

ALKERMES INC  
Form 10-Q  
August 09, 2007

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**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, 2007**
- 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  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

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

<b>Class</b>	<b>As of August 3, 2007</b>
Common Stock, \$.01 par value	101,559,841
Non-Voting Common Stock, \$.01 par value	382,632

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**ALKERMES, INC. AND SUBSIDIARIES**

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

	<b>June 30, 2007</b>	<b>March 31, 2007</b>
	<b>(In thousands, except share and per share amounts)</b>	
<b>ASSETS</b>		
<b>CURRENT ASSETS:</b>		
Cash and cash equivalents	\$ 60,990	\$ 80,500
Investments short-term	264,762	271,082
Receivables	66,782	56,049
Inventory	20,218	18,190
Prepaid expenses and other current assets	9,063	7,054
Total current assets	421,815	432,875
<b>PROPERTY, PLANT AND EQUIPMENT:</b>		
Land	301	301
Building and improvements	31,708	25,717
Furniture, fixtures and equipment	65,042	64,203
Equipment under capital lease	464	464
Leasehold improvements	32,375	32,345
Construction in progress	45,180	42,442
	175,070	165,472
Less: accumulated depreciation and amortization	(44,807)	(41,877)
Property, plant and equipment net	130,263	123,595
RESTRICTED INVESTMENTS	5,144	5,144
OTHER ASSETS	7,036	7,007
<b>TOTAL ASSETS</b>	<b>\$ 564,258</b>	<b>\$ 568,621</b>

**LIABILITIES AND SHAREHOLDERS EQUITY****CURRENT LIABILITIES:**

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Accounts payable and accrued expenses	\$ 26,714	\$ 45,855
Accrued interest	2,975	2,976
Unearned milestone revenue current portion	6,333	11,450
Deferred revenue current portion	705	200
Long-term debt current portion	1,288	1,579
Total current liabilities	38,015	62,060
NON-RECOURSE RISPERDAL CONSTA SECURED 7% NOTES	157,694	156,851
LONG-TERM DEBT	28	47
UNEARNED MILESTONE REVENUE LONG-TERM PORTION	115,738	117,300
DEFERRED REVENUE LONG-TERM PORTION	23,242	22,153
OTHER LONG-TERM LIABILITIES	6,622	6,749
TOTAL LIABILITIES	341,339	365,160
COMMITMENTS AND CONTINGENCIES (Notes 8 and 9)		
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; 102,168,103 and 101,550,673 shares issued, 101,344,426 and 100,726,996 shares outstanding at June 30, 2007 and March 31, 2007, respectively	1,022	1,015
Non-voting common stock, par value, \$0.01 per share; authorized, 450,000 shares; issued and outstanding, 382,632 shares at June 30, 2007 and March 31, 2007	4	4
Treasury stock, at cost (823,677 shares at June 30, 2007 and March 31, 2007)	(12,492)	(12,492)
Additional paid-in capital	848,955	837,727
Accumulated other comprehensive income	228	753
Accumulated deficit	(614,798)	(623,546)
TOTAL SHAREHOLDERS EQUITY	222,919	203,461
TOTAL LIABILITIES AND SHAREHOLDERS EQUITY	\$ 564,258	\$ 568,621

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****(unaudited)**

	<b>Three Months Ended June 30,</b>	
	<b>2007</b>	<b>2006</b>
	<b>(In thousands, except per share amounts)</b>	
<b>REVENUES:</b>		
Manufacturing revenues	\$ 31,517	\$ 22,193
Royalty revenues	6,982	5,139
Research and development revenue under collaborative arrangements	23,450	14,464
Net collaborative profit	6,989	9,742
 Total revenues	 68,938	 51,538
<b>EXPENSES:</b>		
Cost of goods manufactured	10,145	9,338
Research and development	32,619	25,863
Selling, general and administrative	15,400	16,530
 Total expenses	 58,164	 51,731
 OPERATING INCOME (LOSS)	 10,774	 (193)
<b>OTHER INCOME (EXPENSE):</b>		
Interest income	4,402	4,335
Interest expense	(4,073)	(5,473)
Other income (expense), net	26	787
 Total other income (expense)	 355	 (351)
 INCOME (LOSS) BEFORE INCOME TAXES	 11,129	 (544)
INCOME TAXES	2,382	171
 NET INCOME (LOSS)	 \$ 8,747	 \$ (715)
<b>EARNINGS (LOSS) PER COMMON SHARE:</b>		
BASIC	\$ 0.09	\$ (0.01)
 DILUTED	 \$ 0.08	 \$ (0.01)
<b>WEIGHTED AVERAGE NUMBER OF COMMON SHARES OUTSTANDING:</b>		
BASIC	101,324	93,784

