ALKERMES INC Form 10-Q November 09, 2007

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

Form 10-Q

(Mark One)

- **DESCRIPTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
 - For the quarterly period ended September 30, 2007
- o 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)
88 Sidney Street, Cambridge, MA

(Address of principal executive offices)

23-2472830

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

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 b No o

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 b Accelerated filer o Non-accelerated filer o

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

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

As of November 2, 2007

Class

Common Stock, \$.01 par value Non-Voting Common Stock, \$.01 par value 101,822,912 382,632

ALKERMES, INC. AND SUBSIDIARIES

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PART 1. FINANCIAL INFORMATION

Item 1. Condensed Consolidated Financial Statements:

ALKERMES, INC. AND SUBSIDIARIES

CONDENSED CONSOLIDATED BALANCE SHEETS (unaudited)

	-	September 30, Marc 2007 200 (In thousands, except and per share amou			
ASSETS					
CURRENT ASSETS:					
Cash and cash equivalents	\$	86,419	\$	80,500	
Investments short-term		271,381		271,082	
Receivables		43,878		56,049	
Inventory		21,202		18,190	
Prepaid expenses and other current assets		8,246		7,054	
Total current assets		431,126		432,875	
PROPERTY, PLANT AND EQUIPMENT:					
Land		301		301	
Building and improvements		31,858		25,717	
Furniture, fixtures and equipment		67,420		64,203	
Equipment under capital lease		464		464	
Leasehold improvements		33,313		32,345	
Construction in progress		46,480		42,442	
		179,836		165,472	
Less: accumulated depreciation and amortization		(47,992)		(41,877)	
Property, plant and equipment net		131,844		123,595	
RESTRICTED INVESTMENTS		5,146		5,144	
OTHER ASSETS		4,766		7,007	
TOTAL ASSETS	\$	572,882	\$	568,621	
LIABILITIES AND SHAREHOLDERS	FAIIITV	,			
CURRENT LIABILITIES:	LQUIII				
Accounts payable and accrued expenses	\$	21,914	\$	45,855	
Accrued interest	Ψ	2,975	Ψ	2,976	
		2,713		2,770	
				_	

Unearned milestone revenue current portion Deferred revenue current portion Long-term debt current portion	6,073 125 982	11,450 200 1,579
Total current liabilities	32,069	62,060
NON-RECOURSE RISPERDAL CONSTA SECURED 7% NOTES UNEARNED MILESTONE REVENUE LONG-TERM PORTION DEFERRED REVENUE LONG-TERM PORTION OTHER LONG-TERM LIABILITIES	158,553 114,576 23,082 5,842	156,851 117,300 22,153 6,796
TOTAL LIABILITIES	334,122	365,160
COMMITMENTS AND CONTINGENCIES (Notes 7 and 8) SHAREHOLDERS EQUITY: Capital stock, par value, \$0.01 per share; authorized, 4,550,000 shares (includes 3,000,000 shares of preferred stock); issued, none Common stock, par value, \$0.01 per share; authorized, 160,000,000 shares; 102,595,913 and 101,550,673 shares issued, 101,772,236 and 100,726,996 shares outstanding at September 30, 2007 and March 31, 2007, respectively	1,026	1,015
Non-voting common stock, par value, \$0.01 per share; authorized, 450,000 shares;	1,020	1,013
issued and outstanding, 382,632 shares at September 30, 2007 and March 31, 2007 Treasury stock, at cost (823,677 shares at September 30, 2007 and March 31, 2007) Additional paid-in capital Accumulated other comprehensive income Accumulated deficit	4 (12,492) 857,120 203 (607,101)	4 (12,492) 837,727 753 (623,546)
TOTAL SHAREHOLDERS EQUITY	238,760	203,461
TOTAL LIABILITIES AND SHAREHOLDERS EQUITY	\$ 572,882	\$ 568,621

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

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ALKERMES, INC. AND SUBSIDIARIES

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS (unaudited)

	Septem 2007	hree Months Ended September 30, 2007 2006 (In thousands, except pe			Six Months Ended September 30, 2007 2006 per share amounts)		
REVENUES: Manufacturing revenues Royalty revenues Research and development revenue under collaborative arrangements Net collaborative profit	\$ 24,137 7,348 21,206 5,909	\$	26,122 5,813 17,624 11,611	\$	55,654 14,330 44,656 12,898	\$	48,315 10,952 32,088 21,353
Total revenues EXPENSES: Cost of goods manufactured	58,600 9,218		61,170 11,822		127,538 19,363		112,708 21,160
Research and development Selling, general and administrative	28,317 14,487		29,817 15,677		60,936 29,887		55,680 32,207
Total expenses OPERATING INCOME	52,022 6,578		57,316 3,854		110,186 17,352		3,661
OTHER INCOME (EXPENSE): Interest income Interest expense Other income (expense), net	4,246 (4,077) 1,151		4,734 (4,034) (664)		8,648 (8,150) 1,177		9,069 (9,507) 123
Total other income (expense)	1,320		36		1,675		(315)
INCOME BEFORE INCOME TAXES INCOME TAXES	7,898 200		3,890 164		19,027 2,582		3,346 335
NET INCOME	\$ 7,698	\$	3,726	\$	16,445	\$	3,011
EARNINGS PER COMMON SHARE: BASIC	\$ 0.08	\$	0.04	\$	0.16	\$	0.03
DILUTED	\$ 0.07	\$	0.04	\$	0.16	\$	0.03
WEIGHTED AVERAGE NUMBER OF COMMON SHARES OUTSTANDING: BASIC	101,595		101,331		101,663		97,581

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DILUTED 104,315 105,543 104,446 102,536

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

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ALKERMES, INC. AND SUBSIDIARIES

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS (unaudited)

Six Months Ended

	September 30,			
	2007 (In thousa			2006
		(=== ==== =)
CASH FLOWS FROM OPERATING ACTIVITIES:				
Net income	\$	16,445	\$	3,011
Adjustments to reconcile net income to cash flows from operating activities:				
Share-based compensation		10,295		14,718
Depreciation and amortization		6,114		5,767
Other non-cash charges		2,187		2,228
Change in fair value of warrants		(1,426)		(153)
Gain on sale of equipment				(9)
Changes in assets and liabilities:				
Receivables		10,939		(24,482)
Inventory, prepaid expenses and other assets		(8,116)		(12,465)
Accounts payable, accrued expenses and accrued interest		(20,707)		(5,963)
Unearned milestone revenue		(8,101)		63,076
Deferred revenue		2,086		(100)
Other liabilities		(155)		71
Cash flows from operating activities		9,561		45,699
CASH FLOWS FROM INVESTING ACTIVITIES:				
Additions to property, plant and equipment		(14,609)		(14,715)
Proceeds from the sale of equipment				15
Purchases of short and long-term investments	((291,480)		(189,668)
Sales and maturities of short and long-term investments		293,861		190,922
Cash flows from investing activities		(12,228)		(13,446)
CASH FLOWS FROM FINANCING ACTIVITIES:				
Proceeds from issuance of common stock		9,122		4,304
Excess tax benefit from stock options		108		,
Payment of debt		(644)		(588)
Purchase of treasury stock		, ,		(12,492)
Cash flows from financing activities		8,586		(8,776)
NET INCREASE IN CASH AND CASH EQUIVALENTS		5,919		23,477
CASH AND CASH EQUIVALENTS Beginning of period		80,500		33,578
CASH AND CASH EQUIVALENTS End of period	\$	86,419	\$	57,055

SUPPLEMENTAL CASH FLOW DISCLOSURE:

Cash paid for interest	\$ 5,999	\$ 4,569
Cash paid for income taxes	\$ 980	\$ 270
Non-cash investing and financing activities:		
Conversion of 2.5% convertible subordinated notes into common stock	\$	\$ 125,000
Purchased capital expenditures included in accounts payable and accrued expenses	\$ 246	\$
Net share exercise of warrants into common stock of the issuer	\$ 2,994	\$
Receipt of Alkermes shares as payment to satisfy withholding tax obligations related		
to employee stock awards	\$ 924	\$

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

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ALKERMES, INC. AND SUBSIDIARIES

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED)

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 and six months ended September 30, 2007 and 2006 are unaudited and have been prepared on a basis substantially consistent with the audited financial statements for the year ended March 31, 2007. 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 for the year ended March 31, 2007, 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 condensed consolidated financial statements include the accounts of Alkermes, Inc. and its wholly-owned subsidiaries: Alkermes Controlled Therapeutics, Inc.; Alkermes Europe, Ltd. and RC Royalty Sub LLC (Royalty Sub). 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 is non-recourse RISPERDAL CONSTA secured 7% notes (the Non-Recourse 7% Notes). Intercompany accounts and transactions have been eliminated.

