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

		Page No.
	<u>PART I FINANCIAL INFORMATION</u>	
Item 1.	Condensed Consolidated Financial Statements (Unaudited):	3
	Condensed Consolidated Balance Sheets June 30, 2009 and March 31, 2009	3
	Condensed Consolidated Statements of Operations For the Three Months Ended	
	June 30, 2009 and 2008	4
	Condensed Consolidated Statements of Cash Flows For the Three Months Ended	
	June 30, 2009 and 2008	5
	Notes to Condensed Consolidated Financial Statements	6
Item 2.	Management s Discussion and Analysis of Financial Condition and Results of	
	<u>Operations</u>	16
Item 3.	Quantitative and Qualitative Discloures about Market Risk	26
Item 4.	Controls and Procedures	26
	PART II OTHER INFORMATION	
Item 1.	<u>Legal Proceedings</u>	27
Item 2.	Unregistered Sales of Equity Securities and Use of Proceeds	27
Item 5.	Other Information	27
Item 6.	Exhibits	28
Signatures		29
Exhibit Ind		30
EX-10.2 Fir	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	
	le 13a-14(a)/15d-14(a) Certification  which is a second of the Sewhence Oyley Act of 2000	2
EA-32.1 Ce	rtification pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002	<u> </u>
	2	

#### 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	
		-	er	
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.

3

**Table of Contents** 

# ALKERMES, INC. AND SUBSIDIARIES CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS (unaudited)

	Three Months Ended			ded
	June 30, 2009			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

6

Diluted 94,883 96,631

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

4

# ALKERMES, INC. AND SUBSIDIARIES CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS (unaudited)

	<b>Three Months Ended</b>	
	June	*
	2009	2008
CACHELOWCEDOM 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:	101	1,330
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:		
	(2,000)	(2,573)
Additions to property, plant and equipment Sales of property, plant and equipment	(2,099) 23	7,717
Purchases of investments	(203,655)	(177,386)
Sales and maturities of investments	187,712	169,384
Sales and maturities of investments	107,712	107,504
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		
arrangements	107	2,370
Excess tax benefit from share-based compensation		19
Payment of non-recourse RISPERDAL CONSTA secured 7% notes principal	(5,932)	(1.2.100)
Purchase of non-recourse RISPERDAL CONSTA secured 7% notes		(13,409)
Payment of capital leases	(0.510)	(28)
Purchase of common stock for treasury	(2,513)	(12,580)
Cash flows used in financing activities	(8,338)	(23,628)
2-11-1-1-1-1-1-1-1-1-1-1-1-1-1-1-1-1-1-	(0,220)	(20,020)
NET (DECREASE) INCREASE IN CASH AND CASH EQUIVALENTS	(41,993)	5,182
CASH AND CASH EQUIVALENTS Beginning of period	86,893	101,241
	Ф. 44.000	¢ 107 400
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 consolidated financial statements.				

5

# 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.

6

# 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:

7

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

	Three Mo	Three Months Ended			
	June 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		nrealized	Estimated Fair Value	
	Cost	Gains Losses (In thousands)		ran 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
	8			

# 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	-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		
After 5 years through 10 years (1)	19,227	16,719		
After 10 years	10,000	8,277		
Total	\$ 333,279	\$ 328,787	\$ 5,856	\$ 5,856

(1) Investments in available-for-sale securities within these categories, with an amortized cost of \$124.6 million and an estimated fair value of \$121.0 million, have issuer call dates prior to May 2011.

On April 1, 2009, the Company adopted the provisions of FASB Staff Position (FSP) No. FAS 115-2 and FAS 124-2, *Recognition and Presentation of Other-than-Temporary Impairments* (FSP FAS 115-2), which amended the other-than-temporary impairment model for debt securities. The impairment model for equity securities was not affected. Under this FSP, an other-than-temporary impairment must be recognized through earnings if an investor has the intent to sell the debt security or if it is more likely than not that the investor will be required to sell the debt security before recovery of its amortized cost basis. However, even if an investor does not expect to sell a debt security, it must evaluate expected cash flows to be received and determine if a credit loss has occurred. In the event of a credit loss, only the amount associated with the credit loss is recognized in operating results. The amount of loss relating to other factors is recorded in accumulated other comprehensive income. The FSP also requires additional disclosures regarding the calculation of credit losses and the factors considered in reaching a conclusion that an investment is not other-than-temporarily impaired. The adoption of the FSP did not have a material impact on the Company s financial position or results of operations.

The Company conducts periodic reviews to identify and evaluate each investment that has an unrealized loss in accordance with FSP FAS 115-1, *The Meaning of Other-than-Temporary Impairment and its Application to Certain Investments* (FSP FAS 115-1) and FSP FAS 115-2. An unrealized loss exists when the current fair value of an individual security is less than its amortized cost basis. Unrealized losses on available-for-sale securities that are

determined to be temporary, and not related to credit loss, are recorded, net of tax, in accumulated other comprehensive income.

For available-for-sale debt securities with unrealized losses, the Company performs an analysis to assess whether it intends to sell or whether it would more likely than not be required to sell the security before the expected recovery of the amortized cost basis. If the Company intends to sell a security, or may be required to do so, the security s decline in fair value is deemed to be other-than-temporary and the full amount of the unrealized loss is recorded within earnings as an impairment loss. Regardless of its intent to sell a security, the Company performs additional analyses on all securities with unrealized losses to evaluate losses associated with the creditworthiness of the security. Credit losses are identified when the Company does not expect to receive cash flows sufficient to recover the amortized cost basis of a security.

For equity securities, when assessing whether a decline in fair value below its cost basis is other-than-temporary, the Company considers the fair market value of the security, the duration of the security s decline and the financial condition of the issuer. The Company then considers its intent and ability to hold the equity security for a period of time sufficient to recover its carrying value. If the Company determines that it lacks the intent and ability to hold an equity security to its expected recovery, the security s decline in fair value is deemed to be other-than-temporary and is recorded within operating results as an impairment loss.

9

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

The Company s investments in corporate debt securities consist primarily of investment grade subordinated, medium term, callable step-up floating rate notes (FRN) issued by several large European and United States (U.S.) banks. At June 30, 2009, the FRN s had composite ratings by Moody s, Standard & Poor s (S&P) and Fitch of between AA and A-. During the three months ended June 30, 2009, the FRN s had minimal or no trades and as fair value could not be derived from quoted prices, the Company used a discounted cash flow model to determine the estimated fair value of the securities at June 30, 2009. The assumptions used in the discounted cash flow model include estimates for interest rates, expected holding periods and risk adjusted discount rates, which the Company believes to be the most critical assumptions utilized within the analysis. The valuation analysis considered, among other items, assumptions that market participants would use in their estimates of fair value, such as the creditworthiness and credit spreads of the issuer and when callability features may be exercised by the issuer. These securities were also compared, where possible, to securities with observable market data with similar characteristics to the securities held by the Company. The Company estimated the fair value of the FRN s to be \$49.2 million at June 30, 2009.

In making the determination that the decline in fair value of the FRN s was temporary, the Company considered various factors, including but not limited to: the length of time each security was in an unrealized loss position; the extent to which fair value was less than cost; the financial condition and near term prospects of the issuers; and the intent not to sell these securities and assessment that it is more likely than not that it would not be required to sell these securities before the recovery of their amortized cost basis. The estimated fair value of the FRN s could change significantly based on future financial market conditions. The FRN s held by the Company did not trade either because they were nearing their scheduled call dates or due to abnormally high credit spreads on the debt of the issuers. Similar securities the Company has held have been called at par by issuers prior to maturity. The Company will continue to monitor the securities and the financial markets and if there is continued deterioration, the fair value of these securities could decline further resulting in an other-than-temporary impairment charge.