DILUTED

104,191

93,784

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**  
**(unaudited)**

	<b>Three Months Ended</b>	
	<b>June 30,</b>	
	<b>2007</b>	<b>2006</b>
	<b>(In thousands)</b>	
<b>CASH FLOWS FROM OPERATING ACTIVITIES:</b>		
Net income (loss)	\$ 8,747	\$ (715)
Adjustments to reconcile net income (loss) to cash flows from operating activities:		
Share-based compensation	5,747	8,347
Depreciation and amortization	2,930	2,826
Other non-cash charges	1,064	1,215
Change in fair value of warrants	(196)	(846)
Gain on sale of equipment		5
Changes in assets and liabilities:		
Receivables	(11,805)	(1,551)
Inventory, prepaid expenses and other current assets	(7,197)	(5,401)
Accounts payable, accrued expenses and accrued interest	(19,414)	(7,529)
Unearned milestone revenue	(6,679)	81,103
Deferred revenue	2,666	(50)
Other long-term liabilities	(28)	18
Cash flows from operating activities	(24,165)	77,422
<b>CASH FLOWS FROM INVESTING ACTIVITIES:</b>		
Additions to property, plant and equipment	(6,462)	(6,160)
Purchases of short and long-term investments	(140,812)	(63,374)
Sales and maturities of short and long-term investments	146,562	67,096
(Increase) decrease in other assets	(8)	14
Cash flows from investing activities	(720)	(2,424)
<b>CASH FLOWS FROM FINANCING ACTIVITIES:</b>		
Proceeds from issuance of common stock	5,627	2,268
Excess tax benefit from stock options	58	
Payment of debt	(310)	(294)
Purchase of treasury stock		(2,627)
Cash flows from financing activities	5,375	(653)
NET (DECREASE) INCREASE IN CASH AND CASH EQUIVALENTS	(19,510)	74,345
CASH AND CASH EQUIVALENTS Beginning of period	80,500	33,578
CASH AND CASH EQUIVALENTS End of period	\$ 60,990	\$ 107,923

SUPPLEMENTAL CASH FLOW DISCLOSURE:

Cash paid for interest	\$ 3,003	\$ 4,511
Cash paid for income taxes	\$ 380	\$
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	\$ 3,136	\$

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 months ended June 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 s 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 transitions. See Note 8, 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

**Table of Contents****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 at 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 fiscal years beginning after December 15, 2007 and interim periods within those years. 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 (LOSS)**

Comprehensive income (loss) for the three months ended June 30, 2007 and 2006 is as follows:

	<b>Three Months Ended June 30,</b>	
	<b>2007</b>	<b>2006</b>
<b>(In thousands)</b>		
Net income (loss)	\$ 8,747	\$ (715)
Unrealized (loss) gain on available-for-sale investments	(525)	334
Comprehensive income (loss)	\$ 8,222	\$ (381)

**3. EARNINGS (LOSS) PER COMMON SHARE**

Basic earnings (loss) per common share is calculated based upon net income (loss) 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 shares outstanding, as adjusted for the effect of potential outstanding shares, including stock options, stock awards, redeemable convertible preferred stock and convertible debt. For periods during which the Company reports a net loss from operations, basic and diluted net loss

per common share are equal since the impact of potential common shares would have an anti-dilutive effect.

