

ALKERMES INC
Form 10-Q
November 05, 2009

Table of Contents

UNITED STATES SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549
Form 10-Q

(Mark One)

☒ **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the quarterly period ended September 30, 2009

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

For the transition period from to

Commission file number 1-14131
ALKERMES, INC.

(Exact name of registrant as specified in its charter)

PENNSYLVANIA
*(State or other jurisdiction of
incorporation or organization)*

23-2472830
*(I.R.S. Employer
Identification No.)*

88 Sidney Street, Cambridge, MA 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 ☒ No ☐

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 ☐ No ☐

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

Large accelerated filer ☒	Accelerated filer ☐	Non-accelerated filer ☐	Smaller reporting company ☐
(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 ☐ No ☒

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

Class	As of November 2, 2009
Common Stock, \$.01 par value	94,382,663
Non-Voting Common Stock, \$.01 par value	382,632

**ALKERMES, INC. AND SUBSIDIARIES
INDEX**

	Page No.
<u>PART I FINANCIAL INFORMATION</u>	
<u>Item 1. Condensed Consolidated Financial Statements:</u>	3
<u>Condensed Consolidated Balance Sheets September 30, 2009 and March 31, 2009</u>	3
<u>Condensed Consolidated Statements of Operations For the Three and Six Months Ended September 30, 2009 and 2008</u>	4
<u>Condensed Consolidated Statements of Cash Flows For the Six Months Ended September 30, 2009 and 2008</u>	5
<u>Notes to Condensed Consolidated Financial Statements</u>	6
<u>Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	17
<u>Item 3. Quantitative and Qualitative Disclosures about Market Risk</u>	28
<u>Item 4. Controls and Procedures</u>	28
<u>PART II OTHER INFORMATION</u>	
<u>Item 1. Legal Proceedings</u>	30
<u>Item 2. Unregistered Sales of Equity Securities and Use of Proceeds</u>	30
<u>Item 6. Exhibits</u>	30
<u>Signatures</u>	31
<u>Exhibit Index</u>	32
<u>EX-31.1 Section 302 Certification of CEO</u>	
<u>EX-31.2 Section 302 Certification of CFO</u>	
<u>EX-32.1 Section 906 Certification of CEO & CFO</u>	

Table of Contents**PART I. FINANCIAL INFORMATION****Item 1. Condensed Consolidated Financial Statements:**

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

	September 30, 2009	March 31, 2009
	(In thousands, except share and per share amounts)	
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	\$ 52,992	\$ 86,893
Investments short-term	242,098	236,768
Receivables	33,699	24,588
Inventory	18,524	20,297
Prepaid expenses and other current assets	7,856	7,500
Total current assets	355,169	376,046
PROPERTY, PLANT AND EQUIPMENT, NET	94,467	106,461
INVESTMENTS LONG-TERM	74,435	80,821
OTHER ASSETS	3,206	3,158
TOTAL ASSETS	\$ 527,277	\$ 566,486
LIABILITIES AND SHAREHOLDERS EQUITY		
CURRENT LIABILITIES:		
Accounts payable and accrued expenses	\$ 28,272	\$ 36,483
Deferred revenue current	1,880	6,840
Non-recourse RISPERDAL® CONSTA® secured 7% Notes current	25,667	25,667
Total current liabilities	55,819	68,990
NON-RECOURSE RISPERDAL CONSTA SECURED 7% NOTES LONG-TERM	37,862	50,221
DEFERRED REVENUE LONG-TERM	5,115	5,238
OTHER LONG-TERM LIABILITIES	6,450	7,149
Total liabilities	105,246	131,598
COMMITMENTS AND CONTINGENCIES (Note 12)		
SHAREHOLDERS EQUITY:		

Edgar Filing: ALKERMES INC - Form 10-Q

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; 104,304,607 and 104,044,663 shares issued; 94,384,663 and 94,536,212 shares outstanding at September 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 September 30, 2009 and March 31, 2009	4	4
Treasury stock, at cost (9,919,944 and 9,508,451 shares at September 30, 2009 and March 31, 2009, respectively)	(129,431)	(126,025)
Additional paid-in capital	900,076	892,415
Accumulated other comprehensive loss	(4,724)	(6,484)
Accumulated deficit	(344,936)	(326,062)
Total shareholders' equity	422,031	434,888
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	\$ 527,277	\$ 566,486

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

Table of Contents

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

	Three Months Ended September 30,		Six Months Ended September 30,	
	2009	2008	2009	2008
	(In thousands, except per share amounts)			
REVENUES:				
Manufacturing revenues	\$ 32,835	\$ 33,039	\$ 61,639	\$ 71,649
Royalty revenues	8,818	8,439	17,519	17,020
Product sales, net	4,643		8,869	
Research and development revenue under collaborative arrangements	1,174	5,252	2,624	36,702
Net collaborative profit	687	581	5,002	1,932
 Total revenues	 48,157	 47,311	 95,653	 127,303
EXPENSES:				
Cost of goods manufactured and sold	15,092	12,071	27,758	26,385
Research and development	20,664	19,710	46,250	41,971
Selling, general and administrative	20,625	11,679	39,893	23,605
 Total expenses	 56,381	 43,460	 113,901	 91,961
 OPERATING (LOSS) INCOME	 (8,224)	 3,851	 (18,248)	 35,342
 OTHER EXPENSE, NET:				
Interest income	1,088	2,693	2,649	6,309
Interest expense	(1,566)	(4,243)	(3,275)	(8,469)
Other expense, net	(67)	(666)	(130)	(830)
 Total other expense, net	 (545)	 (2,216)	 (756)	 (2,990)
 (LOSS) INCOME BEFORE INCOME TAXES	 (8,769)	 1,635	 (19,004)	 32,352
(BENEFIT) PROVISION FOR INCOME TAXES	(60)	(63)	(130)	967
 NET (LOSS) INCOME	 \$ (8,709)	 \$ 1,698	 \$ (18,874)	 \$ 31,385
 (LOSS) EARNINGS PER COMMON SHARE:				
Basic	\$ (0.09)	\$ 0.02	\$ (0.20)	\$ 0.33
 Diluted	 \$ (0.09)	 \$ 0.02	 \$ (0.20)	 \$ 0.32
 WEIGHTED AVERAGE NUMBER OF COMMON SHARES OUTSTANDING:				
Basic	94,886	95,637	94,830	95,211