The Company s two investments in auction rate securities consist of taxable student loan revenue bonds issued by the Colorado Student Obligation Bond Authority ( Colorado ), with a cost of \$5.0 million, and Brazos Higher Education Service Corporation ( Brazos ), with a cost of \$5.0 million, which service student loans under the Federal Family Education Loan Program ( FFELP ). The bonds are collateralized by student loans purchased by the authorities, which are guaranteed by state sponsored agencies and reinsured by the U.S. Department of Education. Liquidity for these securities is typically provided by an auction process that resets the applicable interest rate at pre-determined intervals. The Colorado and Brazos securities were rated Aaa and Baa3 by Moody s, respectively, at June 30, 2009. Due to repeated failed auctions since January 2008, the Company no longer considers these securities to be liquid and has classified them as long-term investments in the condensed consolidated balance sheets. The securities continue to pay interest during the periods in which the auctions have failed.

Since the security auctions have failed and fair value cannot be derived from quoted prices, the Company used a discounted cash flow model to determine the estimated fair value of the securities at June 30, 2009. The assumptions used in the discounted cash flow model include estimates for interest rates, timing of cash flows, expected holding periods and risk adjusted discount rates, which include provisions for default and liquidity risk, that the Company believes to be the most critical assumptions utilized within the analysis. The valuation analysis considers, among other items, assumptions that market participants would use in their estimates of fair value, such as the collateral underlying the security, the creditworthiness of the issuer and any associated guarantees, the timing of expected future cash flows, the timing of, and the likelihood that the security will have a successful auction or when callability features may be exercised by the issuer. These securities were also compared, where possible, to other observable market data with similar characteristics to the securities held by the Company. The Company estimated the fair value of the auction rate securities to be \$8.3 million at June 30, 2009.

In making the determination that the decline in fair value of the auction rate securities was temporary, the Company considered various factors, including, but not limited to: the length of time each security was in an unrealized loss position; the extent to which fair value was less than cost; financial condition and near term prospects of the issuers; and the intent not to sell these securities and assessment that it is more likely than not that it would not

be required to sell these securities before the recovery of their amortized cost basis. The estimated fair value of the auction rate securities could change significantly based on future financial market conditions. The Company will continue to monitor the securities and the financial markets and if there is continued deterioration, the fair value of these securities could decline further resulting in an other-than-temporary impairment charge.

10

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

At June 30, 2009, the Company s investments in asset backed debt securities consist of medium term floating rate notes (MTN) of Aleutian Investments, LLC (Aleutian) and Meridian Funding Company, LLC (Meridian), which are qualified special purpose entities (QSPE s) of Ambac Financial Group, Inc. (Ambac) and MBIA, Inc. (MBIA), respectively. Ambac and MBIA are guarantors of financial obligations and are referred to as monoline financial guarantee insurance companies. The QSPE s, which purchase pools of assets or securities and fund the purchase through the issuance of MTN s, have been established to provide a vehicle to access the capital markets for asset backed debt securities and corporate borrowers. The MTN s include sinking fund redemption features which match-fund the terms of redemptions to the maturity dates of the underlying pools of assets or securities in order to mitigate potential liquidity risk to the QSPE s. At June 30, 2009, \$4.0 million of the Company s initial \$9.9 million investment in MTN s had been redeemed through scheduled sinking fund redemptions at par value.

The liquidity and fair value of these securities has been negatively impacted by the uncertainty in the credit markets and the exposure of these securities to the financial condition of monoline financial guarantee insurance companies, including Ambac and MBIA. At June 30, 2009, Ambac had ratings of Ba3 and BBB by Moody s and S&P, respectively, and MBIA had ratings of B3 and BBB by Moody s and S&P, respectively. The ratings all attributed to Ambac s and MBIA s inability to maintain adequate capital levels. Because the MTN s are not actively trading in the credit markets and fair value cannot be derived from quoted prices, the Company used a discounted cash flow model to determine the estimated fair value of the securities at June 30, 2009. The Company s valuation analyses consider, among other items, assumptions that market participants would use in their estimates of fair value such as the collateral underlying the security, the creditworthiness of the issuer and the associated guarantees by Ambac and MBIA, the timing of expected future cash flows, including whether the callability features of these investments may be exercised by the issuer. These securities were also compared, where possible, to securities with observable market data with similar characteristics to the securities held by the Company. The Company believes there are several significant assumptions that are utilized in its valuation analyses, the most critical of which is the discount rate, which includes a provision for default and liquidity risk. The Company estimated the fair value of the asset backed securities to be \$5.2 million at June 30, 2009.

The Company may not be able to liquidate its investment in these securities before the scheduled redemptions or until trading in the securities resumes in the credit markets, which may not occur. At June 30, 2009, the Company determined that the securities had been temporarily impaired due to the length of time each security was in an unrealized loss position; the extent to which fair value was less than cost; the financial condition and near term prospects of the issuers; current redemptions made by the issuers; and the intent not to sell these securities and assessment that it is more likely than not that it would not be required to sell these securities before the recovery of their amortized cost basis.

The Company s strategic investments include common stock in companies with which it has or did have a collaborative agreement. For the three months ended June 30, 2009 and 2008, the Company recognized none and less than \$0.1 million, respectively, in charges for other-than-temporary losses on its strategic investments due to declines in the fair value of the common stock of certain companies which the Company did not believe would recover in the near term.

#### 5. FAIR VALUE MEASUREMENTS

On April 1, 2009, the Company adopted the provisions of FSP FAS 157-4, Determining Fair Value When the Volume and Level of Activity for the Asset or Liability Have Significantly Decreased and Identifying Transactions That Are Not Orderly , (FSP FAS 157-4). FSP FAS 157-4 provides additional guidelines for making fair value measurements more consistent with the principles presented in SFAS No. 157, Fair Value Measurements (SFAS No. 157) and provides authoritative guidance in determining whether a market is active or inactive and whether a transaction is distressed. This FSP is applicable to all assets and liabilities (i.e. financial and nonfinancial) and requires enhanced disclosures, including interim and annual disclosure of the input and valuation techniques (or changes in techniques) used to measure fair value and the defining of the major security types comprising debt and equity securities held based upon the nature and risk of the security. The adoption of this FSP did not impact the Company s

financial position or results of operations; however, adoption has enhanced disclosures for the Company s investments in marketable debt securities.

11

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

On April 1, 2009, the Company also adopted the provisions of FSP FAS 107-1 and Accounting Principles Board (APB) 28-1, *Interim Disclosures about Fair Value of Financial Instruments* (FSP FAS 107-1). FSP FAS 107-1 amended SFAS No. 107, *Disclosures about Fair Value of Financial Instruments* and APB Opinion No. 28, *Interim Financial Reporting*, which requires disclosures about the fair value of financial instruments in interim and annual financial statements. The adoption of this standard has resulted in the disclosure of the fair values attributable to the Company s debt instruments within its interim report. Since this FSP addresses disclosure requirements, the adoption of this FSP did not impact the Company s financial position or results of operations.

