expense), net was an income of \$0.8 million for the three months ended June 30, 2006, as compared to an income of \$0.3 million for the three months ended June 30, 2005. Other income (expense), net primarily consists of income or expense recognized for changes in the fair value of warrants of public companies held by us in connection with collaboration and licensing arrangements, which were recorded under

Table of Contents

the caption *Other assets* on the unaudited condensed 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.

Income taxes were \$0.2 million for the three months ended June 30, 2006. We did not record a provision for income taxes for the three months ended June 30, 2005. The provision for income taxes for the three months ended June 30, 2006 related to the U.S. alternative minimum tax. Utilization of our tax loss carryforwards is limited for use against the U.S. alternative minimum tax resulting in federal tax obligations for us in fiscal 2007.

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

Financial Condition

Cash and cash equivalents were \$107.9 million and \$33.6 million as of June 30, 2006 and March 31, 2006, respectively. Short-term investments were \$260.6 million and \$264.4 million as of June 30, 2006 and March 31, 2006, respectively. During the three months ended June 30, 2006, combined cash and cash equivalents and short-term investments increased by \$70.5 million to \$368.5 million, primarily due to the receipt of a \$110.0 million non-refundable milestone payment we received from Cephalon on April 27, 2006 following FDA approval of VIVITROL, partially offset by cash used to fund our operations, to acquire fixed assets, and to service our debt.

We invest in cash equivalents, U.S. government obligations, high-grade corporate notes and commercial paper, with the exception of our \$100.0 million investment in Reliant, and warrants we received in connection with our collaborations and licensing activities. Our investment objectives, other than our investment in Reliant and our warrants, are, first, to assure liquidity and conservation of capital and, second, to obtain investment income. We held approximately \$5.1 million of U.S. government obligations classified as restricted long-term investments as of June 30, 2006 and March 31, 2006, which are pledged as collateral under certain letters of credit and lease agreements.

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

Inventory, net was \$11.4 million and \$7.3 million as of June 30, 2006, and March 31, 2006, respectively. This consisted of RISPERDAL CONSTA inventory of \$5.5 million and \$4.8 million as of June 30, 2006 and March 31, 2006, respectively, and VIVITROL inventory of \$5.9 million and \$2.5 million as of June 30, 2006 and March 31, 2006, respectively. The increase in inventory, net of \$4.1 million during the three months ended June 30, 2006 was primarily due to the increases in VIVITROL work in process and finished goods inventories as manufacturing activity increased in preparation for the launch of the product, and to the capitalization of share-based compensation cost to inventory in the amount of \$0.7 million resulting from the adoption of SFAS 123R. In addition, finished goods inventory of RISPERDAL CONSTA increased due to the timing of shipments to Janssen.

Unearned milestone revenue *current and long-term portions combined*, were \$180.6 million and \$99.5 million as of June 30, 2006 and March 31, 2006, respectively. The increase during the three months ended June 30, 2006 was due to the receipt of the \$110.0 million non-refundable milestone payment from Cephalon on April 27, 2006 following FDA approval of VIVITROL, reduced by \$28.6 million and \$0.3 million of milestone revenue we recognized under the captions *Net collaborative profit* and *Manufacturing revenues*, respectively, in the unaudited condensed consolidated statement of operations during the three month period ended June 30, 2006.

Liquidity and Capital Resources

We have funded our operations primarily through public offerings and private placements of debt and equity securities, bank loans, term loans, equipment financing arrangements and payments received under research and development agreements and other 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,

Table of Contents

clinical trials and facilities expansion. Our costs, including research and development costs for our product candidates and sales, marketing and promotion expenses for any future products to be marketed by us or our collaborators, if any, may exceed revenues in the future, which may result in losses from operations.

We believe that our current cash and cash equivalents and short-term investments, combined with our unused equipment lease line, anticipated interest income, anticipated manufacturing and royalty revenues, anticipated research and development revenue under collaborative arrangements, and anticipated net collaborative profit from our collaboration with Cephalon, will generate sufficient cash flows to meet our anticipated liquidity and capital requirements through at least March 31, 2008.