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

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

	<b>Three Months Ended June 30,</b>	
	<b>2007</b>	<b>2006</b>
<b>(In thousands)</b>		
Numerator:		
Net income (loss)	\$ 8,747	\$ (715)
Denominator:		
Weighted average number of common shares outstanding	101,324	93,784
Effect of dilutive securities:		
Stock options	2,553	
Restricted stock awards	314	
Dilutive common share equivalents	2,867	
Shares used in calculating diluted earnings (loss) per common share	104,191	93,784

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

	<b>Three Months Ended June 30,</b>	
	<b>2007</b>	<b>2006</b>
<b>(In thousands)</b>		
Stock options	11,956	19,420
Restricted stock awards		127
2.5% convertible subordinated notes		7,438
3.75% convertible subordinated notes		10
Redeemable convertible preferred stock		630
Total	11,956	27,625

**4. SHARE-BASED COMPENSATION**

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

	<b>Three Months Ended June 30,</b>	
	<b>2007</b>	<b>2006</b>
<b>(In thousands)</b>		
Cost of goods manufactured	\$ 626	\$ 260
Research and development	1,851	2,836
Selling, general and administrative	3,270	5,251
Total	\$ 5,747	\$ 8,347

As of June 30, 2007 and 2006, \$0.4 million and \$0.7 million, respectively, of share-based compensation cost was capitalized and recorded under the caption "Inventory" in the condensed consolidated balance sheets.



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

	<b>June 30, 2007</b>	<b>March 31, 2007</b>
<b>(In thousands)</b>		
Raw materials	\$ 8,448	\$ 7,238
Work in process	3,967	4,291
Finished goods	7,803	6,661
Total	\$ 20,218	\$ 18,190

**6. ACCOUNTS PAYABLE AND ACCRUED EXPENSES**

Accounts payable and accrued expenses consist of the following:

	<b>June 30, 2007</b>	<b>March 31, 2007</b>
<b>(In thousands)</b>		
Accounts payable and accrued accounts payable	\$ 10,987	\$ 12,097
Accrued expenses related to collaborative arrangements	947	16,155
Accrued compensation	4,645	10,917
Accrued interest	2,975	2,975
Accrued other	7,160	3,711
Total	\$ 26,714	\$ 45,855

**7. RESTRUCTURING OF OPERATIONS**

In June 2004, the Company and its former collaborative partner Genentech, Inc. announced the decision to discontinue commercialization of NUTROPIN DEPOT® (the 2004 Restructuring). In connection with the 2004 Restructuring, the Company recorded net restructuring charges of \$11.5 million in the year ended March 31, 2005. As of June 30, 2007, the Company had paid in cash, written down, recovered and made restructuring charge adjustments that aggregated approximately \$10.5 million in connection with the 2004 Restructuring.

The following table displays the restructuring activity during the three months ended June 30, 2007:

<b>(In thousands)</b>	<b>Balance March 31, 2007</b>	<b>Payments</b>	<b>Balance June 30, 2007</b>
Facility closure	\$ 1,079	\$ (96)	\$ 983
Total	\$ 1,079	\$ (96)	\$ 983

## 8. 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, 2007, the Company determined that the deferred tax assets may not be realized and a full valuation allowance has been recorded.

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**ALKERMES, INC. AND SUBSIDIARIES**

**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

The provision for income taxes in the amount of approximately \$2.4 million for the three months ended June 30, 2007 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 months ended June 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 months ended June 30, 2007 and 2006 was prepared on a discrete quarterly basis, as a yearly effective tax rate was not considered a reliable estimate for the current quarter provision. This provision reflects tax recognition of the entire \$110.0 million nonrefundable milestone payment the Company received from 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 adoption date of April 1, 2007, and also at June 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. ). 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 months ended June 30, 2007, the Company did not recognize any accrued interest and penalties in its condensed consolidated financial statements.

**9. 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 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 generally accepted accounting principles in the U.S. 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,

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**ALKERMES, INC. AND SUBSIDIARIES**

**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

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 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.