The following table presents information about the Company s assets that are measured at fair value on a recurring basis and indicates the fair value hierarchy of the valuation techniques the Company utilized to determine such fair value:

	June 30,			
			Level	
(In thousands)	2009	Level 1	2	Level 3
Cash equivalents	\$ 1,755	\$ 1,755	\$	\$
U.S. government and agency debt securities	243,540	243,540		
Corporate debt securities	71,732	16,275		55,457
Other debt securities	13,515			13,515
Strategic equity investments	876	876		
Total	\$ 331,418	\$ 262,446	\$	\$ 68,972
	March 31,		<b>Y</b> 1	
(In thousands)	2009	Level 1	Level 2	Level 3
(In thousands)	\$ 822			
Cash equivalents	·		\$	\$
U.S. government and agency debt securities	238,265	238,265		50.720
Corporate debt securities	59,730			59,730
Other debt securities	14,147			14,147
Strategic equity investments	791	791		
Total	\$ 313,755	\$ 239,878	\$	\$73,877

The following table illustrates the rollforward of the fair value of the Company s investments whose fair value is determined using Level 3 inputs:

	Fair
(In thousands)	Value
Balance, March 31, 2009	\$ 73,877
Total unrealized gains included in comprehensive loss	2,737
Sales and redemptions, at par value	(7,642)
Balance, June 30, 2009	\$ 68,972

The fair values of the Company s investments in its corporate debt securities and other debt securities, including auction rate securities and asset backed debt securities, are determined using certain inputs that are unobservable and

considered significant to the overall fair value measurement. During the three months ended June 30, 2009, the corporate debt securities and asset backed debt securities held by the Company had minimal or no trades and the security auctions for the Company s auction rate securities had failed. The Company is unable to derive a fair value for these investments using quoted market prices and used discounted cash flow models as described in Note 4, *Investments*.

The carrying amounts reflected in the condensed consolidated balance sheets for cash and cash equivalents, accounts receivable, other current assets, accounts payable and accrued expenses approximate fair value due to their short-term nature. The Company s 7% Notes had a carrying value of \$69.7 million and \$75.9 million and a fair value of \$66.3 million and \$74.7 million at June 30, 2009 and March 31, 2009, respectively. The estimated fair value of the 7% Notes was based on a discounted cash flow model.

12

## ALKERMES, INC. AND SUBSIDIARIES

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

Effective April 1, 2009, the Company adopted the provisions of SFAS No. 157 for its nonfinancial assets and liabilities that are subject to measurement at fair value on a non-recurring basis. The adoption of SFAS No. 157 for nonfinancial assets and liabilities that are measured at fair value on a non-recurring basis did not impact the Company s financial position or results of operations; however this standard may impact the Company in subsequent periods and require additional disclosures.

#### 6. INVENTORY

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

(In thousands)	June 30, 2009	March 31, 2009	
Raw materials	\$ 5,338	\$ 5,916	
Work in process	5,871	5,397	
Finished goods (1)	9,319	7,015	
Consigned-out inventory		1,969	
Inventory	\$ 20,528	\$ 20,297	

(1) At June 30, 2009 and March 31, 2009, the Company had \$0.9 million and none, respectively, of finished goods inventory located at its third-party warehouse and shipping service

provider.

#### 7. PROPERTY, PLANT AND EQUIPMENT

Property, plant and equipment consist of the following:

	June 30,	March 31,	
(In thousands)	2009		
Land	\$ 301	\$ 301	
Building and improvements	36,325	36,325	
Furniture, fixture and equipment	67,805	67,165	
Leasehold improvements	33,980	33,996	
Construction in progress	42,132	41,908	
Subtotal	180,543	179,695	
Less: accumulated depreciation	(83,023)	(73,234)	

Total property, plant and equipment, net

\$ 97,520

\$ 106,461

#### 8. ACCOUNTS PAYABLE AND ACCRUED EXPENSES

Accounts payable and accrued expenses consist of the following:

	<b>June 30,</b>	March 31, 2009	
(In thousands)	2009		
Accounts payable	\$ 6,010	\$ 8,046	
Accrued compensation	5,500	13,817	
Accrued interest	1,235	1,549	
Accured restructuring current	713	743	
Amounts due to Cephalon	527	1,169	
Accrued other	9,903	11,159	
Total accounts payable and accrued expenses	\$ 23,888	\$ 36,483	
13			

# ALKERMES, INC. AND SUBSIDIARIES NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued) 9. SHARE-BASED COMPENSATION

Share-based compensation expense consists of the following:

	Three Months Ended				
	June 30				
(In thousands)	2009	2008			
Cost of goods manufactured and sold	\$ 310	\$ 429			
Research and development	807	1,588			
Selling, general and administrative	2,113	2,478			
Total share-based compensation expense	\$ 3,230	\$ 4,495			

As of June 30, 2009 and March 31, 2009, \$0.5 million and \$0.4 million, respectively, of share-based compensation cost was capitalized and recorded as Inventory in the condensed consolidated balance sheets.

#### 10. RESTRUCTURING

In connection with the 2008 restructuring program, in which the Company and Eli Lilly and Company announced the decision to discontinue the AIR® Insulin development program (the 2008 Restructuring ), the Company recorded net restructuring charges of approximately \$6.9 million in the year ended March 31, 2008. During the three months ended June 30, 2009, the Company paid in cash and made restructuring charge adjustments that totaled \$0.1 million in facility closure costs. At June 30, 2009, the Company had paid in cash, written off, recovered and made restructuring charge adjustments that totaled approximately \$0.9 million in facility closure costs, \$2.9 million in employee separation costs and \$0.2 million in other contract termination costs in connection with the 2008 Restructuring. The \$4.0 million remaining in the restructuring accrual at June 30, 2009 is expected to be paid out through fiscal 2016 and relates primarily to future lease costs associated with an exited facility.

#### 11. 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. At June 30, 2009, the Company determined that it is more likely than not that the deferred tax assets may not be realized and a full valuation allowance continues to be recorded.

The Company recorded an income tax benefit of \$0.1 million for the three months ended June 30, 2009, which represents the amount the Company estimates it will benefit from the Housing and Economic Recovery Act of 2008. This legislation allows for certain taxpayers to forego bonus depreciation in lieu of a refundable cash credit based on certain qualified asset purchases. The income tax provision of \$1.0 million for the three months ended June 30, 2008 is related 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, 2008. The 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 and research and development credits.

#### 12. COMMITMENTS AND CONTINGENCIES

From time to time, the Company may be subject to 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.

In April 2009, the Company entered into a lease agreement in connection with the move of its corporate headquarters from Cambridge, Massachusetts to Waltham, Massachusetts, which is scheduled to occur in early calendar 2010. The initial lease term, which begins upon the Company s move into the new facility, is for 10 years with provisions for the Company to extend the lease term up to an additional 10 years. In June 2009, the Company executed an amendment to the lease agreement which increased the square footage leased by the Company by approximately 15%. Operating expenses and rent will commence for the additional space 9 months and 18 months,

respectively, after the Company moves into the facility, and the lease amendment has the same termination date as the original lease. The total rent expense related to the new headquarters will be approximately \$3.1 million annually during the initial lease term.

14

#### **Table of Contents**

# ALKERMES, INC. AND SUBSIDIARIES NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued) 13. SUBSEQUENT EVENTS

The Company has evaluated events occurring subsequent to June 30, 2009 through August 6, 2009, which is the date the Company s financial statements as of and for the three months ended June 30, 2009 were issued. The Company does not have any recognized or nonrecognized subsequent events to disclose.