Edgar Filing: ALKERMES INC - Form 10-Q

Diluted	94,886	97,356	94,830	96,729
---------	--------	--------	--------	--------

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

4

Table of Contents

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

	Six Months Ended September 30,	
	2009	2008
	(In thousands)	
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net (loss) income	\$ (18,874)	\$ 31,385
Adjustments to reconcile net (loss) income to cash flows from operating activities:		
Depreciation	15,482	4,901
Share-based compensation expense	7,438	8,309
Other non-cash charges	2,093	2,564
Loss on the purchase of non-recourse RISPERDAL CONSTA secured 7% notes		1,989
Changes in assets and liabilities:		
Receivables	(9,111)	2,251
Inventory, prepaid expenses and other assets	10	890
Accounts payable and accrued expenses	(8,702)	(10,785)
Unearned milestone revenue		(3,039)
Deferred revenue	(5,083)	2,092
Other long-term liabilities	(920)	(1,363)
Payment of non-recourse RISPERDAL CONSTA secured 7% notes principal attributable to original issue discount	(1,009)	(4,590)
Cash flows (used in) provided by operating activities	(18,676)	34,604
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchase of property, plant and equipment	(3,885)	(3,567)
Sales of property, plant and equipment	169	7,717
Purchases of investments	(295,318)	(462,412)
Sales and maturities of investments	298,134	463,959
Cash flows (used in) provided by investing activities	(900)	5,697
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from the issuance of common stock for share-based compensation arrangements	183	7,221
Excess tax benefit from share-based compensation		74
Payment of non-recourse RISPERDAL CONSTA secured 7% notes principal	(11,824)	
Purchase of non-recourse RISPERDAL CONSTA secured 7% notes		(67,185)
Payment of capital leases		(47)
Purchase of common stock for treasury	(2,684)	(13,080)
Cash flows used in financing activities	(14,325)	(73,017)
NET DECREASE IN CASH AND CASH EQUIVALENTS	(33,901)	(32,716)
CASH AND CASH EQUIVALENTS Beginning of period	86,893	101,241

Edgar Filing: ALKERMES INC - Form 10-Q

CASH AND CASH EQUIVALENTS	End of period	\$ 52,992	\$ 68,525
SUPPLEMENTAL CASH FLOW DISCLOSURE:			
Cash paid for interest		\$ 2,784	\$ 6,662
Cash paid for taxes		\$ 53	\$ 435
Non-cash investing and financing activities:			
Purchased capital expenditures included in accounts payable and accrued expenses		\$ 1,967	\$ 678
Receipt of Alkermes shares for the purchase of stock options or to satisfy minimum tax withholding obligations related to stock based awards		\$ 722	\$ 568

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

Table of Contents

ALKERMES, INC. AND SUBSIDIARIES

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED)

1. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Basis of Presentation

The accompanying condensed consolidated financial statements of Alkermes, Inc. (the Company or Alkermes) for the three and six months ended September 30, 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 non-recourse 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 \$4.6 million that was previously classified as Purchase of non-recourse RISPERDAL CONSTA 7% notes for the six months ended September 30, 2008, 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 new guidance issued by the Financial Accounting Standards Board (FASB) on the accounting for collaborative arrangements. The guidance defined collaborative arrangements and established reporting requirements for transactions between participants in a collaborative arrangement and between participants in the arrangement and third parties. The adoption of this standard did not have an impact on the Company's financial position or results of operations.

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

On April 1, 2009, the Company adopted new accounting guidance issued by the FASB on fair value measurements for its nonfinancial assets and liabilities that are subject to measurement at fair value on a non-recurring basis. The adoption of this standard 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. Also, effective April 1, 2009, the Company adopted new accounting guidance issued by the FASB on fair value measurements in determining whether a market is active or inactive and whether third-party transactions with similar assets and liabilities are distressed in determining the fair value of its assets and liabilities measured at fair value on a recurring basis. The adoption of this standard did not impact the Company's financial position or results of operations.

In June 2009, the FASB issued accounting guidance regarding the accounting for transfers of financial assets that will 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. The guidance 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 accounting guidance on business combinations and noncontrolling interests in consolidated financial statements. The new guidance revises the method of accounting for a number of aspects of business combinations and noncontrolling interests, including acquisition costs, contingencies (including contingent assets, contingent liabilities and contingent purchase price), the impacts of partial and step-acquisitions (including the valuation of net assets attributable to non-acquired minority interests) and post-acquisition exit activities of acquired businesses. The guidance 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 September 2009, the Emerging Issues Task Force (EITF) of the FASB issued accounting guidance related to revenue recognition that amends the previous guidance on arrangements with multiple deliverables. This guidance provides principles and application guidance on whether multiple deliverables exist, how the arrangements should be separated and how the consideration should be allocated. It also clarifies the method to allocate revenue in an arrangement using the estimated selling price. This guidance is effective for the Company's fiscal year beginning April 1, 2011, 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:

(In thousands)	Three Months Ended September 30		Six Months Ended September 30	
	2009	2008	2009	2008
Net (loss) income	\$ (8,709)	\$ 1,698	\$ (18,874)	\$ 31,385
Unrealized (losses) gains on available-for-sale securities:				
Holding (losses) gains (1)	(228)	(61)	1,760	(266)
Reclassification of unrealized losses to realized losses on available-for-sale securities		559		607
Unrealized (losses) gains on available-for-sale securities	(228)	498	1,760	341
Comprehensive (loss) income	\$ (8,937)	\$ 2,196	\$ (17,114)	\$ 31,726

(1)

During the three months ended September 30, 2009, the Company recorded an out of period adjustment of \$1.9 million for unrealized losses on available-for-sale securities. This adjustment had no impact on reported net loss.