**10. 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. (as used in this section, together with our subsidiaries, us, we or our) is a biotechnology company that develops innovative medicines designed to yield better therapeutic outcomes and improve the lives of patients with serious disease. We currently have two commercial products: RISPERDAL® CONSTA® [(risperidone) long-acting injection], the first and only long-acting atypical antipsychotic medication approved for use in schizophrenia, and marketed worldwide by Janssen-Cilag (Janssen), a wholly owned division of Johnson & Johnson; and VIVITROL® (naltrexone for extended-release injectable suspension), the first and only once-monthly injectable medication approved for the treatment of alcohol dependence and marketed in the United States (U.S.) primarily by Cephalon, Inc. (Cephalon). Our 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. Our headquarters are 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 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 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, royalty revenues, research and development revenues under collaborative arrangements, net collaborative profits, 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 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; the successful continuation of development activities for our programs, including ALKS 29; and the successful manufacture of our products and product candidates, including RISPERDAL CONSTA, 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 continue to grow, particularly because we rely on our partner, 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 scale-up and manufacture our product candidates, including ALKS 29, commercially or economically; (iv) our 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; (v) clinical trials may take more time or consume more resources than initially envisioned; (vi) results of earlier clinical trials may not

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necessarily be predictive of the safety and efficacy results in larger clinical trials; (vii) 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; (viii) after the completion of clinical trials for our product candidates and the submission for marketing approval, the Food and Drug Administration ( 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; (ix) 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; (x) technological change in the biotechnology or pharmaceutical industries could render our products and/or product candidates obsolete or non-competitive; (xi) difficulties or set-backs in obtaining and enforcing our patents and difficulties with the patent rights of others could occur; (xii) we may continue to incur losses in the future; and (xiii) 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.

## **Product Developments**

### **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.

### ***RISPERDAL CONSTA***

Using our proprietary Medisorb® technology, we developed RISPERDAL CONSTA, a long-acting formulation of Janssen's antipsychotic drug RISPERDAL® 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 markets RISPERDAL CONSTA worldwide. We are the exclusive manufacturer of RISPERDAL CONSTA for Janssen, and we earn both manufacturing fees and royalties from Janssen.

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 continues to launch the product around the world.

### ***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

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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<sup>®</sup> 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.

### ***Exenatide LAR***

We are collaborating with Amylin Pharmaceuticals, Inc. ( Amylin ) on the development of a long-acting release ( LAR ) injectable formulation of Amylin's exenatide ( exenatide ) for the treatment of type 2 diabetes. Exenatide injection (trade name BYETTA<sup>®</sup>) 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. Exenatide LAR is being developed as a once-weekly formulation to provide a more patient-friendly treatment option. Amylin entered into a collaboration agreement with Lilly for the development and commercialization of exenatide, including exenatide LAR.

### ***ALKS 29***

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.



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***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<sup>®</sup>, Indevus' currently marketed product for overactive bladder.

***AIR parathyroid hormone***

We are developing inhaled formulations of parathyroid hormone ( PTH ) with Lilly for the treatment of osteoporosis, a progressive disease in which the bones become weak and are more likely to break. The development program utilizes our AIR pulmonary technology in combination with Lilly's recombinant PTH, FORTEO<sup>®</sup> (teriparatide (rDNA origin) injection). FORTEO was approved by the FDA in 2002 to treat osteoporosis in postmenopausal women who are at high risk for bone fracture and to increase bone mass in men with primary or hypogonadal osteoporosis who are at high risk for fracture.

**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 June 30, 2007, we determined that the deferred tax assets may not be realized and a full valuation allowance has been recorded.

We adopted FIN No. 48 on April 1, 2007. The implementation of FIN 48 did not have a material impact on our condensed consolidated financial statements or results of operations. At the adoption date of April 1, 2007, and also at June 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. 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 June 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 June 30, 2007 was \$8.7 million, or \$0.09 per common share basic and \$0.08 per common share diluted, as compared to a net loss of \$0.7 million, or a net loss of \$0.01 per common share basic and diluted, for the three months ended June 30, 2006.

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Total manufacturing revenues were \$31.5 million and \$22.2 million for the three months ended June 30, 2007 and 2006, respectively.