15

#### 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 , our or the Company ) is a fully integrated biotechnology company committed to developing innovative medicines to improve patients lives. We developed, manufacture and commercialize VIVITROL ® for alcohol dependence and manufacture RISPERDAL ® CONSTA® for schizophrenia and bipolar disorder. Our robust 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. We have research facilities in Massachusetts and a commercial manufacturing facility in Ohio. We announced in April 2009 that we will move our corporate headquarters from Cambridge, Massachusetts, to Waltham, Massachusetts in early calendar 2010.

#### **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, product sales and royalty revenues, plans for clinical trials, regulatory approvals, manufacture and commercialization of products and product candidates, spending relating to research and development, manufacturing, and selling and marketing 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 growth of RISPERDAL CONSTA sales; the commercialization of VIVITROL in the United States (U.S.) by us and in Russia and the Commonwealth of Independent States (CIS) by Cilag GmbH International ( Cilag ), a subsidiary of Johnson & Johnson; recognition of milestone payments from Cilag related to the future sales of VIVITROL in Russia and the CIS; the successful continuation of development activities for our programs, including exenatide once weekly, a four-week formulation of RISPERDAL CONSTA, VIVITROL for opioid dependence, ALKS 27, ALKS 29, ALKS 33 and ALKS 36; the expectation and timeline for regulatory approval of the New Drug Application (NDA) submission for exenatide once weekly; and the successful manufacture of our products and product candidates, including RISPERDAL CONSTA, VIVITROL and polymer for exenatide once weekly, by us at a commercial scale, and the successful manufacture of exenatide once weekly by Amylin Pharmaceuticals, Inc. ( Amylin ); 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 from RISPERDAL CONSTA may not continue to grow, particularly because we rely on our partner, Janssen Pharmaceutica, Inc., a division of Ortho-McNeil-Janssen Pharmaceuticals, Inc., and Janssen Pharmaceutica International, a division of Cilag International (together Janssen ), to forecast and market this product; (ii) we may be unable to manufacture RISPERDAL CONSTA, VIVITROL and polymer for exenatide once weekly, in sufficient quantities and with sufficient yields to meet our partners requirements or to add additional production capacity for RISPERDAL CONSTA and VIVITROL, or unexpected events could interrupt manufacturing operations at our RISPERDAL CONSTA and VIVITROL manufacturing facility, which is the sole source of supply for these products; (iii) we may be unable to develop the commercial capabilities, and/or infrastructure, necessary to successfully commercialize VIVITROL; (iv) Cilag may be unable to receive approval for VIVITROL for the treatment of opioid dependence in Russia and for the treatment of alcohol and opioid dependence in the other countries in the CIS; (v) Cilag may be unable to successfully commercialize VIVITROL in Russia and the CIS; (vi) third party payors may not cover or reimburse us for purchases of our products; (vii) if approved, Eli Lilly and Company ( Lilly ) and Amylin may be unable to successfully commercialize exenatide once weekly; (viii) we may be unable to scale-up and manufacture our product candidates commercially or economically; (ix) we may not be able to source raw materials

for our production processes from third parties; (x) Amylin may not be able to successfully operate the manufacturing facility for exenatide once weekly and the U.S. Food and Drug Administration (FDA) may not find the product produced in the Amylin facility comparable to the product used in the pivotal clinical study which was manufactured in our facility; (xi) our product candidates, if approved for marketing, may not be launched successfully in one or all

16

#### **Table of Contents**

indications for which marketing is approved and, if launched, may not produce significant revenues; (xii) we rely on our partners to determine the regulatory and marketing strategies for RISPERDAL CONSTA, including the four-week formulation of RISPERDAL CONSTA currently in development, and our other partnered, non-proprietary programs; (xiii) RISPERDAL CONSTA, VIVITROL and our product candidates in commercial use may have unintended side effects, adverse reactions or incidents of misuse and the FDA or other health authorities could require post approval studies or require removal of our products from the market; (xiv) our collaborators could elect to terminate or delay programs at any time and disputes with collaborators or failure to negotiate acceptable new collaborative arrangements for our technologies could occur; (xv) clinical trials may take more time or consume more resources than initially envisioned; (xvi) results of earlier clinical trials may not necessarily be predictive of the safety and efficacy results in larger clinical trials; (xvii) 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; (xviii) after the completion of clinical trials for our product candidates, including exenatide once weekly, or after the submission for marketing approval of such product candidates, the FDA or other health authorities could refuse to accept such filings, could request additional preclinical or clinical studies be conducted or request a safety monitoring program, any of which could result in significant delays or the failure of such products to receive marketing approval; (xix) 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; (xx) technological change in the biotechnology or pharmaceutical industries could render our products and/or product candidates obsolete or non-competitive; (xxi) difficulties or set-backs in obtaining and enforcing our patents and difficulties with the patent rights of others could occur; (xxii) we may incur losses in the future; (xxiii) 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, which may be further impacted by current economic conditions and the lack of available credit sources; and (xxiv) we may not be able to liquidate or otherwise recoup our investments in corporate debt securities, asset backed debt securities and auction rate securities.

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

#### **Our Strategy**

We leverage our formulation expertise and drug development technologies to develop, both with partners and on our own, innovative and competitively advantaged drug products that can 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 apply our innovative formulation expertise and drug development capabilities to create our own new, proprietary pharmaceutical products. Each of these approaches is discussed in more detail in Products and Development Programs.

# **Products and Development Programs** *RISPERDAL CONSTA*

RISPERDAL CONSTA is a long-acting formulation of risperidone, a product of Janssen, and is the first long-acting, atypical antipsychotic approved by the FDA. The medication uses our proprietary Medisorb <sup>®</sup> technology to deliver and maintain therapeutic medication levels in the body through just one injection every two weeks. RISPERDAL CONSTA is marketed by Janssen and is exclusively manufactured by us. RISPERDAL CONSTA was first approved by regulatory authorities in the United Kingdom and Germany in August 2002 and by the FDA in October 2003. RISPERDAL CONSTA is approved for the treatment of schizophrenia in approximately 85 countries and marketed in approximately 60 countries, and Janssen continues to launch the product around the world. In the U.S., RISPERDAL CONSTA is also approved for the treatment of bipolar I disorder.

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

17

#### **Table of Contents**

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 in patients with schizophrenia. Bipolar disorder is a brain disorder that causes unusual shifts in a person s mood, energy and ability to function. It is often characterized by debilitating mood swings, from extreme highs (mania) to extreme lows (depression). Bipolar I disorder is characterized based on the occurrence of at least one manic episode, with or without the occurrence of a major depressive episode. Clinical data has shown that RISPERDAL CONSTA significantly delayed the time to relapse compared to placebo treatment in patients with bipolar disorder.

#### **VIVITROL**

We developed VIVITROL, an extended-release Medisorb formulation of naltrexone, which is the first and only once-monthly injectable medication for the treatment of alcohol dependence. 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. VIVITROL was approved by the FDA in April 2006 and was launched in June 2006. In August 2008, the Russian regulatory authorities approved VIVITROL for the treatment of alcohol dependence. Our collaborator, Cilag, launched VIVITROL in Russia in March 2009.