Use of Estimates The preparation of the Company's 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 condensed consolidated financial statements; and (3) the reported amounts of revenues and expenses during the reporting period. Actual results could differ from these estimates.

Income Taxes

Effective April 1, 2007, the Company adopted Financial Accounting Standards Board (FASB) Interpretation No. 48, *Accounting for Uncertainty in Income Taxes* (FIN No. 48). FIN No. 48 clarifies the accounting for uncertainty in income taxes recognized in an enterprise s financial statements in accordance with FASB Statement No. 109, *Accounting for Income Taxes*. FIN No. 48 also prescribes a recognition threshold and measurement attribute for the financial statement recognition and measurement of each tax position taken or expected to be taken in a tax return, and provides guidance on derecognition, classification, interest and penalties, accounting in interim periods, disclosures and transition. See Note 7, Income Taxes, to the condensed consolidated financial statements for a discussion of the Company s accounting for uncertain tax positions.

New Accounting Pronouncements

In September 2006, the FASB issued Statement of Financial Accounting Standards (SFAS) No. 157, Fair Value Measurements (SFAS No. 157), which establishes a framework for measuring fair value in GAAP and expands disclosures about the use of fair value to measure assets and liabilities in interim and annual reporting periods subsequent to initial recognition. Prior to SFAS No. 157, which emphasizes that fair value is a market-based measurement and not an entity-specific measurement, there were different definitions of fair value and limited guidance for applying those definitions in GAAP. SFAS No. 157 is effective for the

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ALKERMES, INC. AND SUBSIDIARIES

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Company for the reporting period beginning April 1, 2008. The Company is in the process of evaluating the impact of the adoption of SFAS No. 157 on its consolidated financial statements.

In February 2007, the FASB issued SFAS No. 159, *The Fair Value Option for Financial Assets and Financial Liabilities Including an Amendment of FASB Statement No. 115* (SFAS No. 159). SFAS No. 159 permits entities to elect to measure selected financial instruments and certain other items at fair value. Unrealized gains and losses on items for which the fair value option has been elected are recognized in earnings in each reporting period. SFAS No. 159 is effective for the Company for the reporting period beginning April 1, 2008. The Company is in the process of evaluating the impact of the adoption of SFAS No. 159 on its consolidated financial statements.

In June 2007, the Emerging Issues Task Force (EITF) of the FASB reached a consensus on Issue 07-03, *Accounting for Nonrefundable Advance Payments for Goods or Services to Be Used in Future Research and Development Activities*, (EITF 07-03), which addresses the diversity which exists with respect to the accounting for the non-refundable portion of a payment made by a research and development entity for future research and development activities. Under EITF 07-03, an entity would defer and capitalize non-refundable advance payments made for research and development activities until the related goods are delivered or the related services are performed. EITF 07-03 is effective for the Company for the reporting period beginning April 1, 2008. Accordingly, the Company is in the process of evaluating the impact of EITF 07-03; however, the Company does not expect it to have a significant impact on its consolidated financial statements.

2. COMPREHENSIVE INCOME

Comprehensive income for the three and six months ended September 30, 2007 and 2006 is as follows:

	En	Months ded iber 30,	Six M End Septem	led
(In thousands)	2007	2006	2007	2006
Net income Unrealized (losses) gains on available-for-sale investments	\$ 7,698 (25)	\$ 3,726 119	\$ 16,445 (550)	\$ 3,011 453
Comprehensive income	\$ 7,673	\$ 3,845	\$ 15,895	\$ 3,464

3. EARNINGS PER COMMON SHARE

Basic earnings per common share is calculated based upon net income available to holders of common shares divided by the weighted average number of shares outstanding. For the calculation of diluted earnings per common share, the Company uses the weighted average number of common shares outstanding, as adjusted for the effect of potential outstanding shares, including stock options, stock awards, redeemable convertible preferred stock and convertible debt.

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ALKERMES, INC. AND SUBSIDIARIES

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Basic and diluted earnings per common share are calculated as follows:

	Three Months Ended September 30,			Six M En Septen	ded		
(In thousands)		2007		2006	2007		2006
(== ===================================							
Numerator:							
Net income	\$	7,698	\$	3,726	\$ 16,445	\$	3,011
Denominator:							
Weighted average number of common shares							
outstanding		101,595		101,331	101,663		97,581
Effect of dilutive securities:							
Stock options		2,371		3,086	2,451		4,105
Restricted stock awards		349		312	332		220
Redeemable convertible preferred stock				814			630
Dilutive common share equivalents		2,720		4,212	2,783		4,955
Shares used in calculating diluted earnings per common							
share		104,315		105,543	104,446		102,536

The following amounts are not included in the calculation of net income per common share because their effects are anti-dilutive:

	Three M End Septem	Six Months Ended September 30,			
(In thousands)	2007	2006	2007	2006	
Stock options 2.5% convertible subordinated notes	10,284	11,557	11,760	7,414 3,699	
3.75% convertible subordinated notes		10		10	
Total	10,284	11,567	11,760	11,123	

4. SHARE-BASED COMPENSATION

Share-based compensation expense for the three and six months ended September 30, 2007 and 2006 is as follows:

	Three Months Ended September 30,				Six Months Ended September 3			
(In thousands)	20	007	2	2006		2007		2006
Cost of goods manufactured Research and development Selling, general and administrative		334 ,785 2,429	\$	903 2,232 3,236	\$	960 3,636 5,699	\$	1,163 5,068 8,487
Total	\$ 4	,548	\$	6,371	\$	10,295	\$	14,718

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ALKERMES, INC. AND SUBSIDIARIES

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

As of September 30, 2007 and 2006, \$0.4 million and \$0.6 million, respectively, of share-based compensation cost was capitalized and recorded under the caption Inventory in the condensed consolidated balance sheets.

5. INVENTORY

Inventory is stated at the lower of cost or market value. Cost is determined using the first-in, first-out method. Inventory consists of the following:

(In thousands)	Sej	September 30, 2007		
Raw materials Work in process Finished goods	\$	8,676 7,350 5,176	\$	7,238 4,291 6,661
Total	\$	21,202	\$	18,190

6. ACCOUNTS PAYABLE AND ACCRUED EXPENSES

Accounts payable and accrued expenses consist of the following:

(In thousands)	Sept	March 31, 2007		
Accounts payable and accrued accounts payable Accrued expenses related to collaborative arrangements Accrued compensation Accrued other	\$	5,248 487 8,425 7,754	\$	12,097 16,155 10,917 6,686
Total	\$	21,914	\$	45,855

7. 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 September 30, 2007, the Company determined that it is more likely than not that the deferred tax assets may not be realized and a full valuation allowance continues to be recorded.