Table of Contents**ALKERMES, INC. AND SUBSIDIARIES****NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)****3. EARNINGS PER SHARE**

Basic (loss) 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:

(In thousands)	Three Months Ended September 30		Six Months Ended September 30	
	2009	2008	2009	2008
Numerator:				
Net (loss) income	\$ (8,709)	\$ 1,698	\$ (18,874)	\$ 31,385
Denominator:				
Weighted average number of common shares outstanding	94,886	95,637	94,830	95,211
Effect of dilutive securities:				
Stock options		1,479		1,329
Restricted stock units		240		189
Dilutive common share equivalents		1,719		1,518
Shares used in calculating diluted (loss) earnings per share	94,886	97,356	94,830	96,729

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

(In thousands)	Three Months Ended September 30		Six Months Ended September 30	
	2009	2008	2009	2008
Stock options	17,821	13,384	17,920	13,858
Restricted stock units	407	67	308	
Total	18,228	13,451	18,228	13,858

Table of Contents**ALKERMES, INC. AND SUBSIDIARIES****NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)****4. INVESTMENTS**

Investments consist of the following:

	Amortized Cost	Gross Gains	Unrealized Losses	Estimated Fair Value
(In thousands)				
September 30, 2009				
Short-term investments:				
Available-for-sale securities:				
U.S. government and agency debt securities	\$ 209,896	\$ 389	\$	\$ 210,285
International government agency debt securities	28,692	148		28,840
Other debt securities	3,267		(294)	2,973
Total short-term investments	241,855	537	(294)	242,098
Long-term investments:				
Available-for-sale securities:				
U.S. government and agency debt securities	17,994		(17)	17,977
Corporate debt securities	43,162		(3,162)	40,000
Other debt securities	11,510		(1,788)	9,722
Strategic investments	738	142		880
	73,404	142	(4,967)	68,579
Held-to-maturity securities:				
U.S. government obligations	416			416
Certificates of deposit	5,440			5,440
Total long-term investments	79,260	142	(4,967)	74,435
Total investments	\$ 321,115	\$ 679	\$ (5,261)	\$ 316,533
March 31, 2009				
Short-term investments:				
Available-for-sale securities:				
U.S. government and agency debt securities	\$ 225,490	\$ 2,635	\$ (6)	\$ 228,119
Corporate debt securities	8,160	9		8,169
Other debt securities	500		(20)	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

Edgar Filing: ALKERMES INC - Form 10-Q

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
Total long-term investments	89,780	53	(9,012)	80,821
Total investments	\$ 323,930	\$ 2,697	\$ (9,038)	\$ 317,589

During the six months ended September 30, 2009, the Company had \$298.1 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.

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

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

	Available-for-Sale		Held-to-Maturity	
	Amortized	Estimated	Amortized	Estimated
(in thousands)	Cost	Fair Value	Cost	Fair Value
Within 1 year	\$ 124,069	\$ 124,061	\$ 416	\$ 416
After 1 year through 5 years (1)	131,784	131,700		
After 5 years through 10 years (1)	48,668	45,578		
After 10 years	10,000	8,458		
Total	\$ 314,521	\$ 309,797	\$ 416	\$ 416

(1) Investments in available-for-sale securities within these categories, with an amortized cost of \$151.4 million and an estimated fair value of \$148.2 million, have issuer call dates prior to May 2011.

The Company recognizes other-than-temporary impairments through a charge to earnings if it has the intent to sell the debt security or if it is more likely than not that it will be required to sell the debt security before recovery of its amortized cost basis. However, even if the Company 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. 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.

Certain of the Company's investments in corporate debt securities with a cost of \$14.0 million consist of investment grade subordinated, medium term, callable step-up floating rate notes (FRN) issued by the Royal Bank of Scotland Group (RBS) and UBS AG (UBS). At September 30, 2009, these FRN s had composite ratings by Moody's, Standard & Poor's (S&P) and Fitch of between A and BBB+. During the six months ended September 30, 2009, these FRN s had minimal or no trades and because a 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 September 30, 2009. The assumptions used in the discounted cash flow model included 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 these FRN s to be \$12.2 million at September 30, 2009.

In making the determination that the decline in fair value of these 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

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

issuers; and the intent not to sell these securities and assessment that it is more likely than not that the Company would not be required to sell these securities before the recovery of their amortized cost basis. The estimated fair value of these FRN s could change significantly based on future financial market conditions. These 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, or both. 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 September 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 September 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 \$8.5 million at September 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 the Company 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.

At September 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 September 30, 2009, \$5.1 million of the Company s initial \$9.9 million investment in MTN s had been redeemed through scheduled sinking fund redemptions at par value.

Edgar Filing: ALKERMES INC - Form 10-Q

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 September 30, 2009, Ambac had ratings of Caa2 and CC by Moody's

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

and S&P, respectively, and MBIA had ratings of Ba3 and BB+ by Moody's and S&P, respectively. 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 September 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 \$4.2 million at September 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 September 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 the Company 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 six months ended September 30, 2009 and 2008, the Company recognized none and \$0.6 million, respectively, in charges for other-than-temporary losses on its strategic investments due to declines in their fair value.

5. FAIR VALUE MEASUREMENTS

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:

(In thousands)	September 30, 2009	Level 1	Level 2	Level 3
Cash equivalents	\$ 187	\$ 187	\$	\$
U.S. government and agency debt securities	228,262	228,262		
International government agency debt securities	28,840	28,840		
Corporate debt securities	40,000		27,824	12,176
Other debt securities	12,695			12,695
Strategic equity investments	880	880		
Total	\$ 310,864	\$ 258,169	\$ 27,824	\$ 24,871

(In thousands)	March 31, 2009	Level 1	Level 2	Level 3
Cash equivalents	\$ 822	\$ 822	\$	\$
U.S. government and agency debt securities	238,265	238,265		
Corporate debt securities	59,730			59,730
Other debt securities	14,147			14,147
Strategic equity investments	791	791		

Edgar Filing: ALKERMES INC - Form 10-Q

Total	\$	313,755	\$ 239,878	\$	\$ 73,877
-------	----	---------	------------	----	-----------

12

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

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

(In thousands)	Fair Value
Balance, March 31, 2009	\$ 73,877
Total unrealized gains included in comprehensive loss	3,687
Sales and redemptions, at par value	(18,773)
Transfers out of Level 3	(33,920)
Balance, September 30, 2009	\$ 24,871

The fair values of the Company's investments in certain of 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 six months ended September 30, 2009, certain of 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.