We are also developing VIVITROL for the treatment of opioid dependence, a serious and chronic brain disease characterized by compulsive, prolonged-self administration of opioid substances that are not used for a medical purpose. In June 2008, we initiated a randomized, multi-center registration study of VIVITROL in Russia for the treatment of opioid dependence. The study is designed to assess the efficacy and safety of VIVITROL in more than 250 opioid dependent patients. The clinical data from this study may form the basis of a Supplemental NDA (sNDA) to the FDA for VIVITROL for the treatment of opioid dependence. In April 2009, we completed enrollment for this registration study. We expect data from the study to be available in late calendar 2009.

In November 2008, we and Cephalon, Inc. (Cephalon) agreed to end the collaboration for the development, supply and commercialization of certain products, including VIVITROL in the U.S., effective December 1, 2008 (the

Termination Date ), and we assumed the risks and responsibilities for the marketing and sale of VIVITROL in the U.S. In order to facilitate the full transfer of all commercialization of VIVITROL to us, Cephalon, at our option and on our behalf, agreed to perform certain transition services through May 2009 at a full-time equivalent (FTE) rate agreed to by the parties.

#### Exenatide Once Weekly

We are collaborating with Amylin on the development of exenatide once weekly for the treatment of type 2 diabetes. Exenatide once weekly is an injectable formulation of Amylin's BYETTA® (exenatide). BYETTA is an injection administered twice daily. 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. BYETTA was approved by the FDA in April 2005 as adjunctive therapy to improve blood sugar control in patients with type 2 diabetes who have not achieved adequate control on metformin and/or a sulfonylurea, which are 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 thiazolidinediones, a class of diabetes medications. Amylin has an agreement with Lilly for the development and commercialization of exenatide, including exenatide once weekly. Exenatide once weekly is being developed with the goal of providing patients with an effective and more patient-friendly treatment option.

In May 2009, Amylin submitted an NDA to the FDA for the treatment of type 2 diabetes. The FDA accepted the submission in July 2009.

In July 2009, Amylin, Lilly and we announced positive results from DURATION-3, a study designed to compare exenatide once weekly to Lantus<sup>®</sup> (insulin glargine) in 467 patients with type 2 diabetes taking stable doses of metformin alone or in combination with a sulfonylurea. Patients randomized to exenatide once weekly experienced a statistically superior reduction in A1C, a measure of average blood sugar over three months, of 1.5 percentage points

#### **Table of Contents**

from baseline, compared to a reduction of 1.3 percentage points for Lantus after completing 26 weeks of treatment. At the end of the study, patients treated with exenatide once weekly achieved a mean A1C of 6.8 percent compared with a mean A1C of 7.0 percent in those treated with Lantus. Treatment with exenatide once weekly also produced a statistically significant difference in weight, with a mean weight loss of 5.8 pounds at 26 weeks, compared with a mean weight gain of 3.1 pounds for Lantus, a difference of 8.9 pounds between the treatments. In addition, although patients treated with exenatide once weekly experienced a greater reduction in blood glucose than those treated with Lantus, those patients also reported significantly fewer episodes of confirmed hypoglycemia. Additional studies designed to demonstrate the superiority of exenatide once weekly are ongoing.

#### ALKS 33

ALKS 33 is an oral opioid modulator for the potential treatment of addiction and other nervous system disorders. In May 2009, we announced the initiation of two new clinical trials of ALKS 33. Study ALK33-004 is a phase 1 clinical trial designed to examine the ability of ALKS 33 to block the effects of an opioid following a single oral dose of ALKS 33 in healthy, non-dependent, opioid-experienced subjects. Study ALK33-003 is a phase 1 clinical trial designed to evaluate the pharmacokinetics, safety and tolerability of multiple doses of ALKS 33 in healthy volunteers. We expect to report data from both ALK33-004 and ALK33-003 in the second half of calendar 2009.

#### ALKS 29

We are developing ALKS 29, an oral combination therapy for the treatment of alcohol dependence. ALKS 29 is a co-formulation of ALKS 33, a proprietary opioid modulator, and baclofen, an FDA-approved muscle relaxant and antispasmodic therapeutic. Research suggests that baclofen may attenuate the compulsive component of alcohol dependence. As a co-formulation of ALKS 33 and baclofen, ALKS 29 is designed to address both the compulsive and impulsive components of alcohol dependence.

#### ALKS 27

Using our AIR® pulmonary technology, we are developing an inhaled trospium product for the treatment of chronic obstructive pulmonary disease ( COPD ). COPD is a serious, chronic disease characterized by a gradual loss of lung function.

In August 2009, we announced positive data from a phase 2a study of ALKS 27. The double-blind, cross-over, placebo-controlled study was designed to assess the safety, tolerability, pharmacokinetics and efficacy of ALKS 27 in 24 patients with moderate to severe COPD. The study also explored a combination dose of ALKS 27 and formoterol fumarate, a long-acting beta agonist already approved for the treatment of COPD. In the study, ALKS 27 was generally well tolerated, had a rapid onset of action, and led to statistically significant improvements in lung function compared to placebo. The combination of ALKS 27 and formoterol fumarate showed an additive effect on lung function improvement. We will not pursue further development of ALKS 27 without a partner.

#### ALKS 36

We are developing ALKS 36, a co-formulation of an opioid analgesic and RDC-1036, a novel oral, peripherally-acting opioid antagonist, for the treatment of pain. Research indicates that a high percentage of patients receiving opioids are likely to experience side effects affecting gastrointestinal motility. A pain medication that does not inhibit gastrointestinal motility could provide an advantage over current therapies. We expect to begin a phase 1 study of ALKS 36 in the second half of calendar 2009.

#### **Executive Summary**

Net loss for the three months ended June 30, 2009 was \$10.2 million, or \$0.11 per common share basic and diluted, as compared to net income of \$29.7 million, or \$0.31 per common share basic and diluted, for the three months ended June 30, 2008.

Net loss for the three months ended June 30, 2009 includes \$8.2 million in charges associated with our planned relocation from Cambridge to Waltham, Massachusetts.

19

Also, during the three months ended June 30, 2009, we purchased an additional 309,504 shares of treasury stock for \$2.5 million under our publicly announced share repurchase program and made our first quarterly scheduled principal payment on our Non-Recourse RISPERDAL CONSTA Secured 7% notes (the 7% Notes ) of \$6.4 million.

#### **Results of Operations**

Manufacturing Revenues

					Cł	nange
	Three Months Ended June					
	30,				Favorable/	
(In millions)	2009		2008		(Unfavorable)	
Manufacturing revenues:						
RISPERDAL CONSTA	\$	27.9	\$	36.0	\$	(8.1)
Polymer		0.9				0.9
VIVITROL				2.6		(2.6)
Manufacturing revenues	\$	28.8	\$	38.6	\$	(9.8)

The decrease in RISPERDAL CONSTA manufacturing revenues for the three months ended June 30, 2009, as compared to the three months ended June 30, 2008, was primarily due to a 13% decrease in the number of units shipped to Janssen and a 5% decrease in the net unit sales price, due primarily to the strengthening of the U.S. dollar in relation to the foreign currencies in which the product was sold. Although Janssen s unit sales of RISPERDAL CONSTA to the market increased by 14% during the period, Janssen had a sufficient supply of product to meet the increased demand. The number of RISPERDAL CONSTA units shipped for sale in foreign countries comprised 77% and 81% of the total units shipped during the three months ended June 30, 2009 and 2008, respectively. See Part I, Item 3. Quantitative and Qualitative Disclosures about Market Risk for information on foreign currency exchange rate risk related to RISPERDAL CONSTA revenues.