We may 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, arrangements relating to assets or other financing methods or structures. 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 and, for any future proprietary products, the sales, marketing and promotion expenses associated with marketing such products.

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 sales 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.

On April 27, 2006, we received a nonrefundable milestone payment of \$110.0 million from Cephalon following approval of VIVITROL by the FDA.

Capital expenditures were \$6.2 million for the three months ended June 30, 2006. Our capital expenditures were primarily related to the purchase of equipment to make improvements to and expand our manufacturing facility in Ohio. 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, General Electric Capital Corporation (GE) and Johnson & Johnson Finance Corporation have security interests in certain of our capital assets.

Contractual Obligations

The contractual cash obligations disclosed in our Annual Report on Form 10-K/A for the year ended March 31, 2006, have not changed materially except for the elimination of our obligations related to the 2.5% Subordinated Notes, which we converted into common stock on June 15, 2006 (see Note 5 to the unaudited condensed consolidated financial statements).

Off-Balance Sheet Arrangements

As of June 30, 2006, we were not a party to any off-balance sheet financing arrangements, other than operating leases.

Item 3. *Quantitative and Qualitative Disclosures about Market Risk*

We hold financial instruments in our investment portfolio that are sensitive to market risks. Our investment portfolio, excluding our investment in Reliant, and warrants we receive in connection with our collaborations and licensing activities, is used to preserve capital until it is required to fund operations. Our

Table of Contents

short-term and restricted long-term investments consist of U.S. government obligations, high-grade corporate notes and commercial paper. These debt securities are: (i) classified as available-for-sale; (ii) are recorded at fair value; and (iii) are subject to interest rate risk, and could decline in value if interest rates increase. Due to the conservative nature of our short-term and long-term investments and our investment policy, 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.

We also hold certain marketable equity securities, including warrants to purchase the securities of publicly traded companies we collaborate with, that are classified as available-for-sale and recorded at fair value under the caption

Other assets in the condensed consolidated balance sheets. These marketable equity 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% increase or decrease in market interest rates would not have a material impact on the condensed consolidated financial statements.

As of June 30, 2006, the fair value of our Non-Recourse 7% Notes and our 3.75% convertible subordinated notes (3.75% Subordinated Notes) approximate the carrying values. The interest rates on these notes, and our capital lease obligations, are fixed and therefore not subject to interest rate risk. A 10% increase or decrease in market interest rates would not have a material impact on the consolidated financial statements.

As of June 30, 2006, we have a term loan that bears a floating interest rate equal to the one-month London Interbank Offered Rate (LIBOR) plus 5.45%. A 10% increase or decrease in market interest rates would not have a material impact on the condensed consolidated financial statements.

Foreign Currency Exchange Rate Risk

The royalty revenues we receive on RISPERDAL CONSTA are a percentage of the net sales made by our collaborative partner. Some of these sales are made in foreign countries and are denominated in foreign currencies. The royalty payment on these foreign sales is calculated initially in the foreign currency in which the sale is made and is then converted into U.S. dollars to determine the amount that our collaborative partner pays us for royalty revenues. Fluctuations in the exchange ratio of the U.S. dollar and these foreign currencies will have the effect of increasing or decreasing our royalty revenues even if there is a constant amount of sales in foreign currencies. For example, if the U.S. dollar strengthens against a foreign currency, then our royalty revenues will decrease given a constant amount of sales in such foreign currency.

The impact on our royalty revenues from foreign currency exchange rate risk is based on a number of factors, including the exchange rate (and the change in the exchange rate from the prior period) between a foreign currency and the U.S. dollar, and the amount of sales by our collaborative partner that are denominated in foreign currencies. We do not currently hedge our foreign currency exchange rate risk.

Item 4. Controls and Procedures

(a) Evaluation of Disclosure Controls and Procedures

As of June 30, 2006, our management, with the participation of our Chief Executive Officer and Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures pursuant to Rule 13a-15(b) promulgated under the Securities Exchange Act of 1934, as amended (the Exchange Act). Due to the identification of a material weakness in internal control over financial reporting related to the Company s accounting for stock-based

compensation that resulted in the restatement of previously issued financial statements, as described in our Annual Report on Form 10-K/A for the fiscal year ended March 31, 2006, our Chief Executive Officer and Chief Financial Officer concluded that, as of June 30, 2006, our disclosure controls and procedures were not effective in ensuring that material information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission's rules and forms, including ensuring that such material

Table of Contents

information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate to allow timely decisions regarding required disclosure.

