ALKERMES INC Form 10-Q August 06, 2009

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 June 30, 2009

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

For the transition period from

Commission file number 1-14131 ALKERMES, INC.

(Exact name of registrant as specified in its charter)

PENNSYLVANIA

to

23-2472830

(State or other jurisdiction of incorporation or organization)

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

88 Sidney Street, Cambridge, MA 02139-4234 (617) 494-0171

(Address, including zip code, and telephone number, including area code, of registrant s principal executive offices)

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 has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files): Yes o 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

Smaller reporting

company o

(Do not check if a smaller reporting company)

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 August 3,
Class
Common Stock, \$.01 par value
Non-Voting Common Stock, \$.01 par value
382,632

ALKERMES, INC. AND SUBSIDIARIES QUARTERLY REPORT ON FORM 10-Q FOR THE QUARTERLY PERIOD ENDED JUNE 30, 2009 INDEX

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	st Amendment to Lease Agreement between Alkermes, Inc. and PDM Unit 850, LLC, dated as of June 18, 2009	
	le 13a-14(a)/15d-14(a) Certification	
	<u>le 13a-14(a)/15d-14(a) Certification</u> rtification pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002)
LA-32.1 CE	timeation pursuant to 18 0.s.c. Section 1550, as adopted pursuant to Section 900 of the Sarbanes-Oxiey Act of 200.	<u> </u>
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PART I. FINANCIAL INFORMATION

Item 1. Condensed Consolidated Financial Statements:

ALKERMES, INC. AND SUBSIDIARIES CONDENSED CONSOLIDATED BALANCE SHEETS (unaudited)

	June 30, 2009 (In thousands, o		March 31, 2009 except share and	
	per			
ASSETS		share a	mounts))
CURRENT ASSETS:				
Cash and cash equivalents	\$	44,900	\$	86,893
Investments short-term	Ψ	272,251	Ψ	236,768
Receivables		27,899		24,588
Inventory		20,528		20,297
Prepaid expenses and other current assets		5,403		7,500
Total current assets		370,981		376,046
PROPERTY, PLANT AND EQUIPMENT, NET		97,520		106,461
INVESTMENTS LONG-TERM		63,268		80,821
OTHER ASSETS		3,442		3,158
TOTAL ASSETS	\$	535,211	\$	566,486
LIABILITIES AND SHAREHOLDERS EQUITY CURRENT LIABILITIES:				
Accounts payable and accrued expenses	\$	23,888	\$	36,483
Deferred revenue current NON-RECOURSE RISPERDAL CONSTA SECURED 7% NOTES		2,682		6,840
CURRENT		25,667		25,667
Total current liabilities		52,237		68,990
NON-RECOURSE RISPERDAL CONSTA SECURED 7% NOTES				
LONG-TERM		44,057		50,221
DEFERRED REVENUE LONG-TERM		5,204		5,238
OTHER LONG-TERM LIABILITIES		6,846		7,149
Total liabilities		108,344		131,598

COMMITMENTS AND CONTINGENCIES (Note 12)

SHAREHOLDERS EQUITY:

Capital stock, par value, \$0.01 per share; 4,550,000 shares authorized (includes 3,000,000 shares of preferred stock); none issued Common stock, par value, \$0.01 per share; 160,000,000 shares authorized; 104,291,025 and 104,044,663 shares issued; 94,391,180 and 94,536,212 shares outstanding at June 30, 2009 and March 31, 2009, respectively 1,042 1,040 Non-voting common stock, par value, \$0.01 per share; 450,000 shares authorized; 382,632 shares issued and outstanding at June 30, 2009 and March 31, 2009 4 4 Treasury stock, at cost (9,899,845 and 9,508,451 shares at June 30, 2009 and March 31, 2009, respectively) (129,247)(126,025)Additional paid-in capital 895,791 892,415 Accumulated other comprehensive loss (4,496)(6,484)Accumulated deficit (336,227)(326,062)Total shareholders equity 426,867 434,888 TOTAL LIABILITIES AND SHAREHOLDERS EQUITY \$ \$ 535,211 566,486

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)

	Three Months Ended June 30,			
		June 2009	30,	2008
		(In thousand	s. excei	
		sha	_	or per
		amou	-	
REVENUES:			,	
Manufacturing revenues	\$	28,804	\$	38,610
Royalty revenues		8,701		8,581
Product sales, net		4,226		
Research and development revenue under collaborative arrangements		1,450		31,450
Net collaborative profit		4,315		1,351
Total revenues		47,496		79,992
EXPENSES:				
Cost of goods manufactured and sold		12,666		14,314
Research and development		25,586		22,261
Selling, general and administrative		19,268		11,926
Total expenses		57,520		48,501
OPERATING (LOSS) INCOME		(10,024)		31,491
OTHER EXPENSE, NET:				
Interest income		1,561		3,616
Interest expense		(1,709)		(4,226)
Other expense, net		(63)		(164)
Total other expense, net		(211)		(774)
(LOSS) INCOME BEFORE INCOME TAXES		(10,235)		30,717
(BENEFIT) PROVISION FOR INCOME TAXES		(70)		1,030
NET (LOSS) INCOME	\$	(10,165)	\$	29,687
(LOSS) EARNINGS PER COMMON SHARE:				
Basic	\$	(0.11)	\$	0.31
Diluted	\$	(0.11)	\$	0.31
WEIGHTED AVERAGE NUMBER OF COMMON SHARES OUTSTANDING:				
Basic		94,883		95,361