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. Revenues include a quarterly adjustment from Janssen's estimated unit net sales price to Janssen's actual unit net sales price for product shipped. In the three months ended June 30, 2009 and 2008, 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 in the fiscal year ending March 31, 2010 and beyond.

We record manufacturing revenues under our arrangement with Amylin for polymer sales at an agreed upon price when product is shipped to them. The polymer is used in the formulation of exenatide once weekly. We did not ship any polymer to Amylin during the three months ended June 30, 2008.

We expect that VIVITROL manufacturing revenues in fiscal 2010 and beyond will consist of product shipments to Cilag for resale in Russia. We record manufacturing revenues under our arrangement with Cilag at an agreed upon price when product is shipped to them. We did not ship any VIVITROL to Cilag during the three months ended June 30, 2009. VIVITROL manufacturing revenues for the three months ended June 30, 2008 consisted primarily of \$2.6 million of product shipments to Cephalon. Prior to the termination of the VIVITROL collaboration with Cephalon, we billed Cephalon at cost for finished commercial product shipped to them.

#### Royalty Revenues

					Ch	ange	
	Three Months Ended June						
	30,			Favorable/			
(In millions)	2	2009		2008		(Unfavorable)	
Royalty revenues	\$	8.7	\$	8.6	\$	0.1	

Substantially all of our royalty revenues for the three months ended June 30, 2009 and 2008 were related to sales of RISPERDAL CONSTA. 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. RISPERDAL CONSTA royalty revenues for the three months ended June 30, 2009 and 2008 were based on RISPERDAL CONSTA

20

sales of \$347.8 million and \$343.1 million, respectively.

### Product Sales, net

Upon termination of the VIVITROL collaboration with Cephalon, we assumed the risks and responsibilities for the marketing and sale of VIVITROL in the U.S., effective on the Termination Date. The following table presents the adjustments deducted from VIVITROL product sales, gross to arrive at VIVITROL product sales, net during the three months ended June 30, 2009:

Three Months Ended June

	Three Wohths Ended Julie					
	•	30,				
		% of				
(In millions)	2009	Sales				
Product sales, gross	\$ 5.4	100.0%				
Adjustments to product sales, gross:						
Free product coupons	(0.3)	(5.6)%				
Product returns (1)	(0.2)	(3.7)%				
Medicaid rebates	(0.2)	(3.7)%				
Prompt-pay discounts	(0.1)	(1.9)%				
Other	(0.4)	(7.4)%				
Total adjustments	(1.2)	(22.3)%				
Product sales, net	\$ 4.2	77.7%				

(1) Following the introduction of a return policy for VIVITROL, our estimate for product returns reflects the deferral of the recognition of revenue on shipments of VIVITROL to our customers until the product has left the distribution channel as we do not yet have the history to reasonably estimate returns related to these shipments. We estimate the product

shipments out of the distribution channel through data provided by external sources, including information on inventory levels provided by our customers as well as prescription information.

Net sales of VIVITROL by Cephalon during the three months ended June 30, 2008 were \$4.1 million.

# Research and Development Revenue Under Collaborative Arrangements

					C	hange	
	Three Months Ended June 30,				Favorable/		
(In millions)	illions) 2009		2008		(Unfavorable)		
Research and development programs:							
Four-week RISPERDAL CONSTA	\$	1.1	\$	0.9	\$	0.2	
Exenatide once weekly		0.3		4.9		(4.6)	
AIR Insulin				25.5		(25.5)	
Other		0.1		0.2		(0.1)	
Research and development revenue under collaborative							
arrangements	\$	1.5	\$	31.5	\$	(30.0)	

In January 2009, we announced that our collaborative partner, Johnson & Johnson Pharmaceutical Research and Development, L.L.C. ( J&JPRD ), initiated a phase 1, single-dose, open-label study of a four-week formulation of RISPERDAL CONSTA for the treatment of schizophrenia. RISPERDAL CONSTA is currently marketed as a two-week formulation. The decrease in the revenues earned under the exenatide once weekly development program in the three months ended June 30, 2009, as compared to the three months ended June 30, 2008, was due to reduced activity as the program neared the submission of the NDA to the FDA, which occurred in May 2009. The decrease in revenue from the AIR Insulin program in the three months ended June 30, 2009, as compared to the three months ended June 30, 2008, was due to the one-time \$25.5 million we recognized upon the termination of the AIR Insulin development program with Lilly in June 2008.

21

#### Net Collaborative Profit

					Cł	nange	
	Thr	ee Month	s Ended	June			
		3	0,		Favorable/		
(In millions)	2009		2008		(Unfavorable)		
Net collabortive profit:							
Milestone revenue license	\$		\$	1.3	\$	(1.3)	
Net payments from Cephalon				0.1		(0.1)	
VIVITROL losses funded by Cephalon, post termination		4.3				4.3	
Net collaborative profit	\$	4.3	\$	1.4	\$	2.9	

Net collaborative profit for the quarter ended June 30, 2009 consisted of revenue earned as a result of the \$11.0 million payment we received from Cephalon to fund their share of estimated VIVITROL losses during the one-year period following the Termination Date. We recorded the \$11.0 million as deferred revenue and are recognizing it as revenue through the application of a proportional performance model based on VIVITROL losses. We do not expect to recognize any further net collaborative profit after the \$11.0 million payment has been fully recognized as revenue, which we expect to occur in the three months ended September 30, 2009. Revenue during the three months ended June 30, 2008 consisted of milestone revenue from the license provided to Cephalon to commercialize VIVITROL, which we recognized on a straight-line basis over a 10 year amortization schedule, and net payments we received from Cephalon under the product loss sharing terms of the collaborative arrangement. *Cost of Goods Manufactured and Sold* 

	Th	ree Month	s Ended	l Tune	Ch	nange	
	Three Months Ended June 30,					Favorable/	
(In millions)	2009		2008		(Unfavorable)		
Cost of goods manufactured and sold:							
RISPERDAL CONSTA	\$	9.7	\$	10.8	\$	1.1	
VIVITROL		2.0		3.5		1.5	
Polymer		1.0				(1.0)	
Cost of goods manufactured and sold	\$	12.7	\$	14.3	\$	1.6	

The decrease in cost of goods manufactured for RISPERDAL CONSTA in the three months ended June 30, 2009, as compared to the three months ended June 30, 2008, was due to a 13% decrease in the number of units of RISPERDAL CONSTA shipped to Janssen, partially offset by a 3% increase in the unit cost of RISPERDAL CONSTA. The decrease in cost of goods manufactured and sold for VIVITROL in the three months ended June 30, 2009, as compared to the three months ended June 30, 2008, was due to a decrease in the unit cost of VIVITROL and a decrease in the number of units shipped. During the three months ended June 30, 2008, we did not make any shipments of polymer to Amylin.

# Research and Development Expense

		Change				
	Th	Three Months Ended June				
	30,				Favo	orable/
(In millions)	2	2009	2008		(Unfa	vorable)
Research and development	\$	25.6	\$	22.3	\$	(3.3)

The increase in research and development ( R&D ) expenses in the three months ended June 30, 2009, as compared to the three months ended June 30, 2008, was primarily due to costs we incurred as a result of the decision to move our corporate headquarters from Cambridge to Waltham, Massachusetts. We anticipate that the move will be completed in early calendar year 2010 and expect that the relocation will result in annual savings in fiscal year 2011 and beyond of approximately \$8.0 million. As a result of the planned move, we incurred approximately \$8.0 million of expense in the three months ended June 30, 2009 due to the acceleration of depreciation on laboratory related leasehold improvements located at our current headquarters that will have no benefit or use to us once we exit the Cambridge facility, and the write-down of laboratory equipment that is no longer in use and will be disposed of. Partially offsetting the increase in R&D expense was a decrease in costs related to the development of production lines for the manufacture of RISPERDAL CONSTA and polymer for exenatide once weekly, which were substantially completed

22

during fiscal year 2009.

