

ALKERMES INC  
Form 10-Q  
February 09, 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 December 31, 2008

**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**  
*(Address of principal executive offices)*

**02139-4234**  
*(Zip Code)*

**Registrant's telephone number including area code:  
(617) 494-0171**

*(Former name, former address, and former fiscal year, if changed since last report)*

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes  No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of large accelerated filer, accelerated filer and smaller reporting company 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 February 2, 2009
Common Stock, \$.01 par value	94,501,982
Non-Voting Common Stock, \$.01 par value	382,632



**ALKERMES, INC. AND SUBSIDIARIES  
INDEX**

	<b>Page No.</b>
<b><i>PART I FINANCIAL INFORMATION</i></b>	
Item 1. Condensed Consolidated Financial Statements:	
<u>Condensed Consolidated Balance Sheets December 31, 2008 and March 31, 2008</u>	3
<u>Condensed Consolidated Statements of Income For the Three and Nine Months Ended December 31, 2008 and 2007</u>	4
<u>Condensed Consolidated Statements of Cash Flows For the Nine Months Ended December 31, 2008 and 2007</u>	5
<u>Notes to Condensed Consolidated Financial Statements</u>	6
Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations	15
Item 3. Quantitative and Qualitative Disclosures about Market Risk	28
Item 4. Controls and Procedures	29
<b><i>PART II OTHER INFORMATION</i></b>	
<u>Item 1. Legal Proceedings</u>	31
<u>Item 1A. Risk Factors</u>	31
<u>Item 2. Unregistered Sales of Equity Securities and Use of Proceeds</u>	33
<u>Item 4. Submission of Matters to a Vote of Security Holders</u>	33
<u>Item 5. Other Information</u>	34
<u>Item 6. Exhibits</u>	34
<u>Signatures</u>	35
<u>Exhibit Index</u>	36
<u>Ex-31.1 - Sec 302 Certification of Principal Executive Officer</u>	
<u>Ex-32.1 - Sec 302 Certification of Principal Financial and Accounting Officer</u>	
<u>Ex-32.1 - Sec 906 Certification of Principal Executive Officer and Principal Financial Officer</u>	

**Table of Contents**

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

	<b>December 31, 2008</b>	<b>March 31, 2008</b>
	<b>(In thousands, except share and per share amounts)</b>	
<b>ASSETS</b>		
<b>CURRENT ASSETS:</b>		
Cash and cash equivalents	\$ 63,264	\$ 101,241
Investments short-term	281,464	240,064
Receivables	26,713	47,249
Inventory	21,113	18,884
Prepaid expenses and other current assets	14,920	5,720
<b>Total current assets</b>	<b>407,474</b>	<b>413,158</b>
<b>PROPERTY, PLANT AND EQUIPMENT:</b>		
Land	301	301
Building and improvements	36,460	35,003
Furniture, fixtures and equipment	65,148	63,364
Equipment under capital lease	464	464
Leasehold improvements	33,711	33,387
Construction in progress	41,735	42,859
	177,819	175,378
Less: accumulated depreciation	(70,520)	(62,839)
<b>Total property, plant and equipment net</b>	<b>107,299</b>	<b>112,539</b>
<b>INVESTMENTS LONG-TERM</b>	<b>78,865</b>	<b>119,056</b>
<b>OTHER ASSETS</b>	<b>3,029</b>	<b>11,558</b>
<b>TOTAL ASSETS</b>	<b>\$ 596,667</b>	<b>\$ 656,311</b>
<b>LIABILITIES AND SHAREHOLDERS EQUITY</b>		
<b>CURRENT LIABILITIES:</b>		
Accounts payable and accrued expenses	\$ 30,310	\$ 36,046
Unearned milestone revenue current portion		5,927
Deferred revenue current portion	11,705	
Long-term debt current portion		47
Non-recourse RISPERDAL CONSTA secured 7% notes current portion	23,750	
<b>Total current liabilities</b>	<b>65,765</b>	<b>42,020</b>
<b>NON-RECOURSE RISPERDAL CONSTA SECURED 7% NOTES</b>	<b>68,692</b>	<b>160,324</b>

Edgar Filing: ALKERMES INC - Form 10-Q

UNEARNED MILESTONE REVENUE LONG-TERM PORTION		111,730
DEFERRED REVENUE LONG-TERM PORTION	5,369	27,837
OTHER LONG-TERM LIABILITIES	7,272	9,086
TOTAL LIABILITIES	147,098	350,997

COMMITMENTS AND CONTINGENCIES (Note 13)

SHAREHOLDERS EQUITY:

Capital stock, par value, \$0.01 per share; 4,550,000 shares authorized (includes 3,000,000 shares of preferred stock); none issued and outstanding		
Common stock, par value, \$0.01 per share; 160,000,000 shares authorized; 104,020,561 and 102,977,348 shares issued; 94,516,877 and 95,099,166 shares outstanding at December 31, 2008 and March 31, 2008, respectively	1,040	1,030
Non-voting common stock, par value, \$0.01 per share; 450,000 shares authorized; 382,632 shares issued and outstanding at December 31, 2008 and March 31, 2008	4	4
Treasury stock, at cost (9,503,684 and 7,878,182 shares at December 31, 2008 and March 31, 2008, respectively)	(125,978)	(107,322)
Additional paid-in-capital	888,811	869,695
Accumulated other comprehensive loss	(1,841)	(1,526)
Accumulated deficit	(312,467)	(456,567)
TOTAL SHAREHOLDERS EQUITY	449,569	305,314
TOTAL LIABILITIES AND SHAREHOLDERS EQUITY	\$ 596,667	\$ 656,311

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 INCOME**  
**(unaudited)**

	<b>Three Months Ended</b>		<b>Nine Months Ended</b>	
	<b>December 31,</b>		<b>December 31,</b>	
	<b>2008</b>	<b>2007</b>	<b>2008</b>	<b>2007</b>
	<b>(In thousands, except per share amounts)</b>			
<b>REVENUES:</b>				
Manufacturing revenues	\$ 20,533	\$ 14,275	\$ 92,182	\$ 69,929
Royalty revenues	7,970	7,384	24,990	21,714
Research and development revenue under collaborative arrangements	3,736	23,985	40,438	68,641
Net collaborative profit	123,422	5,127	125,354	18,025
<b>Total revenues</b>	<b>155,661</b>	<b>50,771</b>	<b>282,964</b>	<b>178,309</b>
<b>EXPENSES:</b>				
Cost of goods sold	5,536	7,499	31,921	26,862
Research and development	22,669	30,395	64,640	91,331
Selling, general and administrative	14,568	15,249	38,173	45,136
<b>Total expenses</b>	<b>42,773</b>	<b>53,143</b>	<b>134,734</b>	<b>163,329</b>
<b>OPERATING INCOME (LOSS)</b>	<b>112,888</b>	<b>(2,372)</b>	<b>148,230</b>	<b>14,980</b>
<b>OTHER (EXPENSE) INCOME:</b>				
Gain on sale of investment in Reliant Pharmaceuticals, Inc.		174,631		174,631
Interest income	2,574	4,292	8,883	12,940
Interest expense	(2,436)	(4,088)	(10,905)	(12,238)
Other (expense) income	(641)	(393)	(1,471)	784
<b>Total other (expense) income</b>	<b>(503)</b>	<b>174,442</b>	<b>(3,493)</b>	<b>176,117</b>
<b>INCOME BEFORE INCOME TAXES</b>	<b>112,385</b>	<b>172,070</b>	<b>144,737</b>	<b>191,097</b>
<b>INCOME TAX (BENEFIT) PROVISION</b>	<b>(330)</b>	<b>3,189</b>	<b>637</b>	<b>5,771</b>
<b>NET INCOME</b>	<b>\$ 112,715</b>	<b>\$ 168,881</b>	<b>\$ 144,100</b>	<b>\$ 185,326</b>
<b>EARNINGS PER COMMON SHARE:</b>				
<b>BASIC</b>	<b>\$ 1.18</b>	<b>\$ 1.66</b>	<b>\$ 1.51</b>	<b>\$ 1.82</b>
<b>DILUTED</b>	<b>\$ 1.18</b>	<b>\$ 1.63</b>	<b>\$ 1.49</b>	<b>\$ 1.78</b>
<b>WEIGHTED AVERAGE NUMBER OF COMMON SHARES OUTSTANDING:</b>				
<b>BASIC</b>	<b>95,316</b>	<b>101,703</b>	<b>95,246</b>	<b>101,676</b>