During the three months ended September 30, 2009, trading resumed for certain of the Company's investments in corporate debt securities. At September 30, 2009, the Company derived a fair value for these investments using market observable inputs instead of through the use of a discounted cash flow model. Accordingly, the Company transferred these investments from a Level 3 classification to a Level 2 classification.

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 non-recourse 7% Notes had a carrying value of \$63.5 million and \$75.9 million and a fair value of \$60.4 million and \$74.7 million at September 30, 2009 and March 31, 2009, respectively. The estimated fair value of the non-recourse 7% Notes was based on a discounted cash flow model.

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)	September 30, 2009	March 31, 2009
Raw materials	\$ 5,174	\$ 5,916
Work in process	5,738	5,397
Finished goods (1)	7,430	7,015
Consigned-out inventory (2)	182	1,969
Inventory	\$ 18,524	\$ 20,297

(1) At
September 30,
2009 and
March 31, 2009,

the Company had \$1.5 million and none, respectively, of finished goods inventory located at its third-party warehouse and shipping service provider.

- (2) At September 30, 2009, consigned-out inventory relates to inventory in the distribution channel for which the Company has not recognized revenue. At March 31, 2009, consigned-out inventory consisted of \$1.8 million of consigned-out inventory and \$0.2 million of inventory in the distribution channel for which the Company has not recognized revenue.

Table of Contents**ALKERMES, INC. AND SUBSIDIARIES****NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)****7. PROPERTY, PLANT AND EQUIPMENT**

Property, plant and equipment consist of the following:

(In thousands)	September 30, 2009	March 31, 2009
Land	\$ 301	\$ 301
Building and improvements	36,325	36,325
Furniture, fixture and equipment	66,295	67,165
Leasehold improvements	33,980	33,996
Construction in progress	43,918	41,908
Subtotal	180,819	179,695
Less: accumulated depreciation	(86,352)	(73,234)
Total property, plant and equipment, net	\$ 94,467	\$ 106,461

As a result of the Company's planned relocation of its corporate headquarters from Cambridge, Massachusetts to Waltham, Massachusetts in early calendar year 2010, the Company recorded a charge of \$11.0 million to depreciation during the six months ended September 30, 2009. The depreciation charge relates to the acceleration of depreciation on laboratory related leasehold improvements located at the Company's current headquarters, which will have no benefit or use to the Company once the Company exits the Cambridge facility, and the write-down of laboratory equipment that is no longer in use and will be disposed of.

8. ACCOUNTS PAYABLE AND ACCRUED EXPENSES

Accounts payable and accrued expenses consist of the following:

(In thousands)	September 30, 2009	March 31, 2009
Accounts payable	\$ 5,457	\$ 8,046
Accrued compensation	10,072	13,817
Accrued interest	1,123	1,549
Amounts due to Cephalon		1,169
Accrued other	11,620	11,902
Total accounts payable and accrued expenses	\$ 28,272	\$ 36,483

9. SHARE-BASED COMPENSATION

Share-based compensation expense consists of the following:

(In thousands)	Three Months Ended September 30		Six Months Ended September 30	
	2009	2008	2009	2008
Cost of goods manufactured and sold	\$ 519	\$ 428	\$ 829	\$ 857
Research and development	919	1,282	1,726	2,870
Selling, general and administrative (1)	2,770	2,104	4,883	4,582

Total share-based compensation expense	\$ 4,208	\$ 3,814	\$ 7,438	\$ 8,309
--	----------	----------	----------	----------

(1) In September 2009, in connection with the resignation of its former President and Chief Executive Officer, the Company entered into a separation agreement that provided for, among other things: the acceleration of vesting of certain stock options and restricted stock awards that were scheduled to vest through June 30, 2010; and the period in which vested stock options are exercisable was extended until the earlier of June 30, 2011 or the stated expiration date of the stock options. As a result of these stock option and award modifications, the Company recorded an expense of \$0.9 million during the three months ended September 30, 2009.

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

Table of Contents**ALKERMES, INC. AND SUBSIDIARIES****NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)****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 charges of \$6.9 million during the year ended March 31, 2008. Activity related to the 2008 Restructuring was as follows:

	(in thousands)
Accrued restructuring, March 31, 2009	\$ 4,193
Payments for facility closure costs	(416)
Other adjustments	106
Accrued restructuring, September 30, 2009	\$ 3,883

At September 30, 2009 and March 31, 2009, the restructuring liability related to the 2008 Restructuring consists of \$0.7 million classified as current, respectively, and \$3.2 million and \$3.5 million classified as long-term, respectively, in the accompanying condensed consolidated balance sheets. As of September 30, 2009, the Company has paid in cash, written off, recovered and made restructuring charge adjustments that totaled approximately less than \$0.1 million in facility closure costs, \$2.9 million in employee separation costs and \$0.1 million in other contract termination costs in connection with the 2008 Restructuring. The \$3.9 million remaining in the restructuring accrual at September 30, 2009 is expected to be paid out through fiscal year 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 September 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 and six months ended September 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 benefit of \$0.1 million and provision of \$1.0 million for the three and six months ended September 30, 2008, respectively, 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 benefit and charge were recorded in the three and six months ended September 30, 2008, respectively. 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 year 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%. The total rent expense related to the new headquarters will be approximately \$3.1 million annually during the initial lease term.

In April 2009, the Company entered into an agreement to sublease a portion of its Cambridge, Massachusetts headquarters. Under the terms of the agreement, the Company exited and made available certain of its Cambridge, Massachusetts facility to the leasee on August 1, 2009 and recorded a charge of \$1.0 million, which equals the amount of rent expense in excess of estimated sublease income associated with the vacated space the Company expects to collect through the remainder of the lease term.