The provision for income taxes in the amount of \$0.2 million and \$2.6 million for the three and six months ended September 30, 2007, respectively, and \$0.2 million and \$0.3 million for the three and six months ended September 30, 2006, respectively, relates to the U.S. alternative minimum tax (AMT). The utilization of tax loss carryforwards is limited in the calculation of AMT and as a result, a federal tax charge was recorded in the three and six months ended September 30, 2007 and 2006. The current AMT liability is available as a credit against future tax obligations upon the full utilization or expiration of the Company s net operating loss carryforward. The provision for income taxes for the three and six months ended September 30, 2007 and 2006 was prepared on a discrete quarterly and year to date basis, respectively. For the three and six months ended September 30, 2007, the yearly effective tax rate was not considered a reliable estimate for the current quarter and year to date provision. This provision reflects tax recognition of the entire \$110.0 million nonrefundable milestone payment the Company received from Cephalon, Inc. (Cephalon) in the first quarter of fiscal 2007 under its collaborative arrangement.

The Company adopted FIN No. 48 on April 1, 2007. The implementation of FIN No. 48 did not have a material impact on the Company s condensed consolidated financial statements or results of operations. At the

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ALKERMES, INC. AND SUBSIDIARIES

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

adoption date of April 1, 2007, and also at September 30, 2007, the Company had no significant unrecognized tax benefits. The tax years 1993 through 2006 remain open to examination by major taxing jurisdictions to which the Company is subject, which are primarily in the United States (U.S.), as carryforward attributes generated in years past may still be adjusted upon examination by the Internal Revenue Service (IRS) or state tax authorities if they have or will be used in a future period. The Company is currently in the process of conducting a study of its research and development credit carryforwards. This study may result in an adjustment to the Company s research and development credit carryforwards, however, until the study is completed and any adjustment is known, no amounts are being presented as an uncertain tax position under FIN No. 48. A full valuation allowance has been provided against the Company s research and development credits and, if an adjustment is required, this adjustment would be offset by an adjustment to the valuation allowance. Thus, there would be no impact to the condensed consolidated balance sheet or statement of operations if an adjustment were required.

In addition, the Company recently concluded a study of its net operating loss (NOL) carryforwards to determine whether such amounts are limited under IRC Sec. 382. The Company does not believe the limitations will significantly impact its ability to offset income with available NOLs.

The Company has elected to include interest and penalties related to uncertain tax positions as a component of its provision for taxes. For the three and six months ended September 30, 2007, the Company did not recognize any accrued interest and penalties in its condensed consolidated financial statements.

8. LEGAL MATTERS

On October 10, 2006, a purported shareholder derivative lawsuit, captioned Thomas Bennett, III vs. Richard Pops et al. and docketed as CIV-06-3606, was filed ostensibly on the Company s behalf in Middlesex County Superior Court, Massachusetts. The complaint in that lawsuit alleged, among other things, that in connection with certain stock option grants made by the Company, certain of its directors and officers committed violations of state law, including breaches of fiduciary duty. The complaint named the Company as a nominal defendant, but did not seek monetary relief from the Company. The lawsuit sought recovery of damages allegedly caused to the Company as well as certain other relief, including an order requiring the Company to take action to enhance its corporate governance and internal procedures. The defendants moved to dismiss the lawsuit and, following oral argument, the Massachusetts Superior Court issued a decision dated July 10, 2007 granting the defendants motion to dismiss the lawsuit in its entirety. The plaintiff did not appeal the Court is decision and the plaintiff is time to appeal has expired.

The Company has received four letters, allegedly sent on behalf of owners of its securities, which claim, among other things, that certain of the Company s officers and directors breached their fiduciary duties to the Company by, among other allegations, allegedly violating the terms of its stock option plans, allegedly violating GAAP by failing to recognize compensation expenses with respect to certain option grants during certain years, and allegedly publishing materially inaccurate financial statements relating to the Company. The letters demand, among other things, that the Company s board of directors take action on its behalf to recover from the current and former officers and directors identified in the letters the damages allegedly sustained by the Company as a result of their alleged conduct, among other amounts. The letters do not seek any monetary recovery from the Company. The Company s board of directors appointed a special independent committee of the board of directors to investigate, assess and evaluate the allegations contained in these and any other demand letters relating to the Company s stock option granting practices and to report its findings, conclusions and recommendations to the Company s board of directors. The special independent

committee was assisted by independent outside legal counsel. In November 2006, based on the results of its investigation, the special independent committee of the Company s board of directors concluded that the assertions contained in the demand letters lacked merit, that nothing had come to its attention that would cause it to believe that there are any instances where management of the Company or the Compensation Committee of the Company had

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ALKERMES, INC. AND SUBSIDIARIES

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

retroactively selected a date for the grant of stock options during the 1995 through 2006 period, and that it would not be in the Company s best interests or the best interests of the Company s shareholders to commence litigation against its current or former officers or directors as demanded in the letters. The findings and conclusions of the special independent committee of the Company s board of directors have been presented to and adopted by the Company s board of directors.

From time to time, the Company may be subject to other legal proceedings and claims in the ordinary course of business. The Company is not aware of any such proceedings or claims that it believes will have, individually or in the aggregate, a material adverse effect on its business, financial condition or results of operations.

9. SEGMENT INFORMATION

The Company operates as one business segment, which is the business of developing, manufacturing and commercializing innovative medicines designed to yield better therapeutic outcomes and improve the lives of patients with serious disease. The Company s chief decision maker, the Chief Executive Officer, reviews the Company s operating results on an aggregate basis and manages the Company s operations as a single operating unit.

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

Alkermes, Inc. (Alkermes or the Company as used in this section, together with our subsidiaries, us , we or our) biotechnology company that uses proprietary technologies and know-how to create innovative medicines designed to yield better therapeutic outcomes for patients with serious disease. Alkermes manufactures RISPERDAL® CONSTA®, marketed by Janssen-Cilag (Janssen, L.P.), a wholly owned division of Johnson & Johnson, and developed and manufactures VIVITROL®, marketed in the United States (U.S.) primarily by Cephalon, Inc. (Cephalon). The Company s pipeline includes extended-release injectable, pulmonary and oral products for the treatment of prevalent, chronic diseases, such as central nervous system disorders, addiction and diabetes. Alkermes is headquartered in Cambridge, Massachusetts, with 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 certain collaborative arrangements 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 selling, 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, royalty revenues, research and development revenues under collaborative arrangements, net collaborative profit, research and development activities and spending, plans for clinical trials and regulatory approvals, spending relating to selling and marketing, income taxes, 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 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. These forward-looking statements include, but are 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 and VIVITROL; the successful continuation of development activities for our programs, including AIR® Insulin, ALKS 27, ALKS 29 and once-weekly exenatide; and the successful manufacture of our products and product candidates, including RISPERDAL CONSTA and VIVITROL, at a commercial scale. 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 grow, particularly because we rely on our partner, Janssen, L.P., 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, L.P. 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) manufacturing and other revenues for VIVITROL may not grow; (iv) we may be unable to manufacture VIVITROL in sufficient quantities and with

sufficient yields to meet commercial requirements, or unexpected events could interrupt manufacturing operations at our VIVITROL facility, which is the sole source of supply for that product; (v) we may be unable to scale-up and manufacture our product candidates, including AIR Insulin, ALKS 27, ALKS 29 and once-weekly exenatide commercially or economically; (vi) our product candidates, if approved for marketing,

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may not be launched successfully in one or all indications for which marketing is approved and, if launched, may not produce significant revenues; (vii) clinical trials may take more time or consume more resources than initially envisioned; (viii) results of earlier clinical trials may not necessarily be predictive of the safety and efficacy results in larger clinical trials; (ix) 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 or terminated; (x) after the completion of clinical trials for our product candidates and the submission for marketing approval, the U.S. Food and Drug Administration (FDA) or foreign regulatory 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; (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 products and/or product candidates obsolete or non-competitive; (xiii) difficulties or set-backs in obtaining and enforcing our patents and difficulties with the patent rights of others could occur; (xiv) we may continue to incur losses in the future; and (xv) we may need to raise substantial additional funding to continue research and development programs and clinical trials and other operations and could incur difficulties or setbacks in raising such funds.