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Diluted 94,883 96,631

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)

	Three Months Ended	
	June	*
	2009	2008
CACH ELOWCEDOM ODED ATING ACTIVITIES.	(In thou	isanas)
CASH FLOWS FROM OPERATING ACTIVITIES:	¢ (10.165)	\$ 29,687
Net (loss) income Adjustments to reconcile net (loss) income to cash flows from operating activities:	\$ (10,165)	\$ 29,687
Share-based compensation expense	3,230	4,495
Depreciation	9,948	2,517
Other non-cash charges	481	1,336
Changes in assets and liabilities:	401	1,550
Receivables	(3,311)	6,599
Inventory, prepaid expenses and other assets	1,167	1,845
Accounts payable and accrued expenses	(11,882)	(13,917)
Unearned milestone revenue	, , ,	(1,552)
Deferred revenue	(4,192)	1,219
Other long-term liabilities	(427)	130
Payment of non-recourse RISPERDAL CONSTA secured 7% notes principal		
attributable to original issue discount	(485)	(691)
Cash flows (used in) provided by operating activities	(15,636)	31,668
CASH FLOWS FROM INVESTING ACTIVITIES:		
Additions to property, plant and equipment	(2,099)	(2,573)
Sales of property, plant and equipment	23	7,717
Purchases of investments	(203,655)	(177,386)
Sales and maturities of investments	187,712	169,384
	, -	,
Cash flows used in investing activities	(18,019)	(2,858)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from the issuance of common stock for share-based compensation	107	2,370
arrangements Excess tax benefit from share-based compensation	107	2,370
Payment of non-recourse RISPERDAL CONSTA secured 7% notes principal	(5,932)	19
Purchase of non-recourse RISPERDAL CONSTA secured 7% notes	(3,732)	(13,409)
Payment of capital leases		(28)
Purchase of common stock for treasury	(2,513)	(12,580)
1 dienas of tenamen seem for trousury	(=,010)	(12,000)
Cash flows used in financing activities	(8,338)	(23,628)
NET (DECDEASE) INCDEASE IN CASH AND CASH FOLIWALENDS	(41.002)	£ 100
NET (DECREASE) INCREASE IN CASH AND CASH EQUIVALENTS CASH AND CASH EQUIVALENTS Beginning of period	(41,993)	5,182
CASH AND CASH EQUIVALENTS Beginning of period	86,893	101,241
CASH AND CASH EQUIVALENTS End of period	\$ 44,900	\$ 106,423
	,	,

SUPPLEMENTAL CASH FLOW DISCLOSURE:

Cash paid for interest	\$	1,348	\$	2,975
Cash paid for taxes	\$		\$	160
Non-cash investing and financing activities:				
Purchased capital expenditures included in accounts payable and accrued expenses	\$	713	\$	2,812
Receipt of Alkermes shares for the purchase of stock options or to satisfy minimum				
tax withholding obligations related to stock based awards	\$	709	\$	444
The accompanying notes are an integral part of these unaudited condensed consolidate	ed finar	ncial stater	nents.	

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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, 2009 and 2008 are unaudited and have been prepared on a basis substantially consistent with the audited financial statements for the year ended March 31, 2009. The year-end condensed consolidated balance sheet data was derived from audited financial statements, but does not include all disclosures required by accounting principles generally accepted in the United States of America (commonly referred to as GAAP). In the opinion of management, the condensed consolidated financial statements include all adjustments, which are of a normal recurring nature, that are necessary to present fairly the results of operations for the reported periods.

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, 2009, 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 7% Notes), and the assets of Alkermes are not available to satisfy obligations of Royalty Sub. 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.

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 diseases. 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.

Reclassifications \$0.7 million that was previously classified as Purchase of non-recourse RISPERDAL CONSTA 7% notes was reclassified to Payment of non-recourse RISPERDAL CONSTA secured 7% notes principal attributable to original issue discount in the accompanying condensed consolidated statements of cash flows to conform to current period presentation.

New Accounting Pronouncements

On April 1, 2009, the Company adopted the Financial Accounting Standards Board's (FASB) Emerging Issues Task Force (EITF) Issue No. 07-1, *Accounting for Collaborative Arrangements Related to the Development and Commercialization of Intellectual Property* (EITF No. 07-1). The adoption of this standard had no impact on its financial position or results of operations.