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 September 30, 2009 through November 5, 2009, which is the date the Company's financial statements as of and for the three and six months ended September 30, 2009 were issued. The Company does not have any recognized or nonrecognized subsequent events to disclose.

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

Alkermes, Inc. (as used in this section, together with our subsidiaries, us, we, 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 are relocating our corporate headquarters from Cambridge, Massachusetts, to Waltham, Massachusetts in early calendar year 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, VIVITROL for opioid dependence, ALKS 29, ALKS 33, ALKS 36 and ALKS 37; 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 or 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

Table of Contents

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 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 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; (xxiv) our methodology for determining the fair value of our investments may change; and (xxv) 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 and only long-acting, atypical antipsychotic approved by the FDA for both the treatment of both schizophrenia and bipolar I disorder. The medication uses our proprietary Medisorb® 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.

Table of Contents

Schizophrenia is a brain disorder characterized by disorganized thinking, delusions and hallucinations. Studies have demonstrated that as many as 75 percent of patients with schizophrenia have difficulty taking their oral medication on a regular basis, which can lead to worsening of symptoms. Clinical data has shown that treatment with RISPERDAL CONSTA may lead to improvements in symptoms, sustained remission and decreases in hospitalization 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.

In August 2009, we received notification from Johnson & Johnson Pharmaceutical Research and Development, L.L.C. (J&JPRD) that based on a portfolio review it has decided not to pursue further development of the four-week long-acting injectable formulation of risperidone.

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 for the Russian and CIS markets, 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 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 year 2009.

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 the DURATION-3 study designed to compare exenatide once weekly to LANTUS® (insulin glargine) in 467 patients with type 2 diabetes taking stable

Table of Contents

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 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 central nervous system disorders. In October 2009, we announced positive topline data from two clinical trials of ALKS 33. Data from the studies, ALK33-003 and ALK33-004, showed that ALKS 33 was generally well tolerated and successfully blocked the effects of an opioid with a duration of action that supports once daily dosing. ALK33-003 was a phase 1 randomized, double-blind, placebo-controlled, multi-dose study designed to assess the steady-state pharmacokinetics, safety and tolerability of ALKS 33 in 30 healthy subjects. ALK33-004 was a phase 1, randomized, single-blind, placebo-controlled, single-dose study designed to test the ability of ALKS 33 to block the subjective and objective effects of a potent opioid agonist, remifentanyl (a commercially available analgesic) in twenty-four healthy, non-dependent, opioid-experienced subjects. Based on these results, we expect to initiate a phase 2 study of ALKS 33 by the end of calendar year 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 tropism 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 a placebo. The combination of ALKS 27 and formoterol fumarate showed an additive effect on lung function improvement. We do not plan to pursue further development of ALKS 27 without a partner.

ALKS 37

We are developing ALKS 37, an investigational oral, peripherally-restricted opioid antagonist for the treatment of opioid-induced constipation. Research indicates that a high percentage of patients receiving opioids are likely to experience side effects affecting gastrointestinal motility. There are currently no available oral treatments for this condition, which has severe quality of life implications. In October 2009, we initiated a phase 1 study of ALKS 37 in approximately 40 healthy volunteers. The randomized, double-blind, placebo-controlled study will assess the safety, tolerability, pharmacokinetic and pharmacologic effects of a single oral administration of five doses of ALKS 37. We expect to report topline results from the study in the first half of calendar 2010. ALKS 37 is a component of ALKS 36.

Table of Contents**ALKS 36**

ALKS 36, an investigational co-formulation of an opioid analgesic and an oral, peripherally-restricted opioid antagonist, is being developed for the treatment of pain without the side effects of constipation. 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, such as ALKS 36, could provide an advantage over current therapies.

Executive Summary

Net loss for the three months ended September 30, 2009 was \$8.7 million, or \$0.09 per common share basic and diluted, as compared to net income of \$1.7 million, or \$0.02 per common share basic and diluted, for the three months ended September 30, 2008. Net loss for the six months ended September 30, 2009 was \$18.9 million, or \$0.20 per common share basic and diluted, as compared to net income of \$31.4 million, or \$0.33 per common share basic and \$0.32 per common share diluted, for the six months ended September 30, 2008. Net loss for the three and six months ended September 30, 2009 includes \$4.1 million and \$12.3 million, respectively, in charges associated with the planned relocation of our corporate headquarters from Cambridge, Massachusetts to Waltham, Massachusetts.

Results of Operations**Manufacturing Revenues**

(In millions)	Three Months Ended September 30		Change Favorable/ (Unfavorable)	Six Months Ended September 30		Change Favorable/ (Unfavorable)
	2009	2008		2009	2008	
Manufacturing revenues:						
RISPERDAL CONSTA	\$ 31.9	\$ 30.7	\$ 1.2	\$ 59.8	\$ 66.6	\$ (6.8)
Polymer	0.4		0.4	1.4		1.4
VIVITROL	0.5	2.3	(1.8)	0.4	5.0	(4.6)
Manufacturing revenues	\$ 32.8	\$ 33.0	\$ (0.2)	\$ 61.6	\$ 71.6	\$ (10.0)

The increase in RISPERDAL CONSTA manufacturing revenues for the three months ended September 30, 2009, as compared to the three months ended September 30, 2008, was primarily due to a 10% increase in the number of units shipped to Janssen, partially offset by a decrease in the net unit sales price. The decrease in RISPERDAL CONSTA manufacturing revenues for the six months ended September 30, 2009, as compared to the six months ended September 30, 2008, was primarily due to a 2% decrease in the number of units shipped to Janssen and a decrease in the net unit sales price. The decrease in the net unit sales price in the three and six months ended September 30, 2009 is primarily due to a stronger U.S. dollar in relation to the foreign currencies in which the product was sold, as compared to the three and six months ended September 30, 2008. The number of RISPERDAL CONSTA units shipped for sale in foreign countries comprised 74% and 84% of the total units shipped during the three months ended September 30, 2009 and 2008, respectively, and 75% and 82% of the total units shipped during the six months ended September 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 and six months ended September 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

Table of Contents

price when product is shipped to them. The polymer is used in the formulation of exenatide once weekly. During the three and six months ended September 30, 2008, we did not make any shipments of polymer to Amylin.