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.

Our Strategy

We leverage our unique formulation expertise and drug development technologies to develop, both with partners and on our own, innovative and competitively advantaged drug products that enhance patient outcomes in major therapeutic areas. We enter into select collaborations with pharmaceutical and biotechnology companies to develop significant new product candidates, based on existing drugs and incorporating our technologies. In addition, we develop our own proprietary therapeutics by applying our innovative formulation expertise and drug development capabilities to create new pharmaceutical products. Each of these approaches is discussed in more detail below.

Product Developments

RISPERDAL CONSTA

Using our proprietary Medisorb® technology, we developed RISPERDAL CONSTA, a long-acting formulation of Janssen, L.P. s antipsychotic drug RISPERDA® for the treatment of schizophrenia. Schizophrenia is a brain disorder characterized by disorganized thinking, delusions and hallucinations. Studies have demonstrated that as many as 75 percent of patients with schizophrenia have difficulty taking their oral medication on a regular basis, which can lead to worsening of symptoms. Clinical data has shown that treatment with RISPERDAL CONSTA may lead to improvements in symptoms, sustained remission, and decreases in hospitalization. RISPERDAL CONSTA is administered via intramuscular injection every two weeks, alleviating the need for daily dosing. Janssen, L.P. markets RISPERDAL CONSTA worldwide. We are the exclusive manufacturer of RISPERDAL CONSTA for Janssen, L.P., and we earn both manufacturing fees and royalties from Janssen, L.P.

RISPERDAL CONSTA was approved by regulatory authorities in the United Kingdom and Germany in August 2002 and was approved by the FDA in October 2003. RISPERDAL CONSTA is approved in approximately 83 countries and marketed in approximately 61 countries, and Janssen, L.P. continues to launch the product around the world.

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VIVITROL

We developed VIVITROL, an extended-release Medisorb formulation of naltrexone, for the treatment of alcohol dependence in patients who are able to abstain from drinking in an outpatient setting and are not actively drinking prior to treatment initiation. Alcohol dependence is a serious and chronic brain disease characterized by cravings for alcohol, loss of control over drinking, withdrawal symptoms and an increased tolerance for alcohol. Adherence to medication is particularly challenging with this patient population. In clinical trials, when used in combination with psychosocial support, VIVITROL was shown to reduce the number of drinking days and heavy drinking days and to prolong abstinence in patients who abstained from alcohol the week prior to starting treatment. Each injection of VIVITROL provides medication for one month and alleviates the need for patients to make daily medication dosing decisions. Cephalon, Inc. is primarily responsible for marketing VIVITROL in the U.S. We are the exclusive manufacturer of VIVITROL.

VIVITROL was approved by the FDA in April 2006 and launched in June 2006. In March 2007, we submitted a Marketing Authorization Application (MAA) for VIVITROL to regulatory authorities in the United Kingdom and Germany. The MAA for VIVITROL was submitted under a decentralized procedure, in which the United Kingdom will act as the Reference Member State and Germany will act as the Concerned Member State for the application. If successful, a filing under the decentralized procedure would result in a simultaneous approval of VIVITROL as a treatment for alcohol dependence in these two countries. The MAA submission reflects the Company s targeted approach to commercialize VIVITROL in Europe on a country by country basis.

AIR Insulin

We are collaborating with Eli Lilly and Company (Lilly) to develop inhaled formulations of insulin and other potential products for the treatment of diabetes based on our AIR pulmonary technology. Diabetes is a disease in which the body does not produce or properly use insulin. Diabetes can result in serious health complications, including cardiovascular, kidney and nerve disease. Our inhaled insulin formulation, AIR Insulin, is currently in phase 3 clinical development.

Once-Weekly Exenatide

We are collaborating with Amylin Pharmaceuticals, Inc. (Amylin) on the development of an extended-release, injectable formulation of Amylin s exenatide (exenatide) for the treatment of type 2 diabetes. Exenatide injection (trade name BYETTA®) was approved by the FDA in April 2005 as adjunctive therapy to improve blood sugar control in patients with type 2 diabetes who have not achieved adequate control on metformin and/or sulfonylurea; two commonly used oral diabetes medications. In December 2006, the FDA approved BYETTA as an add-on therapy for people with type 2 diabetes unable to achieve adequate glucose control on thiazolidinedione, a class of diabetes medications. BYETTA is a twice-daily injection. Extended-release exenatide is being developed as a once-weekly formulation. Amylin entered into a collaboration agreement with Lilly for the development and commercialization of exenatide, including once-weekly exenatide.

In October 2007, we, Amylin and Lilly announced positive results from a 30-week comparator study of once-weekly exenatide injection and BYETTA taken twice daily in patients with type 2 diabetes. Once-weekly exenatide showed a statistically significant improvement in A1C of approximately 1.9 percentage points from baseline, compared to an improvement of approximately 1.5 percentage points for BYETTA. Approximately three out of four subjects treated with once-weekly exenatide achieved an A1C of 7 percent or less. A1C of less than 7 percent is the target for good glucose control as recommended by the American Diabetes Association. After 30 weeks of treatment, both once-weekly exenatide and BYETTA treatment resulted in an average weight loss of approximately eight pounds. Nearly 90 percent of subjects in both groups completed the study, which enrolled patients not achieving adequate

glucose control with either diet and exercise or with use of oral glucose-lowering agents. The companies anticipate a regulatory submission to the FDA by the end of the first half of 2009.

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ALKS 29

We are developing ALKS 29, an oral compound for the treatment of alcohol dependence, which could offer a new treatment option for people suffering from this disease. In July 2007, we announced positive preliminary results from a clinical trial of ALKS 29 in alcohol dependent patients. Based on these results, we plan to move forward with a development program for oral product candidates to treat alcohol dependence. The clinical trial for ALKS 29, a phase 1/2 multi-center, randomized, double-blind, placebo-controlled, eight-week study was designed to assess the efficacy and safety of ALKS 29 in approximately 150 alcohol dependent patients. In the study, ALKS 29 was generally well tolerated and led to both a statistically significant increase in the percent of days abstinent and a decrease in drinking compared to placebo when combined with psychosocial therapy. The study endpoints included the percent of days abstinent, percent of heavy drinking days and number of drinks per day. Heavy drinking was defined as five or more drinks per day for men and four or more drinks per day for women.

ALKS 27

Using our AIR pulmonary technology, we are developing ALKS 27, an inhaled formulation of trospium chloride, with Indevus Pharmaceuticals, Inc. (Indevus), for the treatment of chronic obstructive pulmonary disease (COPD). COPD is a serious, chronic disease characterized by a gradual loss of lung function. Trospium chloride is a muscarinic receptor antagonist that relaxes smooth muscle tissue and has the potential to improve airflow in patients with COPD. Trospium chloride is the active ingredient in SANCTURA®, Indevus currently marketed product for overactive bladder.

In September 2007, we and Indevus announced positive preliminary results from a randomized, double-blind, placebo-controlled, phase 2a clinical study of ALKS 27 in patients with COPD. In the study, single doses of ALKS 27 demonstrated a rapid onset of action and produced a significant improvement in lung function (p<0.0001) over 24 hours compared to a placebo. ALKS 27 was well tolerated, and all enrolled patients completed the study. No treatment-related adverse events were reported in this study. Based on these positive results, we are moving forward with Indevus to identify a partner for the future development and commercialization of ALKS 27.