RISPERDAL CONSTA manufacturing revenues were \$30.2 million and \$19.1 million for the three months ended June 30, 2007 and 2006, respectively. The increase in RISPERDAL CONSTA revenues for the three months ended June 30, 2007, as compared to the three months ended June 30, 2006, was due to increased shipments of RISPERDAL CONSTA to Janssen to satisfy demand.

Under our manufacturing and supply agreement with Janssen, we earn manufacturing revenues when product is shipped to Janssen, based on a percentage of Janssen's estimated unit net sales price. This percentage is determined based on Janssen's forecasted unit demand for the calendar year and varies based on the volume of units shipped, with a minimum manufacturing percentage of 7.5%. Revenues include a monthly adjustment from Janssen's estimated unit net sales price to Janssen's actual unit net sales price for product shipped. For the three months ended June 30, 2007 and 2006, our RISPERDAL CONSTA manufacturing revenues were based on an average of 7.5% of Janssen's unit net sales price of RISPERDAL CONSTA. We anticipate that we will earn manufacturing revenues at 7.5% of Janssen's unit net sales price of RISPERDAL CONSTA for product shipped to Janssen in the fiscal year ending March 31, 2008 and beyond.

VIVITROL manufacturing revenues were \$1.3 million and \$3.1 million for the three months ended June 30, 2007 and 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 months ended June 30, 2007, as compared to the three months ended June 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 sufficient quantities 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 June 30, 2007. VIVITROL manufacturing revenues for the three months ended June 30, 2007 consisted entirely of idle capacity costs, which consisted of current period manufacturing costs related to underutilized VIVITROL manufacturing capacity. There were no billings to Cephalon for VIVITROL idle capacity costs in the three months ended June 30, 2006. VIVITROL manufacturing revenues for the three months ended June 30, 2007 and 2006 included \$0.1 million and \$0.3 million, respectively, of milestone revenue related to manufacturing profit on VIVITROL, which draws down from unearned milestone revenue.

Royalty revenues were \$7.0 million and \$5.1 million for the three months ended June 30, 2007 and 2006, respectively, all of which were related to sales of RISPERDAL CONSTA. The increase in royalty revenues for the three months ended June 30, 2007, as compared to the three months ended June 30, 2006, 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 period that the product is sold by Janssen.

Research and development revenue under collaborative arrangements ( R&D revenue ) was \$23.4 million and \$14.5 million for the three months ended June 30, 2007 and 2006, respectively. The increase in R&D revenue for the three months ended June 30, 2007, as compared to the three months ended June 30, 2006, was primarily due to increases in revenues related to work performed on the AIR<sup>®</sup> Insulin, AIR PTH and exenatide LAR programs. A component of the AIR PTH program revenue in the three months ended June 30, 2007 included recognition of a 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, and based on the level of effort incurred to date and the payments we expect to receive under this arrangement, we were able to recognize all of this milestone payment when achieved. In addition, R&D revenue for the three months ended June 30, 2007 included revenue of \$1.2 million 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.

Net collaborative profit was \$7.0 million and \$9.7 million for the three months ended June 30, 2007 and 2006, respectively. For the three months ended June 30, 2007 and 2006, we recognized \$5.3 million and

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\$27.4 million of milestone revenue cost recovery, respectively, to offset net losses on VIVITROL that were funded by us. We were responsible to fund the first \$124.6 million of cumulative net losses incurred on 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 months ended June 30, 2007 and 2006, we recognized \$1.3 million and \$1.2 million, respectively, of milestone revenue related to the license provided to Cephalon to commercialize VIVITROL. During the three months ended June 30, 2007 and 2006, we made payments of \$5.2 million and \$18.9 million, respectively, to Cephalon to reimburse their net losses on VIVITROL, and during the three months ended June 30, 2007 we received payments of \$5.6 million from Cephalon to reimburse us for our expenses on VIVITROL, incurred after the cumulative loss cap was reached. In the aggregate, net collaborative profit of \$7.0 million and \$9.7 million for the three months ended June 30, 2007 and 2006, respectively, consisted of \$6.6 million and \$28.6 million of milestone revenue, respectively, offset by net payments from/(to) Cephalon of \$0.4 million and (\$18.9) million, respectively.