We record manufacturing revenues under our arrangement with Cilag at an agreed upon price when product is shipped to them. VIVITROL manufacturing revenues for the three and six months ended September 30, 2009 consisted entirely of product shipments to Cilag for resale in Russia. VIVITROL manufacturing revenues for the three and six months ended September 30, 2008 consisted of \$1.9 million and \$4.6 million, respectively, of billings to Cephalon, Inc. (Cephalon) under the collaborative arrangement in existence at the time, and \$0.4 million of billings to Cilag for shipments of VIVITROL to support the commercialization of VIVITROL in Russia. Effective December 1, 2008 (the Termination Date), we ended our collaboration with Cephalon and assumed full responsibility for the marketing and sale of VIVITROL in the U.S. As such, we expect that VIVITROL manufacturing revenues in fiscal year 2010 and beyond will consist of product shipments to Cilag for resale in Russia.

Royalty Revenues

(In millions)	Three Months Ended September 30		Change Favorable/ (Unfavorable)	Six Months Ended September 30		Change Favorable/ (Unfavorable)
	2009	2008		2009	2008	
Royalty revenues	\$ 8.8	\$ 8.4	\$ 0.4	\$ 17.5	\$ 17.0	\$ 0.5

Substantially all of our royalty revenues for the three and six months ended September 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 and six months ended September 30, 2009 were based on RISPERDAL CONSTA sales of \$352.6 million and \$700.3 million, respectively. Royalty revenues for the three and six months ended September 30, 2008 were based on RISPERDAL CONSTA sales of \$337.5 million and \$680.7 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 and six months ended September 30, 2009:

(In millions)	Three Months Ended		Six Months Ended	
	September 30		September 30	
	2009	% of Sales	2009	% of Sales
Product sales, gross	\$ 5.2	100.0%	\$ 10.5	100.0%
Adjustments to product sales, gross:				
Wholesaler fees	(0.2)	(3.8)%	(0.4)	(3.7)%
Medicaid rebates	(0.1)	(1.9)%	(0.3)	(2.9)%
Free product coupons		%	(0.3)	(2.9)%
Prompt-pay discounts	(0.1)	(1.9)%	(0.2)	(1.9)%
Product returns (1)	0.1	1.9%	(0.1)	(1.0)%
Other	(0.3)	(5.8)%	(0.3)	(2.9)%
Total adjustments	(0.6)	(11.5)%	(1.6)	(15.3)%
Product sales, net	\$ 4.6	88.5%	\$ 8.9	84.7%

Table of Contents

- (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 and six months ended September 30, 2008 were \$4.1 million and \$8.2 million, respectively.

Research and Development Revenue Under Collaborative Arrangements

(In millions)	Three Months Ended September 30		Change Favorable/ (Unfavorable)	Six Months Ended September 30		Change Favorable/ (Unfavorable)
	2009	2008		2009	2008	

Research and development
programs:

Four-week RISPERDAL

CONSTA	\$ 0.9	\$ 1.0	\$ (0.1)	\$ 1.9	\$ 1.9	\$
Exenatide once weekly	0.1	2.9	(2.8)	0.4	7.8	(7.4)
AIR Insulin		1.1	(1.1)		26.6	(26.6)
Other	0.2	0.3	(0.1)	0.3	0.4	(0.1)

Research and development
revenue under collaborative
arrangements

\$ 1.2	\$ 5.3	\$ (4.1)	\$ 2.6	\$ 36.7	\$ (34.1)
--------	--------	----------	--------	---------	-----------

In August 2009, we announced that our collaborative partner, J&JPRD, decided not to pursue further development of the four-week formulation of RISPERDAL CONSTA for the treatment of schizophrenia. Accordingly, we do not expect to recognize revenue from this development program in the future. The NDA for exenatide once weekly was filed with the FDA in May 2009 and as a result, revenues under the program decreased in the three and six months ended September 30, 2009, as compared to the three and six months ended September 30, 2008. The decrease in revenue from the AIR Insulin program in the three and six months ended September 30, 2009, as compared to the three and six months ended September 30, 2008, was due to the termination of the AIR Insulin development program in March 2008.

Net Collaborative Profit

(In millions)	Three Months Ended September 30		Change Favorable/ (Unfavorable)	Six Months Ended September 30		Change Favorable/ (Unfavorable)
	2009	2008		2009	2008	
Net collaborative profit:						
Milestone revenue license	\$	\$ 1.3	\$ (1.3)	\$	\$ 2.6	\$ (2.6)
Net payments to Cephalon		(0.7)	0.7		(0.7)	0.7
VIVITROL losses funded by Cephalon, post termination	0.7		0.7	5.0		5.0
Net collaborative profit	\$ 0.7	\$ 0.6	\$ 0.1	\$ 5.0	\$ 1.9	\$ 3.1

Net collaborative profit for the three and six months ended September 30, 2009 consisted of revenue earned as a result of the \$11.0 million payment we received from Cephalon to fund its share of estimated VIVITROL losses during the one-year period following the Termination Date. We recorded the \$11.0 million payment as deferred revenue and recognized it as revenue through the application of a proportional performance model based on VIVITROL losses. The deferred revenue was recognized in full during the three months ended September 30, 2009, and we do not expect to recognize any further net collaborative profit. Net collaborative profit during the three and six months ended September 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.