AIR parathyroid hormone

We and Lilly recently completed a phase 1 study of inhaled formulations of parathyroid hormone (PTH) in healthy, post menopausal women. The data from the study indicates that additional feasibility and formulation work are required. At this time, we and Lilly are not planning to pursue further development of AIR PTH.

Critical Accounting Policies

A summary of significant accounting policies and a description of accounting policies that are considered critical may be found in Part II, Item 7 of our Annual Report on Form 10-K for the year ended March 31, 2007 in the Critical Accounting Policies section. Other than as described below, our critical accounting policies and estimates are as set forth in the Form 10-K.

Provision for Income Taxes We record 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 September 30, 2007, we determined that it was more likely than not that the deferred tax assets may not be realized and a full valuation allowance continues to be recorded.

We adopted Financial Accounting Standards Board (FASB) Interpretation No. 48, *Accounting for Uncertainty in Income Taxes* (FIN No. 48) on April 1, 2007. The implementation of FIN No. 48 did not have a material impact on

our condensed consolidated balance sheets or results of operations. At the adoption date of April 1, 2007, and also at September 30, 2007, we had no significant unrecognized tax benefits. The tax years 1993 through 2006 remain open to examination by major taxing jurisdictions to which we are subject, which are primarily in the U.S., as carryforward attributes generated in years past may still be

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adjusted upon examination by the IRS or state tax authorities if they have or will be used in a future period. We are currently in the process of conducting a study of our research and development credit carryforwards. This study may result in an adjustment to our research and development credit carryforwards, however, until the study is completed and any adjustment is known, no amounts are being presented as an uncertain tax position under FIN No. 48. A full valuation allowance has been provided against our research and development credits, and, if an adjustment is required, this adjustment would be offset by an adjustment to the valuation allowance. Thus, there would be no impact to the condensed consolidated balance sheet or statement of operations if an adjustment were required.

In addition, we recently concluded a study of our net operating loss (NOL) carryforwards to determine whether such amounts are limited under IRC Sec. 382. We do not believe the limitations will significantly impact our ability to offset income with available NOLs.

We have elected to include interest and penalties related to uncertain tax positions as a component of our provision for taxes. For the three months ended September 30, 2007, we did not recognize any accrued interest and penalties in our condensed consolidated financial statements.

Results of Operations

Net income for the three months ended September 30, 2007 was \$7.7 million, or \$0.08 per common share basic and \$0.07 per common share diluted, as compared to net income of \$3.7 million, or \$0.04 per common share basic and diluted, for the three months ended September 30, 2006.

Net income for the six months ended September 30, 2007 was \$16.4 million, or \$0.16 per common share basic and diluted, as compared to net income of \$3.0 million, or \$0.03 per common share basic and diluted, for the six months ended September 30, 2006.

Total manufacturing revenues were \$24.1 million and \$55.7 million for the three and six months ended September 30, 2007, respectively, as compared to \$26.1 million and \$48.3 million for the three and six months ended September 30, 2006, respectively.

RISPERDAL CONSTA manufacturing revenues were \$22.9 million and \$53.2 million for the three and six months ended September 30, 2007, respectively, as compared to \$20.9 million and \$40.0 million for the three and six months ended September 30, 2006, respectively. The increase in RISPERDAL CONSTA revenues for the three months ended September 30, 2007, as compared to the three months ended September 30, 2006, was primarily due to increases in the net sales price of units of RISPERDAL CONSTA shipped to Janssen, L.P. The increase in RISPERDAL CONSTA revenues for the six months ended September 30, 2007, as compared to the six months ended September 30, 2006, was due to increases in the net sales price and quantities of RISPERDAL CONSTA shipped to Janssen, L.P. The increases in the net sales price of RISPERDAL CONSTA in the three and six months ended September 30, 2007, as compared to the three and six months ended September 30, 2006, was due in part to fluctuations in the exchange ratio of the U.S. dollar and the foreign currencies of the countries in which the product was sold. See Part I, Item 3. Quantitative and Qualitative Disclosures about Market Risk for information on foreign currency exchange rate risk related to RISPERDAL CONSTA revenues. We expect manufacturing revenues related to RISPERDAL CONSTA to be lower in the quarter ended December 31, 2007 compared to the previous two quarters, as Janssen L.P. is working to reduce its level of RISPERDAL CONSTA inventory. This reduction is related to the increased efficiencies and reliability we have experienced in our manufacturing processes over the last several quarters.

Under our manufacturing and supply agreement with Janssen, L.P., we earn manufacturing revenues when product is shipped to Janssen, L.P., based on a percentage of Janssen, L.P. s estimated unit net sales price. Revenues include a quarterly adjustment from Janssen, L.P. s estimated unit net sales price to Janssen, L.P. s actual unit net sales price for

product shipped. For the three and six months ended September 30, 2007 and 2006, our RISPERDAL CONSTA manufacturing revenues were based on an average of 7.5% of Janssen, L.P. s unit net sales price of RISPERDAL CONSTA. We anticipate that we will earn manufacturing revenues at

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7.5% of Janssen, L.P. s unit net sales price of RISPERDAL CONSTA for product shipped in the fiscal year ending March 31, 2008 and beyond.

VIVITROL manufacturing revenues were \$1.2 million and \$2.5 million for the three and six months ended September 30, 2007, respectively, as compared to \$5.2 million and \$8.3 million for the three and six months ended September 30, 2006, respectively. Under our agreements with Cephalon, we bill Cephalon at cost for finished commercial product shipped to them and for idle capacity charges incurred in the period. The decrease in VIVITROL manufacturing revenues for the three and six months ended September 30, 2007, as compared to the three and six months ended September 30, 2006, was due to reduced shipments of VIVITROL to Cephalon. We began shipping VIVITROL to Cephalon for the first time during the quarter ended June 30, 2006, and during that quarter we shipped quantities sufficient to build inventory in anticipation of the commercial launch of the product. We are currently managing our manufacturing volumes of VIVITROL to avoid excess inventory and did not ship any product to Cephalon during the three and six months ended September 30, 2007. VIVITROL manufacturing revenues for the three and six months ended September 30, 2007 consisted entirely of current period idle capacity costs related to underutilized VIVITROL manufacturing capacity which are reimbursable by Cephalon as incurred. There were no VIVITROL idle capacity costs in the three and six months ended September 30, 2006. VIVITROL manufacturing revenues for the three and six months ended September 30, 2007 included \$0.1 million and \$0.2 million, respectively, of milestone revenue related to manufacturing profit on VIVITROL, which draws down from unearned milestone revenue, as compared to \$0.5 million and \$0.8 million for the three and six months ended September 30, 2006, respectively.

All royalty revenues for the three and six months ended September 30, 2007 and 2006 were related to sales of RISPERDAL CONSTA. Under our license agreements with Janssen, L.P., we record royalty revenues equal to 2.5% of Janssen, L.P. s net sales of RISPERDAL CONSTA in the period that the product is sold by Janssen, L.P. Royalty revenues were \$7.3 million for the three months ended September 30, 2007, based on RISPERDAL CONSTA sales of \$293.6 million, and \$14.3 million for the six months ended September 30, 2007, based on RISPERDAL CONSTA sales of \$572.3 million, as compared to \$5.8 million for the three months ended September 30, 2006, based on RISPERDAL CONSTA sales of \$232.1 million, and \$11.0 million for the six months ended September 30, 2006, based on RISPERDAL CONSTA sales of \$437.3 million. The increase in the net sales of RISPERDAL CONSTA in the three and six months ended September 30, 2007, as compared to the three and months ended September 30, 2006, was due in part to fluctuations in the exchange ratio of the U.S. dollar and the foreign currencies of the countries in which the product was sold. See Part I, Item 3. Quantitative and Qualitative Disclosures about Market Risk for information on foreign currency exchange rate risk related to RISPERDAL CONSTA revenues.