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ALKERMES, INC. AND SUBSIDIARIES NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

In June 2009, the FASB issued Statement of Financial Accounting Standards (SFAS) Number 166, Accounting for Transfers of Financial Assets an amendment of FASB Statement No. 140 (SFAS No. 166). SFAS No. 166 was issued to improve the relevance, representational faithfulness and comparability of the information that a reporting entity provides in its financial statements about a transfer of financial assets, the effects of such a transfer on its financial position, financial performance and cash flows; and provide information as to a transferor s continuing involvement, if any, in transferred financial assets. SFAS No. 166 is effective for the Company s fiscal year beginning April 1, 2010, and the Company does not expect the adoption of this standard to have a significant impact on its financial position or results of operations.

In June 2009, the FASB issued SFAS Number 167, Amendments to FASB Interpretation No. 46(R) (SFAS No. 167). SFAS No. 167 was issued to improve financial reporting by enterprises involved with variable interest entities and amends the consolidation guidance that applies to variable interest entities. SFAS No. 167 is effective for the Company s fiscal year beginning April 1, 2010, and the Company does not expect the adoption of this standard to have a significant impact on its financial position or results of operations.

2. COMPREHENSIVE (LOSS) INCOME

Comprehensive (loss) income is as follows:

	Three Months Ended June 30		
(In thousands)	2009	2008	
Net (loss) income	\$ (10,165)	\$ 29,687	
Unrealized gains (losses) on available for sale securities:			
Holding gains (losses)	1,988	(205)	
Reclassification of unrealized losses to realized losses on available for sale securities		48	
Unrealized gains (losses) on available for sale securities	1,988	(157)	
Comprehensive (loss) income	\$ (8,177)	\$ 29,530	

3. EARNINGS PER SHARE

Basic earnings per common share is calculated based upon net (loss) 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 and stock awards.

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

		Three Months Ended June 30		
(In thousands)	2009	2008		
Numerator:				
Net (loss) income	\$ (10,165)	\$ 29,687		
Denominator:				
Weighted average number of common shares outstanding	94,883	95,361		
Effect of dilutive securities:				
Stock options		1,172		
Restricted stock units		98		

Dilutive common share equivalents 1,270

Shares used in calculating diluted (loss) earnings per share

94,883 96,631

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

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ALKERMES, INC. AND SUBSIDIARIES NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

	Three Mo	Three Months Ended			
	Ju	ne 30			
(In thousands)	2009	2008			
Stock options	17,444	14,506			
Restricted stock units	254	9			
Total	17,698	14,515			

4. INVESTMENTS

Investments consist of the following:

	Amortized	Gross Unrealized Gains Losses (In thousands)		Estimated	
	Cost			Fair Value	
June 30, 2009			,		
Short-term investments:					
Available-for-sale securities:					
U.S. government and agency debt securities	\$ 234,967	\$ 1,600	\$ (24)	\$ 236,543	
Corporate debt securities	32,242	346		32,588	
Other debt securities	3,434		(314)	3,120	
Total short-term investments	270,643	1,946	(338)	272,251	
Long-term investments:					
Available-for-sale securities:					
U.S. government and agency debt securities	6,999		(3)	6,996	
Corporate debt securities	43,163		(4,018)	39,145	
Other debt securities	12,475		(2,080)	10,395	
Strategic investments	738	138		876	
	63,375	138	(6,101)	57,412	
Held-to-maturity securities:					
U.S. government obligations	416			416	
Certificates of deposit	5,440			5,440	
	5,856			5,856	
Total long-term investments	69,231	138	(6,101)	63,268	
Total investments	\$ 339,874	\$ 2,084	\$ (6,439)	\$ 335,519	

March 31, 2009

Short-term investments:

Available-for-sale securities:

U.S. government and agency debt securities Corporate debt securities Other debt securities	\$ 225,490 8,160 500	\$ 2,635 9	\$ (6) (20)	\$ 228,119 8,169 480
Total short-term investments	234,150	2,644	(26)	236,768
Long-term investments: Available-for-sale securities:				
U.S. government and agency debt securities	10,149		(3)	10,146
Corporate debt securities	57,887		(6,326)	51,561
Other debt securities	16,350		(2,683)	13,667
Strategic investments	738	53		791
	85,124	53	(9,012)	76,165
Held-to-maturity securities:				
U.S. government obligations	416			416
Certificates of deposit	4,240			4,240
	4,656			4,656
Total long-term investments	89,780	53	(9,012)	80,821
Total investments	\$ 323,930	\$ 2,697	\$ (9,038)	\$ 317,589
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ALKERMES, INC. AND SUBSIDIARIES NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

During the three months ended June 30, 2009, the Company had \$187.7 million of proceeds from the sales and maturities of marketable securities. The proceeds from the sales and maturities of its marketable securities resulted in realized gains of \$0.2 million and realized losses of less than \$0.1 million.

The Company s available-for-sale and held-to-maturity securities at June 30, 2009 have contractual maturities in the following periods:

	Available-for-Sale		Held-to	Held-to-Maturity	
	Amortized	Estimated	Amortized	Estimated	
				Fair	
(in thousands)	Cost	Fair Value	Cost	Value	
Within 1 year	\$ 156,436	\$ 156,640	\$ 5,856	\$ 5,856	
After 1 year through 5 years (1)	147,616	147,151			