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 negotiated FTE or hourly rate. This rate has been established by us based on our annual budget of employee compensation, employee benefits and the billable non-project-specific costs mentioned above and is generally increased annually based on increases in the consumer price index. Each collaborative partner is billed using a negotiated FTE or hourly rate for the hours worked by our employees on a particular project, plus direct external 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 Expense

					Cł	nange
	Three					
		30,			Fav	orable/
(In millions)	2009		2008		(Unfavorable	
Selling, general and administrative	\$ 1	19.3	\$	11.9	\$	(7.4)

The increase in selling, general and administrative costs for the three months ended June 30, 2009, as compared to the three months ended June 30, 2008, was primarily due to increased sales and marketing costs as we became responsible for commercialization of VIVITROL in the U.S. beginning December 1, 2008.

### Other Expense, Net

					Ch	nange
	Thr	ee Month		June	_	orable/
(In millions)		30,				
	20	009	2	800	(Unfa	vorable)
Interest income	\$	1.6	\$	3.6	\$	(2.0)
Interest expense		(1.7)		(4.2)		2.5
Other expense, net		(0.1)		(0.2)		0.1
Total other expense, net	\$	(0.2)	\$	(0.8)	\$	0.6

The decrease in interest income for the three months ended June 30, 2009, as compared to the three months ended June 30, 2008, was due to a lower average balance of cash and investments as well as lower interest rates earned as we continue to invest proceeds from maturing securities in lower yielding, shorter term U.S. government and agency investments. The decrease in interest expense for the three months ended June 30, 2009, as compared to the three months ended June 30, 2008, was the result of our repurchase of an aggregate total of \$93.0 million principal amount, or approximately 55%, of our 7% Notes, in five separately negotiated transactions during the year ended March 31, 2009. We also made our first scheduled principal payment on our 7% Notes in April 2009, which reduced interest expense in the three months ended June 30, 2009.

### **Provision for Income Taxes**

			Change	
	Three Months	Three Months Ended June		
	30	,	Favorable/	
(In millions)	2009	2008	(Unfavorable)	

(Benefit) provision for income taxes

\$ (0.1)

\$ 1.0

\$

1.1

The income tax benefit of \$0.1 million for the three months ended June 30, 2009 represents the amount we expect to benefit from the Housing and Economic Recovery Act of 2008. This legislation allows for certain taxpayers to forego bonus depreciation in lieu of a refundable cash credit based on certain qualified asset purchases. The income tax provision of \$1.0 million for the three months ended June 30, 2008 is related 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, 2008. The AMT liability is available as a credit against future tax obligations upon the full utilization or expiration of our net operating loss carryforward.

23

#### **Liquidity and Capital Resources**

We have funded our operations primarily with funds generated by our business operations and 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 as we expand the development of our proprietary product candidates, including costs related to preclinical studies and clinical trials. Our costs, including research and development costs for our product candidates, manufacturing, and sales, marketing and promotional expenses for any current or future products marketed by us or our collaborators, if any, may exceed revenues in the future, which may result in losses from operations. In addition, we have an ongoing share repurchase plan and have repurchased our outstanding debt and may continue to do either or both in the future. We believe that our current cash and cash equivalents and short and long-term investments, combined with anticipated interest income and anticipated revenues will generate sufficient cash flows to meet our anticipated liquidity and capital requirements for the foreseeable future.

Our financial condition is summarized as follows:

(In millions)	ıne 30, 2009	rch 31, 2009
Cash and cash equivalents	\$ 44.9	\$ 86.9
Investments short-term Investments long-term	272.2 63.3	236.8 80.8
Total cash, cash equivalents and investments	\$ 380.4	\$ 404.5
Working capital	\$ 318.7	\$ 307.1
Outstanding borrowings current and long-term	\$ 69.7	\$ 75.9

### Cash and Cash Equivalents

Our cash flows for the three months ended June 30, 2009 and 2008 were as follows:

	Three Months Ended June 30,						
(In millions)		2008					
Cash and cash equivalents, beginning of period	\$	86.9	\$	101.2			
Cash (used in) provided by operating activities		(15.6)		31.7			
Cash used in investing activities		(18.0)		(2.9)			
Cash used in financing activities		(8.4)		(23.6)			
Cash and cash equivalents, end of period	\$	44.9	\$	106.4			

### **Operating Activities**

The change in cash used in operating activities in the three months ended June 30, 2009, as compared to the cash provided by operating activities in the three months ended June 30, 2008, is primarily due to the \$40.0 million we received from Lilly related to the termination of the AIR Insulin development program in the three months ended June 30, 2008.

### **Investing Activities**

The increase in cash used in investing activities during the three months ended June 30, 2009, as compared to the three months ended June 30, 2008, was primarily due to an increase in the net purchases of investments and a decrease in cash provided from sales of property, plant and equipment.

# Financing Activities

The decrease in cash used in financing activities during the three months ended June 30, 2009, as compared to the three months ended June 30, 2008, was primarily due to the fact that we did not make any purchases of our 7% Notes during the three months ended June 30, 2009, and we purchased less common stock for treasury, partially offset by the

24

#### **Table of Contents**

first scheduled principal payment for the 7% Notes, which we made in April 2009.

#### Investments

We invest our cash reserves in bank deposits, certificates of deposit, commercial paper, corporate notes, U.S. and foreign government instruments and other interest bearing marketable debt instruments in accordance with our investment policy. We mitigate credit risk in our cash reserves by maintaining a well diversified portfolio that limits the amount of investment exposure as to institution, maturity and investment type. However, the value of these securities may be adversely affected by the instability of the global financial markets which could, in turn, adversely impact our financial position and our overall liquidity.

As noted in Note 4, *Investments* and Note 5, *Fair Value Measurements*, in the Notes to Condensed Consolidated Financial Statements, 21% of our investments are valued using unobservable, or Level 3, inputs to determine fair value. These investments are valued using discounted cash flow models, which use several inputs to determine fair value, including estimates for interest rates, the timing of cash flows, expected holding periods and risk adjusted discount rates, which include provisions for default and liquidity risk. We validate the fair values, when possible, by comparing the fair values to other observable market data with similar characteristics to the securities held by us. While we believe the valuation methodologies are appropriate, the use of valuation methodologies is highly judgmental and changes in methodologies can have a material impact on the values of these assets, our financial position and overall liquidity.

# **Borrowings**

At June 30, 2009, our borrowings consisted of \$70.6 million principal amount of the 7% Notes, which have a carrying value of \$69.7 million. We made our first scheduled quarterly principal payment on the 7% Notes on April 1, 2009, and the 7% Notes are scheduled to be paid in full on January 1, 2012.