Research and development revenue under collaborative arrangements (R&D revenue) was \$21.2 million and \$44.7 million for the three and six months ended September 30, 2007, respectively as compared to \$17.6 million and \$32.1 million for the three and six months ended September 30, 2006, respectively. The increase in R&D revenue for the three and six months ended September 30, 2007, as compared to the three and six months ended September 30, 2006, was primarily due to increases in revenues related to work performed on the AIR Insulin, AIR PTH and once-weekly exenatide development programs. A component of the AIR PTH program revenue in the three and six months ended September 30, 2007 included recognition of a portion of the milestone payment we received from Lilly upon first dosing in the phase I clinical trial. We are recognizing revenue under the proportional performance method for this single unit arrangement. In addition, R&D revenue for the three and six months ended September 30, 2007 included revenue of \$0 and \$1.2 million, respectively, for FTE-related costs we incurred that were reimbursed by Cephalon for the construction of the additional VIVITROL manufacturing lines at our Ohio manufacturing facility. We and Lilly recently completed a phase 1 study of AIR PTH in healthy, post menopausal women. The data from the study indicates that additional feasibility and formulation work are required. At this time, we and Lilly are not planning to pursue further development of AIR PTH.

Net collaborative profit was \$5.9 million and \$12.9 million for the three and six months ended September 30, 2007, respectively. For the three and six months ended September 30, 2007, we recognized \$0 million and \$5.3 million of milestone revenue cost recovery, respectively, to offset net losses on

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VIVITROL (the cumulative loss cap). We reached this cumulative loss cap in April 2007, at which time Cephalon became responsible to fund all net losses incurred on VIVITROL through December 31, 2007. In addition, during the three and six months ended September 30, 2007, we recognized \$1.3 million and \$2.6 million, respectively, of milestone revenue related to the licenses provided to Cephalon to commercialize VIVITROL. During the three and six months ended September 30, 2007, we made payments of \$0 and \$5.2 million, respectively, to Cephalon to reimburse their net losses on VIVITROL, and we received payments of \$4.6 million and \$10.2 million, respectively, from Cephalon to reimburse us for our expenses on VIVITROL, which we incurred after the cumulative loss cap was reached. In the aggregate, net collaborative profit of \$5.9 million and \$12.9 million for the three and six months ended September 30, 2007, respectively, consisted of \$1.3 million and \$7.9 million of milestone revenue, respectively, in addition to net payments from Cephalon of \$4.6 million and \$5.0 million, respectively.

Net collaborative profit was \$11.6 million and \$21.4 million for the three and six months ended September 30, 2006, respectively. For the three and six months ended September 30, 2006, we recognized \$16.2 million and \$43.6 million of milestone revenue—cost recovery, respectively, to offset net losses on VIVITROL that we funded. In addition, during the three and six months ended September 30, 2006, following FDA approval of VIVITROL, we recognized \$1.4 million and \$2.6 million, respectively, of milestone revenue related to the licenses provided to Cephalon to commercialize VIVITROL. During the three and six months ended September 30, 2006, we made payments of \$5.9 million and \$24.8 million, respectively, to Cephalon to reimburse their net losses on VIVITROL. In the aggregate, net collaborative profit of \$11.6 million and \$21.4 million for the three and six months ended September 30, 2006, respectively, consisted of approximately \$17.5 million and \$46.2 million of milestone revenue, respectively, partially offset by \$5.9 million and \$24.8 million, respectively, of payments we made to Cephalon to reimburse their net losses on VIVITROL. Net collaborative profit for the three and six months ended September 30 was as follows:

	Three Months Ended September 30,				Six Months Ended September 30			
(In thousands)	2007 2006		2007			2006		
Milestone revenue cost recovery(1) Milestone revenue license	\$ 1,	312	\$	16,162 1,392	\$	5,256 2,621	\$	43,586 2,583
Total milestone revenue cost recovery and license Payments to Cephalon to reimburse their net losses up to the	1,	312		17,554		7,877		46,169
cumulative loss cap Payments from Cephalon to reimburse our expenses incurred				(5,943)		(5,223)		(24,816)
after the cumulative loss cap was reached	4,	597				10,244		
Net collaborative profit	\$ 5,	909	\$	11,611	\$	12,898	\$	21,353

⁽¹⁾ Through September 30, 2007, the cumulative net losses on VIVITROL were \$162.2 million, of which \$61.5 million was incurred by us on behalf of the collaboration and \$100.7 million was incurred by Cephalon on behalf of the collaboration.

Gross sales of VIVITROL by Cephalon were \$4.7 million and \$8.8 million for the three and six months ended September 30, 2007, respectively.

If VIVITROL is profitable before December 31, 2007, net profits will be shared between us and Cephalon. After December 31, 2007, all net profits or losses earned on VIVITROL will be shared between us and Cephalon. The net profits earned or losses incurred on VIVITROL after December 31, 2007 will be dependent upon end-market sales, which are difficult to predict at this time, and on the level of expenditures by both us and Cephalon in developing, manufacturing and commercializing VIVITROL, all of which is subject to change.

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Cost of goods manufactured was \$9.2 million and \$19.4 million for the three and six months ended September 30, 2007, respectively and \$11.8 million and \$21.2 million for the three and six months ended September 30, 2006, respectively.

Cost of goods manufactured for RISPERDAL CONSTA was \$8.1 million and \$17.2 million for the three and six months ended September 30, 2007, respectively, and \$7.1 million and \$13.6 million for the three and six months ended September 30, 2006, respectively. The increase in cost of goods manufactured for RISPERDAL CONSTA for the three months ended September 30, 2007, as compared to the three months ended September 30, 2006, was due to increases in the unit cost of RISPERDAL CONSTA shipped to Janssen, L.P. The increase in cost of goods manufactured for RISPERDAL CONSTA for the six months ended September 30, 2007, as compared to the six months ended September 30, 2006, was due to increases in the quantity of RISPERDAL CONSTA shipped to Janssen, L.P.

Cost of goods manufactured for VIVITROL was \$1.1 million and \$2.2 million for the three and six months ended September 30, 2007, respectively, and \$4.7 million and \$7.6 million for the three and six months ended September 30, 2006. The decrease in cost of goods manufactured for VIVITROL for the three and six months ended September 30, 2007, as compared to the three and six months ended September 30, 2006, was due to reduced shipments of VIVITROL to Cephalon. We began shipping VIVITROL to Cephalon for the first time during the quarter ended June 30, 2006, and during this quarter we shipped quantities sufficient to build inventory in anticipation of the commercial launch of the product. We are currently managing our manufacturing volumes of VIVITROL to avoid excess inventory and did not ship any product to Cephalon during the quarter ended September 30, 2007. Cost of goods manufactured for VIVITROL for the three and six months ended September 30, 2007 consisted entirely of idle capacity costs, which consisted of current period manufacturing costs related to underutilized VIVITROL manufacturing capacity. There were no idle capacity costs charged to VIVITROL cost of goods manufactured in the three and six months ended September 30, 2006.