The Public Company Accounting Oversight Board's Auditing Standard No. 2 defines a material weakness as a significant deficiency, or a combination of significant deficiencies, that results in there being a more than remote likelihood that a material misstatement of the annual or interim financial statements will not be prevented or detected. Management identified a material weakness in internal control over financial reporting in connection with this assessment. Specifically, the Company did not design and implement controls necessary to provide reasonable assurance that the measurement date for stock option grants was appropriately determined. As a result the measurement date used for certain option grants was not appropriate resulting in those grants not being accounted for in accordance with accounting principles generally accepted in the United States. This material weakness resulted in the restatement of previously issued financial statements as described in our Annual Report on Form 10-K/A for the fiscal year ended March 31, 2006. This deficiency was determined to be a material weakness due to the actual misstatements identified, the potential for additional material misstatements to have occurred as a result of the deficiency, and the lack of other mitigating controls.

(b) Change in Internal Control over Financial Reporting

During the period covered by this report, there have been no changes in our internal control over financial reporting that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Regarding the material weakness described above, the Company has adopted new stock option granting procedures to remediate this weakness and, after consultation with our outside legal counsel, believes that such procedures will remediate this material weakness.

Table of Contents

PART II. OTHER INFORMATION

Item 1A. Risk Factors

The following Risk Factor should be read in conjunction with the Risk Factors disclosed in our Annual Report on Form 10-K/A for the year ended March 31, 2006.

We face risks related to the restatement of our financial statements and a pending informal SEC investigation regarding our past practices with respect to equity incentives.

In May 2006, we were mentioned in a third-party report suggesting that we were at moderate risk for options backdating (the Report) with respect to our annual grants of options to all employees of the Company dated October 28, 1999 and November 20, 2000. Shortly after the Report appeared, we were contacted by the Securities and Exchange Commission (SEC) with respect to our option practices for the years mentioned in the Report. We have cooperated fully with the SEC's informal inquiry, which is ongoing. As a result of the appearance of the Report, and concurrent with the SEC's informal inquiry, the audit committee of the Board of Directors undertook an investigation into our option practices for the period 1999 to 2000 as well as for 2001 and 2002. The review was conducted with the assistance of outside legal counsel and outside accounting consultants. The audit committee has completed its investigation and has concluded that nothing has come to its attention that would cause it to believe that there were any instances where management of the Company or the compensation committee of the Company retroactively selected a date for the grant of stock options during the 1999 through 2002 period. Also, management reviewed its option grant practices for the period from 2003 to date. In the course of the inquiries conducted by the audit committee and management, certain issues were identified with respect to the measurement date for one grant in each of 2000 and 2005 as a result of changes that may have been made to option grants for a limited number of non-executive employees subsequent to the grant date, and the Company has determined that the accounting for the 2000 and 2005 grants should be adjusted. In both instances, the aggregate amount of options granted decreased after the grant date. No options from either the 2000 or 2005 grants have been exercised. As a result of the review, we have restated our consolidated balance sheets as of March 31, 2006 and 2005, our consolidated statements of operations for the years ended March 31, 2005 and 2004, our consolidated statements of cash flows for the years ended March 31, 2005 and 2004, our consolidated statements of changes in stockholders equity for the years ended March 31, 2006, 2005 and 2004, and the related disclosures. With respect to the 2005 grant, since the new measurement date for the 2005 grant had a lower stock price than that used in its original accounting, no adjustment to expenses recorded in our financial statements was required.

At this point we are unable to predict what, if any, consequences these issues relating to our option grants may have on us. The filing of our restated financial statements to correct the discovered accounting errors may not resolve the pending informal SEC investigation into our grants of employee stock options, and the SEC may or may not agree with the adjustments we are making to our financial statements. There could be considerable legal and other expenses associated with the SEC inquiry and any private litigation that might be filed relating to these issues.