Net collaborative profit for the three months ended June 30 was as follows:

	2007	2006
<b>(In thousands)</b>		
Milestone revenue cost recovery(1)	\$ 5,256	\$ 27,424
Milestone revenue license	1,309	1,191
Total milestone revenue cost recovery and license	6,565	28,615
Payments to Cephalon to reimburse their net losses up to the cumulative loss cap	(5,223)	(18,873)
Payments from Cephalon to reimburse our expenses incurred after the cumulative loss cap was reached	5,647	
Net collaborative profit	\$ 6,989	\$ 9,742

- (1) For the three months ended June 30, 2007, consists of the portion of Cephalon's net losses and Alkermes expenses incurred on VIVITROL that were funded by us up to the cumulative loss cap. For the three months ended June 30, 2006, consists of \$18.9 million of Cephalon's net losses incurred on VIVITROL that were funded by us, \$8.3 million of our expenses incurred on VIVITROL on behalf of the collaboration and \$0.2 million of our expenses incurred on VIVITROL outside the collaboration, for which we were solely responsible.

We were responsible for the first \$124.6 million of cumulative net losses incurred on VIVITROL (the cumulative net loss cap). The cumulative net loss cap was reached in April 2007, at which time Cephalon became responsible to fund all net losses incurred on VIVITROL through December 31, 2007. 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.

Through June 30, 2007, the cumulative net losses on VIVITROL were \$144.1 million, of which \$56.9 million was incurred by us on behalf of the collaboration and \$87.2 million was incurred by Cephalon on behalf of the collaboration.



Cost of goods manufactured was \$10.1 million and \$9.3 million for the three months ended June 30, 2007 and 2006, respectively. Cost of goods manufactured for RISPERDAL CONSTA was \$9.0 million and \$6.5 million for the three months ended June 30, 2007 and 2006, respectively. The increase in cost of goods manufactured for RISPERDAL CONSTA for the three months ended June 30, 2007, as compared to the three months ended June 30, 2006, was due to increased shipments of RISPERDAL CONSTA to Janssen to satisfy demand. Cost of goods manufactured for VIVITROL was \$1.1 million and \$2.8 million for the three months ended June 30, 2007 and 2006, respectively. The decrease in cost of goods manufactured for VIVITROL for the three months ended June 30, 2007, as compared to the three months ended June 30, 2006, was due to

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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 sufficient quantities 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 June 30, 2007. Cost of goods manufactured for VIVITROL for the three months ended June 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 months ended June 30, 2006.

Research and development expenses were \$32.6 million and \$25.9 million for the three months ended June 30, 2007 and 2006, respectively. The increase in research and development expenses for the three months ended June 30, 2007, as compared to the three months ended June 30, 2006, was primarily due to increased personnel-related costs and materials consumed during work we performed, notably on the AIR Insulin, AIR PTH and exenatide LAR programs.

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 \$15.4 million and \$16.5 million for the three months ended June 30, 2007 and 2006, respectively. The decrease in selling, general and administrative expenses for the three months ended June 30, 2007, as compared to the three months ended June 30, 2006, was primarily due to decreased share-based compensation expense.

Interest income was \$4.4 million and \$4.3 million for the three months ended June 30, 2007 and 2006, respectively. The average cash and investment balances held and interest rates earned during the three months ended June 30, 2007 and 2006 were comparable and resulted in similar interest income in the quarters.

Interest expense was \$4.1 million and \$5.5 million for the three months ended June 30, 2007 and 2006, respectively. The decrease for the three months ended June 30, 2007, as compared to the three months ended June 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 months ended June 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 income of \$0.03 million and \$0.8 million for the three months ended June 30, 2007 and 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 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.

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Income taxes were \$2.4 million and \$0.2 million for the three months ended June 30, 2007 and 2006, respectively. The provision for income taxes for the three months ended June 30, 2007 and 2006 was prepared on a discrete quarterly basis and therefore 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 months ended June 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 three months ended June 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.