Research and development expenses were \$28.3 million and \$60.9 million for the three and six months ended September 30, 2007, respectively, as compared to \$29.8 million and \$55.7 million for the three and six months ended September 30, 2006, respectively. The decrease in research and development expenses for the three months ended September 30, 2007, as compared to the three months ended September 30, 2006, was primarily due to decreased external costs related to legacy clinical trials for VIVITROL and decreased share-based compensation expense. The increase in research and development expenses for the six months ended September 30, 2007, as compared to the six months ended September 30, 2006, was primarily due to increased personnel-related costs on work we performed on the AIR Insulin, AIR PTH and once-weekly exenatide development programs, increased costs on the ALKS 27 development program and increased occupancy costs, partially offset by decreased external costs related to legacy clinical trials for VIVITROL and decreased share-based compensation expense.

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 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 taking into consideration 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 \$14.5 million and \$29.9 million for the three and six months ended September 30, 2007, respectively, as compared to \$15.7 million and \$32.2 million for the three and six months ended September 30, 2006, respectively. The decrease in selling, general and administrative

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expenses for the three and six months ended September 30, 2007, as compared to the three and six months ended September 30, 2006, was primarily due to decreased share-based compensation expense.

Interest income was \$4.2 million and \$8.6 million for the three and six months ended September 30, 2007, respectively, as compared to \$4.7 million and \$9.1 million for the three and six months ended September 30, 2006, respectively. The decrease in interest income for the three and six months ended September 30, 2007, as compared to the three and six months ended September 30, 2006, was primarily due to lower interest rates earned on our investments. In response to disruptions in the U.S. credit markets during the quarter ended September 30, 2007, our investments in maturing commercial paper were reinvested in higher credit quality commercial paper and U.S. government securities at slightly lower interest rates.

Interest expense was \$4.1 million and \$8.2 million for the three and six months ended September 30, 2007, respectively, as compared to \$4.0 million and \$9.5 million for the three and six months ended September 30, 2006. The decrease in interest expense for the six months ended September 30, 2007, as compared to the six months ended September 30, 2006, was primarily due to the conversion of our 2.5% convertible subordinated notes due 2023 (the 2.5% Subordinated Notes) in June 2006. Interest expense for the three and six months ended September 30, 2006 included a one-time interest charge of \$0.6 million for a payment we made in June 2006 in connection with the conversion of our 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 begins on April 1, 2009.

Other income (expense), net was a net income of \$1.2 million and \$1.2 million for the three and six months ended September 30, 2007, respectively, and a net expense of \$0.7 million and a net income of \$0.1 million for the three and six months ended September 30, 2006, respectively. Other income (expense), net consists primarily of income or expense recognized on the changes in the fair value of warrants of public companies held by us in connection with collaboration and licensing arrangements, which are recorded under the caption. Other Assets in the condensed consolidated balance sheets, and the accretion of discounts related to restructuring and asset retirement obligations. The recorded value of warrants we hold can fluctuate significantly based on fluctuations in the market value of the underlying securities of the issuer of the warrants. In September 2007, we exercised warrants to purchase common stock of a collaborative partner, which are considered marketable equity securities under Statement of Financial Accounting Standards (SFAS) No. 115, Accounting for Certain Investments in Debt and Equity Securities and are recorded under the caption. Investments short-term in the accompanying condensed consolidated balance sheet as of September 30, 2007. Future changes in the fair value of this common stock will be recorded in other comprehensive income until realized. As a result of our September 2007 warrant exercise, future recorded income or expense on changes in the fair value of our remaining holdings of warrants of public companies is expected to be less than the amounts recorded in previous reporting periods.

Income taxes were \$0.2 million and \$2.6 million for the three and six months ended September 30, 2007, respectively and \$0.2 million and \$0.3 million for the three and six months ended September 30, 2006. The provision for income taxes for the three and six months ended September 30, 2007 and 2006 was prepared on a discrete quarterly and year to date basis, respectively, and related to the U.S. alternative minimum tax (AMT). Utilization of tax loss carryforwards is limited in the calculation of AMT. As a result, a federal tax charge was recorded in the three and six months ended September 30, 2007 and 2006. The current AMT liability is available as a credit against future tax obligations upon the full utilization or expiration of our net operating loss carryforward. The provision for income taxes for the six months ended September 30, 2007 included tax recognition of the \$110 million nonrefundable milestone payment received from Cephalon in the first quarter of fiscal 2007.

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

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Financial Condition

Cash and cash equivalents and short-term investments were \$357.8 million and \$351.6 million as of September 30, 2007 and March 31, 2007, respectively. Short-term investments were \$271.4 million and \$271.1 million as of September 30, 2007 and March 31, 2007, respectively. During the six months ended September 30, 2007, combined cash and cash equivalents and short-term investments increased by \$6.2 million primarily due to normal changes in working capital and to the acquisition of fixed assets, partially offset by proceeds from the issuance of common stock related to our equity compensation plans.

We invest in cash equivalents, U.S. government obligations, high-grade corporate notes and commercial paper. Our investment objectives 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 September 30, 2007 and March 31, 2007, which are pledged as collateral under certain letters of credit and lease agreements. In response to disruptions in the U.S. credit markets during the quarter ended September 30, 2007, our investments in maturing commercial paper were reinvested in higher credit quality commercial paper and U.S. government securities.

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

Receivables were \$43.9 million and \$56.0 million as of September 30, 2007 and March 31, 2007, respectively. The decrease of \$12.1 million during the six months ended September 30, 2007 was primarily due to decreases in amounts due from Janssen, L.P. for RISPERDAL CONSTA product deliveries related to the timing of invoices and subsequent payments.

Inventory was \$21.2 million and \$18.2 million as of September 30, 2007 and March 31, 2007, respectively. This consisted of RISPERDAL CONSTA inventory of \$13.0 million and \$11.2 million as of September 30, 2007 and March 31, 2007, respectively, and VIVITROL inventory of \$8.2 million and \$7.0 million as of September 30, 2007 and March 31, 2007, respectively. The increase in RISPERDAL CONSTA inventory during the six months ended September 30, 2007 was primarily due to increases in work in process inventory and to decreases in finished goods inventory due to the timing of shipments to Janssen, L.P. The increase in VIVITROL inventory during the six months ended September 30, 2007 was primarily due to increases in raw materials inventory. As of September 30, 2007 and March 31, 2007, inventory included \$0.4 million and \$0.6 million of share-based compensation costs, respectively.

Accounts payable and accrued expenses were \$21.9 million and \$45.9 million as of September 30, 2007 and March 31, 2007, respectively. The decrease during the six months ended September 30, 2007 was primarily due to decreases in amounts due to Cephalon under our agreements as well as decreases in accounts payable and compensation accruals.

Unearned milestone revenue current and long-term portions, combined, were \$120.6 million and \$128.8 million as of September 30, 2007 and March 31, 2007, respectively. The decrease during the six months ended September 30, 2007 was due to the recognition of approximately \$8.0 million and \$0.2 million of milestone revenue under the captions Net collaborative profit and Manufacturing revenues, respectively, in the condensed consolidated statement of operations during the six months ended September 30, 2007.

Deferred revenue current and long-term portions, combined, were \$23.2 million and \$22.4 million as of September 30, 2007 and March 31, 2007, respectively. The increase during the six months ended September 30, 2007 was due to the receipt of \$1.5 million of deferred revenue related to funding from Cephalon of the cost of the two VIVITROL manufacturing lines currently under construction, partially offset by a decrease in deferred revenue related

to the recognition of revenue on a portion of the upfront and milestone payments we received from Lilly under the AIR PTH program. Because we will operate and maintain the two VIVITROL manufacturing lines currently under construction, and intend to do so for the foreseeable future, the continued payments made by Cephalon are being treated as additional consideration and recorded as deferred revenue.

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Cash flows from investing activities were a use of cash of \$12.2 million and \$13.4 million for the six months ended September 30, 2007 and 2006, respectively, primarily due to additions of property, plant and equipment.