Table of Contents**Cost of Goods Manufactured and Sold**

(In millions)	Three Months Ended September 30		Change Favorable/ (Unfavorable)	Six Months Ended September 30		Change Favorable/ (Unfavorable)
	2009	2008		2009	2008	
Cost of goods manufactured and sold:						
RISPERDAL CONSTA	\$ 12.1	\$ 8.1	\$ (4.0)	\$ 21.8	\$ 18.9	\$ (2.9)
VIVITROL	2.6	4.0	1.4	4.6	7.5	2.9
Polymer	0.4		(0.4)	1.4		(1.4)
Cost of goods manufactured and sold	\$ 15.1	\$ 12.1	\$ (3.0)	\$ 27.8	\$ 26.4	\$ (1.4)

The increase in cost of goods manufactured for RISPERDAL CONSTA in the three months ended September 30, 2009, as compared to the three months ended September 30, 2008, was due to a 10% increase in the number of units of RISPERDAL CONSTA shipped to Janssen, an increase in costs incurred for failed product batches and an increase in overhead and support costs allocated to cost of goods manufactured as a result of decreased development activities at our Ohio manufacturing facility, which shifted overhead and support costs from research and development (R&D) expense to cost of goods manufactured during the period. The increase in cost of goods manufactured for RISPERDAL CONSTA in the six months ended September 30, 2009, as compared to the six months ended September 30, 2008, was due to the increase in overhead and support costs allocated to cost of goods manufactured for the reason previously discussed and an increase in costs incurred for failed product batches, partially offset by a 2% decrease in the number of units of RISPERDAL CONSTA shipped to Janssen.

The decrease in cost of goods manufactured and sold for VIVITROL in the three months ended September 30, 2009, as compared to the three months ended September 30, 2008, is primarily due to a \$2.4 million decrease in costs incurred for failed batches and costs related to the restart of the manufacturing line following a shutdown of the line, partially offset by a 162% increase in the number of units sold during the period. The decrease in cost of goods manufactured and sold for VIVITROL in the six months ended September 30, 2009, as compared to the six months ended September 30, 2008, is primarily due to a \$3.6 million decrease in costs incurred for failed batches and costs related to the restart of the manufacturing line following a shutdown of the line, partially offset by a 1% increase in the number of units sold during the period.

During the three and six months ended September 30, 2008, we did not make any shipments of polymer to Amylin.

Research and Development Expense

(In millions)	Three Months Ended September 30		Change Favorable/ (Unfavorable)	Six Months Ended September 30		Change Favorable/ (Unfavorable)
	2009	2008		2009	2008	
Research and development	\$ 20.7	\$ 19.7	\$ (1.0)	\$ 46.3	\$ 42.0	\$ (4.3)

The increase in R&D expenses in the three and six months ended September 30, 2009, as compared to the three and six months ended September 30, 2008, was primarily due to costs we incurred as a result of the decision to move our corporate headquarters from Cambridge, Massachusetts, to Waltham, Massachusetts. As a result of the planned move, we recorded approximately \$4.1 million and \$12.1 million of expense in the three and six months ended September 30, 2009, respectively, due primarily to the acceleration of depreciation on laboratory related leasehold improvements located at our current headquarters, which 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. In addition, R&D

expenses increased in the three and six months ended September 30, 2009, as compared to the three and six months ended September 30, 2008, due to an increase in the number of pre-clinical and toxicology studies we conducted. Partially offsetting these increases in R&D expenses was a decrease in labor and benefits due to a reduction in R&D headcount and a decrease in overhead and support costs allocated to R&D at our Ohio manufacturing facility, as discussed above.

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

Table of Contents

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

(In millions)	Three Months Ended September 30		Change Favorable/ (Unfavorable)	Six Months Ended September 30		Change Favorable/ (Unfavorable)
	2009	2008		2009	2008	
Selling, general and administrative	\$ 20.6	\$ 11.7	\$ (8.9)	\$ 39.9	\$ 23.6	\$ (16.3)

The increase in selling, general and administrative costs for the three and six months ended September 30, 2009, as compared to the three and six months ended September 30, 2008, was primarily due to increased sales and marketing costs as we became responsible for the commercialization of VIVITROL in the U.S. beginning December 1, 2008 and \$2.3 million in severance costs we recorded in connection with the resignation of our former President and Chief Executive Officer in September 2009.

Other Expense, Net

(In millions)	Three Months Ended September 30		Change Favorable/ (Unfavorable)	Six Months Ended September 30		Change Favorable/ (Unfavorable)
	2009	2008		2009	2008	
Interest income	\$ 1.1	\$ 2.7	\$ (1.6)	\$ 2.6	\$ 6.3	\$ (3.7)
Interest expense	(1.6)	(4.2)	2.6	(3.3)	(8.5)	5.2
Other expense, net	(0.1)	(0.7)	0.6	(0.1)	(0.8)	0.7
Total other expense, net	\$ (0.6)	\$ (2.2)	\$ 1.6	\$ (0.8)	\$ (3.0)	\$ 2.2

The decrease in interest income for the three and six months ended September 30, 2009, as compared to the three and six months ended September 30, 2008, was due to a lower average balance of cash and investments as well as lower interest rates earned. The decrease in interest expense for the three and six months ended September 30, 2009, as compared to the three and six months ended September 30, 2008, was the result of our repurchase of an aggregate total of \$93.0 million principal amount, or approximately 55%, of our non-recourse RISPERDAL CONSTA secured 7% Notes (the "non-recourse 7% Notes"), in five separately negotiated transactions during the year ended March 31, 2009. We also began making quarterly scheduled principal payments on our non-recourse 7% Notes, beginning in April 2009, which reduced interest expense in the three and six months ended September 30, 2009. The decrease in other expense, net, for the three and six months ended September 30, 2009, as compared to the three and six months ended September 30, 2008, was due to other-than-temporary impairment charges taken in the three months ended September 30, 2008 on our investment in the common stock of certain publicly held companies.

Provision for Income Taxes

	Three Months Ended September 30		Change Favorable/	Six Months Ended September 30		Change Favorable/

Edgar Filing: ALKERMES INC - Form 10-Q

(In millions)	2009	2008	(Unfavorable)	2009	2008	(Unfavorable)
(Benefit) provision for income taxes	\$ (0.1)	\$ (0.1)	\$	\$ (0.1)	\$ 1.0	\$ 1.1

The income tax benefit of \$0.1 million for the three and six months ended September 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 benefit of \$0.1 million and income tax provision of \$1.0 million for the three and six months ended September 30, 2008, respectively, 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 benefit and charge was recorded in the three and six months ended September 30, 2008, respectively. The AMT liability is available as a credit against future tax obligations upon the full utilization or expiration of our net operating loss carryforward.