## **Financial Condition**

Cash and cash equivalents and short-term investments were \$325.8 million and \$351.6 million as of June 30, 2007 and March 31, 2007, respectively. Short-term investments were \$264.8 million and \$271.1 million as of June 30, 2007 and March 31, 2007, respectively. During the three months ended June 30, 2007, combined cash and cash equivalents and short-term investments decreased by \$25.8 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.

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 June 30, 2007 and March 31, 2007, which are pledged as collateral under certain letters of credit and lease agreements.

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

Receivables were \$66.8 million and \$56.0 million as of June 30, 2007 and March 31, 2007, respectively. The increase of \$10.8 million during the three months ended June 30, 2007 was primarily due to: increased development revenues related to the AIR programs and to the timing of payments received from our partner Lilly with respect to these programs; amounts due from Lilly for the reimbursement of costs we incurred related to the construction of the second manufacturing line at our commercial-scale production facility for inhaled medications; amounts due from Cephalon related to VIVITROL manufacturing costs and reimbursement for costs we incurred on the construction of the two VIVITROL manufacturing lines; and increases in amounts due from Janssen for RISPERDAL CONSTA product deliveries related to the timing of invoices and subsequent payments.

Inventory was \$20.2 million and \$18.2 million as of June 30, 2007 and March 31, 2007, respectively. This consisted of RISPERDAL CONSTA inventory of \$12.6 million and \$11.2 million as of June 30, 2007 and March 31, 2007, respectively, and VIVITROL inventory of \$7.6 million and \$7.0 million as of June 30, 2007 and March 31, 2007, respectively. The increase in RISPERDAL CONSTA inventory during the three months ended June 30, 2007 was primarily due to increases in raw materials and to increases in finished goods inventory due to the timing of shipments to Janssen. As of June 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 \$26.7 million and \$45.9 million as of June 30, 2007 and March 31, 2007, respectively. The decrease during the three months ended June 30, 2007 was primarily due to decreases in amounts due to Cephalon under our agreements and to decreases in compensation accruals due to the timing of payroll and bonus payments.

Unearned milestone revenue – current and long-term portions, combined, were \$122.1 million and \$128.8 million as of June 30, 2007 and March 31, 2007, respectively. The decrease during the three months ended June 30, 2007 was due to the recognition of \$6.6 million and \$0.1 million of milestone revenue under the captions – Net collaborative profit and – Manufacturing revenues , respectively, in the condensed consolidated statement of operations during the quarter.

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Deferred revenue – current and long-term portions, combined, were \$23.9 million and \$22.4 million as of June 30, 2007 and March 31, 2007, respectively. In the three months ended June 30, 2007, we recorded approximately \$1.5 million of deferred revenue related to funding from Cephalon of the cost of the two VIVITROL manufacturing lines currently under construction. Because we continue to operate and maintain this equipment and intend to do so for the foreseeable future, the continued payments made by Cephalon for our two VIVITROL manufacturing lines currently under construction are being treated as additional consideration and recorded as deferred revenue.

## **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 June 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 \$15.0 million to \$20.0 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 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.

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### **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 June 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. and warrants we receive in connection with our collaborations and licensing activities, are used to preserve capital until it is required to fund operations. Although our investments, excluding our investment in Reliant Pharmaceuticals, Inc. 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 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 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 market price our marketable equity securities would not have a material impact on the condensed consolidated financial statements.

As of June 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 June 30, 2007, we have a term loan in the amount of \$1.2 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 royalty revenues we receive on RISPERDAL CONSTA are a percentage of the net sales made by our collaborative partner, Janssen. 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 Janssen 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.

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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 RISPERDAL CONSTA sales by Janssen 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 June 30, 2007. Based upon that evaluation, our principal executive officer and principal financial officer concluded that, as of June 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 9. 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 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 June 30, 2007 pursuant to publicly announced repurchase programs. We acquired, by means of net share settlements, 22,791 shares of Company common stock during the three months ended June 30, 2007, at an average price of \$15.22 per share, related to the vesting of employee stock awards to satisfy withholding tax obligations.

**Item 6. *Exhibits***

(a) List of Exhibits:

**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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**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: August 9, 2007

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**EXHIBIT INDEX**

**Exhibit  
No.**

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