Cash flows from financing activities were a source of cash of \$8.6 million and a use of cash of \$8.8 million for the six months ended September 30, 2007 and 2006, respectively, For the six months ended September 30, 2007, cash provided by financing activities was primarily due to the issuance of common stock related to our equity compensation plans. For the six months ended September 30, 2006, cash used by financing activities was primarily due to the purchase of treasury stock under our publicly announced share repurchase program, partially offset by cash provided by the issuance of common stock related to our equity compensation plans.

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, clinical trials and the expansion of our facilities. 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 and anticipated revenues will generate sufficient cash flows to meet our anticipated liquidity and capital requirements through at least September 30, 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.

Our capital expenditures 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.

Capital expenditures are expected in the range from \$20.0 million to \$25.0 million for the year ending March 31, 2008, net of reimbursements from our collaborative partners. Our manufacturing facility in Chelsea, Massachusetts is undergoing a significant expansion. Under our commercial manufacturing agreement with

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Lilly for AIR Insulin, Lilly funds the construction of a second manufacturing line at this facility and funds all operating costs of the portion of the facility used to manufacture AIR Insulin products.

Contractual Obligations

The contractual cash obligations disclosed in our Annual Report on Form 10-K for the year ended March 31, 2007 have not changed materially since the date of that report.

Off-Balance Sheet Arrangements

As of September 30, 2007, we do not have any significant relationships with unconsolidated entities or financial partnerships, such as entities often referred to as structured finance or special purpose entities, which would have been established for the purpose of facilitating off-balance sheet arrangements or other contractually narrow or limited purposes. As such, we are not exposed to any financing, liquidity, market or credit risk that could arise if we had engaged in such relationships.

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 Pharmaceuticals, Inc. (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. Although our investments, excluding our investment in Reliant and warrants we receive in connection with our collaborations and licensing activities, 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 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 credit and interest rate risk, and could decline in value if interest rates increase. These debt securities are sensitive to changes in interest rates, and 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 instruments. A 10% increase or decrease in market interest rates would not have a material impact on the condensed consolidated financial statements.

We hold certain marketable equity securities of publicly traded companies we collaborate with that are classified as available-for-sale and are recorded at fair value under the caption. Investments—short term—in the condensed consolidated balance sheets. We also hold other 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 the market price of the underlying securities. Market price changes would result in a change in the fair value of these securities due to differences between their market price and purchase price. A 10% increase or decrease in the market price of our marketable equity securities would not have a material impact on the condensed consolidated financial statements.

As of September 30, 2007, the fair value of our Non-Recourse 7% Notes approximated the carrying value. The interest rate on these notes, and our capital lease obligations, are fixed and therefore not subject to interest rate risk.

As of September 30, 2007, we have a term loan in the amount of \$0.9 million that bears a floating interest rate equal to the one-month London Interbank Offered Rate (LIBOR) plus 5.45 basis points.

Foreign Currency Exchange Rate Risk

The manufacturing and royalty revenues we receive on RISPERDAL CONSTA are a percentage of the net sales made by our collaborative partner, Janssen, L.P. Some of these sales are made in foreign countries and are denominated in foreign currencies. The manufacturing and 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 Janssen, L.P. pays us for manufacturing and royalty revenues. Fluctuations in the

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exchange ratio of the U.S. dollar and these foreign currencies will have the effect of increasing or decreasing our manufacturing and royalty revenues even if there is a constant amount of sales in foreign currencies. For example, if the U.S. dollar weakens against a foreign currency, then our manufacturing and royalty revenues will increase given a constant amount of sales in such foreign currency.

The impact on our manufacturing and 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 RISPERDAL CONSTA sales by Janssen, L.P. 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

We have carried out an evaluation, under the supervision and the participation of our management, including our principal executive officer and principal financial officer, of the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rule 13a-15(e) under the Securities Exchange Act of 1934, as amended, or the Securities Exchange Act) as of September 30, 2007. Based upon that evaluation, our principal executive officer and principal financial officer concluded that, as of September 30, 2007, our disclosure controls and procedures are effective in providing reasonable assurance that (a) the information required to be disclosed by us in the reports that we file or submit under the Securities Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC s rules and forms, and (b) such information is accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate to allow timely decisions regarding required disclosure. In designing and evaluating our disclosure controls and procedures, our management recognized that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives, and our management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

(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.

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PART II. OTHER INFORMATION

Item 1. Legal Proceedings

Note 8, Legal Matters, in the Notes to Condensed Consolidated Financial Statements in Part I of this report on Form 10-Q is incorporated into this item by reference. Please see the Legal Proceedings section of our Annual Report on Form 10-K for the year ended March 31, 2007 for more information on litigation to which we are a party.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds

There was no stock repurchase activity during the three months ended September 30, 2007 pursuant to publicly announced repurchase programs. During the six months ended September 30, 2007, we acquired, by means of net share settlements, 22,791 shares of Alkermes common stock, at an average price of \$15.22 per share, related to the vesting of employee stock awards to satisfy withholding tax obligations. During the six months ended September 30, 2007, we acquired 8,675 shares of Alkermes common stock, at an average price of \$16.77 per share, tendered by employees as payment of the exercise price of stock options granted under our equity compensation plans.

Item 4. Submission of Matters to a Vote of Security Holders

We held our annual meeting of shareholders on October 9, 2007. The following proposals were voted upon at the meeting:

1. A proposal to elect nine members of the board of directors, each to serve until the next annual meeting of shareholders and until his or her successor is duly elected and qualified, was approved with the following vote:

Nominee	Votes For	Authority Withheld
Floyd E. Bloom	92,156,104	1,377,293
Robert A. Breyer	87,640,010	5,893,387
Geraldine Henwood	92,486,924	1,046,473
Paul J. Mitchell	92,571,224	962,173
Richard F. Pops	91,527,324	2,006,073
Alexander Rich	92,237,160	1,296,237
David A. Broecker	91,709,597	1,823,800
Mark B. Skaletsky	92,348,099	1,185,298
Michael A. Wall	91,520,702	2,012,695

- 2. A proposal to approve an amended and restated 1999 Stock Option Plan was approved with 71,980,471 votes for, 10,645,595 votes against, 112,190 abstentions and 10,795,121 broker non-votes.
- 3. A proposal to approve an amendment to the 2002 Restricted Stock Award Plan to increase the number of shares issuable as restricted stock awards thereunder, by 700,000 shares, was approved with 73,781,414 votes for, 8,903,568 votes against, 53,294 abstentions and 10,795,121 broker non-votes.
- 4. A proposal to approve an amendment to the 2006 Stock Option Plan for Non-Employee Directors to increase the number of shares issuable upon the exercise of options granted thereunder, by 240,000 shares, was approved with

74,469,515 votes for, 8,207,040 votes against, 61,721 abstentions and 10,795,121 broker non-votes.

5. A proposal to ratify PricewaterhouseCoopers LLP as our independent registered public accountants for fiscal year 2008 was approved with 92,596,439 votes for, 699,228 votes against, 237,730 abstentions and 0 broker non-votes.

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Item 5. Other Information

In October 2007, Reliant filed amendments to its S-1 with the Securities and Exchange Commission for an initial public offering of its common stock. The S-1 filing identifies Alkermes as a seller of one million shares of Reliant common stock in the event the offering is successful. In December 2001, we made a \$100.0 million investment in Series C convertible, redeemable preferred units of Reliant, which represents an approximately 13% equity interest in Reliant.

Item 6. Exhibits

(a) List of Exhibits:

Exhibit

No.

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

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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/ David A. Broecker

David A. Broecker President and Chief Executive Officer (Principal Executive Officer)

By: /s/ James M. Frates

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

Date: November 9, 2007

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EXHIBIT INDEX

Exhibit

No

- 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).

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