Our CEO has received a letter, dated August 11, 2006, on behalf of purported owners of our securities, purportedly constituting demands under Pennsylvania law. The letter claims, among other things, that certain of our officers and directors breached their fiduciary duty to us by allegedly violating the terms of the Company's stock option plans, violating generally accepted accounting practices by failing to recognize compensation expenses with respect to certain option grants during the years 1995-2002, and disseminating inaccurate financial statements. The letter requests, among other things, that our Board of Directors take action on our behalf to recover from the officers and directors the amount of damages sustained by the Company as a result of the alleged misconduct, among other

amounts. As required by applicable law, our Board of Directors is currently considering the letter and will respond in a time and manner consistent with Pennsylvania law.

The above and any other similar matters could divert management's attention from other business concerns. Such matters could also result in significant monetary liability for the Company, or require that we take other actions not presently contemplated.

Table of Contents**Item 2. *Unregistered Sales of Equity Securities and Use of Proceeds***

A summary of our stock repurchase activity for the three months ended June 30, 2006 is set forth in the table below:

Period	Total Number of Shares Purchased(a)(b)	Average Price Paid per Share (in thousands, except share and per share amounts)	Total Number of Shares	Approximate Dollar Value of Shares
			Purchased as Part of a Publicly Announced Program(a)(b)	That May Yet be Purchased Under the Program
April 1 through April 30		\$		\$ 15,000
May 1 through May 31	65,500	19.27	65,500	13,735
June 1 through June 30	69,130	19.75	69,130	12,373
Total	134,630	\$ 19.52	134,630	

(a) In September 2005, our Board of Directors authorized a share repurchase program of up to \$15.0 million of common stock to be repurchased in the open market or through privately negotiated transactions. The repurchase program has no set expiration date and may be suspended or discontinued at any time. We publicly announced the share repurchase program in our press release for the fiscal 2006 second quarter financial results dated November 3, 2005.

In addition to the stock repurchases above, we purchased, by means of employee forfeitures, 23,565 shares on June 16, 2006, at an average price of \$18.99, to pay withholding taxes on employee stock awards.

Item 5. *Other Information*

The Company's policy governing transactions in its securities by its directors, officers and employees permits its officers, directors and employees to enter into trading plans in accordance with Rule 10b5-1 under the Exchange Act. During the quarter ended June 30, 2006, subsequent to FDA approval of VIVITROL and the Company's announcement of its financial results for the fiscal year ended March 31, 2006, Mr. Richard F. Pops, Mr. David A. Broecker, Mr. James M. Frates and Mr. Michael J. Landine, executive officers of the Company, entered into trading plans in accordance with Rule 10b5-1 and the Company's policy governing transactions in its securities by its directors, officers and employees. The Company undertakes no obligation to update or revise the information provided herein, including for revision or termination of an established trading plan.

Item 6. *Exhibits*

(a) List of Exhibits:

Exhibit Index

**Exhibit
No.**

- 10.1 Alkermes Fiscal 2007 Named Executive Bonus Plan (filed as exhibit 10.1 to the Current Report on Form 8-K on May 8, 2006 and incorporated herein by reference).

- 31.1 Rule 13a-14(a)/15d-14(a) Certification (furnished herewith).

- 31.2 Rule 13a-14(a)/15d-14(a) Certification (furnished herewith).

- 32.1 Certification pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (furnished herewith).

Table of Contents

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)

By: /s/ Richard F. Pops

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

Date: August 14, 2006

By: /s/ James M. Frates

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

Date: August 14, 2006

Table of Contents

EXHIBIT INDEX

**Exhibit
No.**

- 10.1 Alkermes Fiscal 2007 Named Executive Bonus Plan (filed as exhibit 10.1 to the Current Report on Form 8-K on May 8, 2006 and incorporated herein by reference).
- 31.1 Rule 13a-14(a)/15d-14(a) Certification (furnished herewith).
- 31.2 Rule 13a-14(a)/15d-14(a) Certification (furnished herewith).
- 32.1 Certification pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (furnished herewith).