### **Contractual Obligations**

In April 2009, we entered into a lease agreement in connection with the move of our corporate headquarters from Cambridge, Massachusetts to Waltham, Massachusetts, which is scheduled to occur in early calendar 2010. The initial lease term, which begins upon our move into the new facility, is for 10 years with provisions for us to extend the lease term up to an additional 10 years. In June 2009, we executed an amendment to the lease agreement which increased the square footage leased by us by approximately 15%. Operating expenses and rent will commence for the additional space 9 months and 18 months, respectively, after we move into the facility, and the lease amendment has the same termination date as the original lease. The total rent expense related to the new headquarters will be approximately \$3.1 million annually during the initial lease term. There are no other material changes to the contractual cash obligations as disclosed in our Annual Report on Form 10-K for the year ended March 31, 2009.

### **Off-Balance Sheet Arrangements**

At June 30, 2009, we were not a party to any off-balance sheet arrangements that have, or are reasonably likely to have, a current or future effect on our financial condition, changes in financial condition, revenue or expenses, results of operations, liquidity, capital expenditures or capital resources.

### **Critical Accounting Estimates**

The discussion and analysis of our financial condition and results of operations is based on our financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States of America (GAAP). The preparation of these financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results may differ from these estimates under different assumptions or conditions. Refer to Part II, Item 7 of our Annual Report on Form 10-K for the year ended March 31, 2009 in the Critical Accounting Estimates section for a discussion of our critical accounting estimates.

On April 1, 2009, we adopted the provisions of FASB Staff Position (FSP) No. FAS 115-2 and FAS 124-2, *Recognition and Presentation of Other-than-Temporary Impairments* (FSP FAS 115-2), which amended the other-than-temporary impairment model for debt securities. In connection with the adoption of this standard, our process for reviewing debt securities with unrealized losses for possible impairment was enhanced to include a

#### **Table of Contents**

determination as to if we have the intent to sell a debt security or if it is more likely than not that we would be required to sell the security before recovery of its amortized cost basis. The adoption of the FSP did not have a material impact on our financial position or results of operations.

# **New Accounting Standards**

Refer to *New Accounting Pronouncements* included in Note 1, *Summary of Significant Accounting Policies* in the Notes to Condensed Consolidated Financial Statements for a discussion of new accounting standards.

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

Our market risks, and the ways we manage them, are summarized in Part II, Item 7A, Quantitative and Qualitative Disclosures About Market Risk of our Annual Report on Form 10-K for the year ended March 31, 2009. In response to the instability in the global financial markets, we have regularly reviewed our marketable securities holdings and shifted our investment holdings to those deemed to have reduced risk. Apart from such adjustments to our investment portfolio, there have been no material changes in the first three months of fiscal year 2010 to our market risks and we do not anticipate any near-term changes in the nature of our market risk exposures or in our management s objectives and strategies with respect to managing such exposures.

We are exposed to foreign currency exchange risk related to manufacturing and royalty revenues we receive on RISPERDAL CONSTA as summarized in Part II, Item 7A, Quantitative and Qualitative Disclosures About Market Risk of our Annual Report on Form 10-K for the year ended March 31, 2009. There has been no material change in our assessment of our sensitivity to foreign currency exchange rate risk during the first three months of fiscal year 2010.

#### **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) at June 30, 2009. Based upon that evaluation, our principal executive officer and principal financial officer concluded that, at June 30, 2009, 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 Securities and Exchange Commission s (SEC) 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.

26

#### PART II. OTHER INFORMATION

# Item 1. Legal Proceedings

From time to time, we may be subject to legal proceedings and claims in the ordinary course of business. We are not aware of any such proceedings or claims that we believe will have, individually or in the aggregate, a material adverse effect on our business, results of operations and financial condition.

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

A summary of our stock repurchase activity for the three months ended June 30, 2009 is as follows:

				Total Number of Shares	Val	pproximate Dollar lue of Shares that
	Total Number		erage Price	Purchased as	]	May Yet be Purchased Under the
	of Shares Purchased		Paid per	Part of a Publicly Announced		Program
Period	(a)	$\mathbf{S}$	hare	Program (a)	(i	in millions)
April 1 through April 30		\$			\$	103.7
May 1 through May 31		\$			\$	103.7
June 1 through June 30	309,504	\$	8.12	309,504	\$	101.1
Total	309,504	\$	8.12	309,504		

(a) On November 21, 2007, we publicly announced that our board of directors authorized a program to repurchase up to \$175.0 million of our common stock to be repurchased at the discretion of management from time to time in the open market or through privately negotiated transactions. On June 16, 2008,

we publicly announced that our board of directors authorized the expansion of this repurchase program by an additional \$40.0 million, bringing the total authorization under this program to \$215.0 million. The repurchase program has no set expiration date and may be suspended or discontinued at any time. At June 30, 2009, we have purchased a total of 8,847,442 shares under this program at a cost of \$113.9 million.

In addition to the stock repurchases above, during the three months ended June 30, 2009 we acquired, by means of net share settlements, 81,890 shares of Alkermes common stock at an average price of \$8.66 per share related to the vesting of employee stock awards to satisfy withholding tax obligations.

### Item 5. Other Information

The Company s policy governing transactions in its securities by its directors, officers and employees permits its officers, directors and employees to enter into trading plans in accordance with Rule 10b5-1 under the Exchange Act. During the quarter ended June 30, 2009, Mr. Richard F. Pops, a director of the Company, and Ms. Kathryn L. Biberstein, Mr. David A. Broecker, Mr. Elliot Ehrich, Mr. James M. Frates and Mr. Michael J. Landine, each an executive officer of the Company, entered into trading plans in accordance with Rule 10b5-1 and the Company s policy governing transactions in its securities by its directors, officers and employees. The Company undertakes no obligation to update or revise the information provided herein, including for revision or termination of an established trading plan.

27

#### Item 6. Exhibits

(a) List of Exhibits:

# **Exhibit**

### No.

- 10.1 Lease Agreement, dated as of April 22, 2009 between PDM Unit 850, LLC and Alkermes, Inc. (incorporated by reference to Exhibit 10.5 to the Registrant's Report on Form 10-K for the fiscal year ended March 31, 2009).
- First Amendment to Lease Agreement between Alkermes, Inc. and PDM Unit 850, LLC, dated as of June 18, 2009 (filed herewith).
- 10.3 Alkermes, Inc. 2008 Stock Option and Incentive Plan, Restricted Stock Unit Award Certificate (Time Vesting Only) (incorporated by reference to Exhibit 10.1 to the Registrant s Current Report on Form 8-K filed on May 22, 2009).
- Alkermes, Inc. 2008 Stock Option and Incentive Plan, Restricted Stock Unit Award Certificate (Performance Vesting Only) (incorporated by reference to Exhibit 10.2 to the Registrant s Current Report on Form 8-K filed on May 22, 2009).
- 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).

28

#### **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 6, 2009

29

### **EXHIBIT INDEX**

# **Exhibit** No 10.1 Lease Agreement, dated as of April 22, 2009 between PDM Unit 850, LLC and Alkermes, Inc. (incorporated by reference to Exhibit 10.5 to the Registrant's Report on Form 10-K for the fiscal year ended March 31, 2009). 10.2 First Amendment to Lease Agreement between Alkermes, Inc. and PDM Unit 850, LLC, dated as of June 18, 2009 (filed herewith). 10.3 Alkermes, Inc. 2008 Stock Option and Incentive Plan, Restricted Stock Unit Award Certificate (Time Vesting Only) (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed on May 22, 2009). 10.4 Alkermes, Inc. 2008 Stock Option and Incentive Plan, Restricted Stock Unit Award Certificate (Performance Vesting Only) (incorporated by reference to Exhibit 10.2 to the Registrant s Current Report on Form 8-K filed on May 22, 2009). 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).