Table of Contents**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 a portion of our outstanding debt and may continue with some or all of these activities 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)	September 30 2009	March 31, 2009
Cash and cash equivalents	\$ 53.0	\$ 86.9
Investments short-term	242.1	236.8
Investments long-term	74.4	80.8
Total cash, cash equivalents and investments	\$ 369.5	\$ 404.5
Working capital	\$ 299.4	\$ 307.1
Outstanding borrowings current and long-term	\$ 63.5	\$ 75.9

Cash and Cash Equivalents

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

(In millions)	Six Months Ended September 30	
	2009	2008
Cash and cash equivalents, beginning of period	\$ 86.9	\$ 101.2
Cash (used in) provided by operating activities	(18.7)	34.6
Cash (used in) provided by investing activities	(0.9)	5.7
Cash used in financing activities	(14.3)	(73.0)
Cash and cash equivalents, end of period	\$ 53.0	\$ 68.5

Operating Activities

The change in cash used in operating activities in the six months ended September 30, 2009, as compared to the cash provided by operating activities in the six months ended September 30, 2008, is primarily due to the \$40.0 million payment we received from Lilly related to the termination of the AIR Insulin development program in June 2008. In addition, we used more cash for working capital during the six months ended September 30, 2009, partially offset by a decrease in cash used for the purchase of our non-recourse 7% Notes, in which the portion attributable to the original issue discount was charged to operating activities.

Investing Activities

The change in cash used in investing activities in the six months ended September 30, 2009, as compared to the cash provided by investing activities in the six months ended September 30, 2008, is primarily due to a decrease in

cash provided from sales of property, plant and equipment.

26

Table of Contents

Financing Activities

The decrease in cash used in financing activities during the six months ended September 30, 2009, as compared to the six months ended September 30, 2008, was due to the fact that we did not make any purchases of our non-recourse 7% Notes during the six months ended September 30, 2009, we purchased \$10.4 million less common stock for treasury and we received \$7.0 million less in cash from the exercise of employee stock options, partially offset by the scheduled quarterly principal payments we made on our non-recourse 7% Notes in April and July, 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. The primary objective of our investment policy is the preservation of capital with a secondary objective of generating income on our investments. 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 explained in Note 4, Investments and Note 5, Fair Value Measurements, in the Notes to Condensed Consolidated Financial Statements, 8% of our investments, which are reported at fair value on a recurring basis, 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.

During the three months ended September 30, 2009, trading resumed for certain of our investments in corporate debt securities. At September 30, 2009, we derived a fair value for these investments using market observable inputs instead of through the use of a discounted cash flow model. Accordingly, we transferred these investments from a Level 3 classification to a Level 2 classification.

Borrowings

At September 30, 2009, our borrowings consisted of \$64.2 million principal amount of our non-recourse 7% Notes, which have a carrying value of \$63.5 million. Principal and interest payments on the non-recourse 7% Notes are due quarterly, and the non-recourse 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 year 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.

Table of Contents

Off-Balance Sheet Arrangements

At September 30, 2009, we were not a party to any off-balance sheet arrangements.

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 new accounting guidance on the recognition and presentation of other-than-temporary impairments and enhanced our process for reviewing debt securities with unrealized losses for possible impairment to include a 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. Also, an other-than-temporary impairment shall be considered to have occurred if we do not expect to recover the entire amortized cost basis of a security, regardless of our intent to hold the security to maturity. This enhancement to our impairment assessment process 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 six 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 six 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 September 30, 2009. Based upon that evaluation, our principal executive officer and principal financial officer concluded that, at September 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 SEC rules and forms, and (b) such information is accumulated and

Table of Contents

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.

Table of Contents**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 September 30, 2009 is as follows:

Period	Total Number of Shares Purchased (a)	Average Price Paid per Share	Total Number of Shares Purchased as Part of a Publicly Announced Program (a)	Approximate Dollar Value of Shares that May Yet be Purchased Under the Program (In millions)
July 1 through July 31		\$		\$ 101.1
August 1 through August 31		\$		\$ 101.1
September 1 through September 30	18,900	\$ 9.04	18,900	\$ 101.0
Total	18,900	\$ 9.04	18,900	

(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 September 30, 2009, we have purchased a total of 8,866,342 shares under this program at a cost of \$114.0 million.

In addition to the stock repurchases above, during the three months ended September 30, 2009 we acquired, by means of net share settlements, 1,199 shares of Alkermes common stock at an average price of \$10.84 per share related to the vesting of employee stock awards to satisfy withholding tax obligations.

Item 6. Exhibits

(a) List of Exhibits:

Exhibit

No.

- | | |
|------|---|
| 10.1 | Separation Agreement by and between Alkermes, Inc. and David A. Broecker, dated September 10, 2009 (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed on September 11, 2009). |
| 10.2 | Amendment No. 2 to Employment Agreement by and between Alkermes, Inc. and Richard F. Pops, dated September 10, 2009 (incorporated by reference to Exhibit 10.2 to the Registrant's Current Report on Form 8-K filed on September 11, 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).

30

Table of Contents

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

ALKERMES, INC.
(Registrant)

By: /s/ Richard F. Pops
Richard F. Pops
Chairman, President and Chief
Executive Officer (Principal Executive
Officer)

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

Date: November 5, 2009

Table of Contents

EXHIBIT INDEX

Exhibit

No.

- | | |
|------|---|
| 10.1 | Separation Agreement by and between Alkermes, Inc. and David A. Broecker, dated September 10, 2009 (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed on September 11, 2009). |
| 10.2 | Amendment No. 2 to Employment Agreement by and between Alkermes, Inc. and Richard F. Pops, dated September 10, 2009 (incorporated by reference to Exhibit 10.2 to the Registrant's Current Report on Form 8-K filed on September 11, 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). |