Edgar Filing: ALKERMES INC - Form 10-Q

DILUTED	95,818	103,914	96,398	104,097
---------	--------	---------	--------	---------

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)**

	<b>Nine Months Ended</b>	
	<b>December</b>	<b>December</b>
	<b>31,</b>	<b>31,</b>
	<b>2008</b>	<b>2007</b>
	<b>(In thousands)</b>	
<b>CASH FLOWS FROM OPERATING ACTIVITIES:</b>		
Net income	\$ 144,100	\$ 185,326
Adjustments to reconcile net income to cash flows from operating activities:		
Share-based compensation	11,590	15,477
Depreciation	7,501	9,380
Other non-cash charges	4,531	4,225
Loss on the purchase of non-recourse RISPERDAL CONSTA 7% Notes	1,989	
Gain on sale of investment in Reliant Pharmaceuticals, Inc.		(174,631)
Change in the fair value of warrants		(1,425)
Changes in assets and liabilities:		
Receivables	11,585	14,368
Inventory, prepaid expenses and other assets	(4,746)	(7,904)
Accounts payable and accrued expenses	(4,722)	(14,004)
Unearned milestone revenue	(117,657)	(9,537)
Deferred revenue	(9,529)	6,909
Other liabilities	(1,415)	(180)
 Cash flows provided by operating activities	 43,227	 28,004
 <b>CASH FLOWS FROM INVESTING ACTIVITIES:</b>		
Purchases of property, plant and equipment	(4,145)	(17,618)
Sales of property, plant and equipment	7,717	
Purchases of investments	(543,408)	(371,342)
Sales and maturities of investments	540,721	453,403
Proceeds from the sale of investment in Reliant Pharmaceuticals, Inc.		166,865
 Cash flows provided by investing activities	 885	 231,308
 <b>CASH FLOWS FROM FINANCING ACTIVITIES:</b>		
Proceeds from issuance of common stock	7,606	9,510
Excess tax benefit from stock options	75	211
Payment of debt	(47)	(975)
Purchase of non-recourse RISPERDAL CONSTA secured 7% Notes	(71,775)	
Purchase of treasury stock	(17,948)	(27,627)
 Cash flows used in financing activities	 (82,089)	 (18,881)
 NET (DECREASE) INCREASE IN CASH AND CASH EQUIVALENTS	 (37,977)	 240,431
CASH AND CASH EQUIVALENTS Beginning of period	101,241	80,500

Edgar Filing: ALKERMES INC - Form 10-Q

CASH AND CASH EQUIVALENTS	End of period	\$ 63,264	\$ 320,931
SUPPLEMENTAL CASH FLOW DISCLOSURE:			
Cash paid for interest		\$ 7,663	\$ 9,004
Cash paid for income taxes		\$ 435	\$ 980
Non-cash investing and financing activities:			
Purchased capital expenditures included in accounts payable and accrued expenses		\$ 1,883	\$ 328
Net share exercise of warrants into common stock of the issuer		\$	\$ 2,994
Receipt of Alkermes shares for the purchase of stock options or as payment to satisfy minimum withholding tax obligations related to stock based awards		\$ 707	\$ 1,480

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. DESCRIPTION OF BUSINESS AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES*****Description of Business***

Alkermes, Inc. (the Company) is a fully integrated biotechnology company committed to developing innovative medicines to improve patients' lives. Alkermes developed, manufactures and commercializes VIVITROL® for alcohol dependence and manufactures RISPERDAL® CONSTA® for schizophrenia. Alkermes' 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. Headquartered in Cambridge, Massachusetts, Alkermes has research facilities in Massachusetts and a commercial manufacturing facility in Ohio.

***Basis of Presentation***

The accompanying condensed consolidated financial statements of the Company for the three and nine months ended December 31, 2008 and 2007 are unaudited and have been prepared on a basis substantially consistent with the audited financial statements for the year ended March 31, 2008. 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 (U.S.) (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, 2008, as filed with the Securities and Exchange Commission (SEC).

The results of the Company's operations for any interim period are not necessarily indicative of the results of the Company's operations for any other interim period or for a full fiscal year.

***Principles of Consolidation***

The condensed consolidated financial statements include the accounts of Alkermes, Inc. and its wholly-owned subsidiaries: Alkermes Controlled Therapeutics, Inc.; Alkermes Europe, Ltd. and RC Royalty Sub LLC (Royalty Sub). The assets of Royalty Sub are not available to satisfy obligations of Alkermes and its subsidiaries, other than the obligations of Royalty Sub, including Royalty Sub's non-recourse RISPERDAL CONSTA secured 7% notes (the 7% Notes). 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.

***Revenue Recognition***

The Company recognizes revenue from the sale of VIVITROL in accordance with the Securities and Exchange Commission's Staff Accounting Bulletin No. 101, *Revenue Recognition in Financial Statements* (SAB 101), as amended by SEC Staff Accounting Bulletin No. 104, *Revenue Recognition* (SAB 104). Specifically, revenue is recognized when persuasive evidence of an arrangement exists, delivery has occurred and title to the product and associated risk of loss has passed to the customer, the sales price is fixed or determinable, and collectibility is reasonably assured.

The Company sells VIVITROL primarily to wholesalers, distributors and specialty pharmacies. In accordance with Statement of Financial Accounting Standards (SFAS) No. 48, *Revenue Recognition When Right of Return Exists* (SFAS No. 48), the Company cannot recognize revenue on product shipments until it can reasonably estimate returns related to these shipments. The Company defers the recognition of revenue on shipments of VIVITROL to its customers until the product has left the distribution channel. The Company estimates product shipments out of the distribution channel through data provided by external sources,



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

including information on inventory levels provided by its wholesalers, specialty distributor and specialty pharmacies, as well as prescription information. In order to match the cost of goods related to products shipped to customers with the associated revenue, the Company is deferring the recognition of the cost of goods to the period in which the associated revenue is recognized.

In connection with the termination of the collaboration agreement with Cephalon, Inc. ( Cephalon ) as discussed in Note 2, *Collaborations*, the Company recognized \$120.7 million of net collaborative profit, consisting of \$113.9 million of unearned milestone revenue and \$6.8 million of deferred revenue remaining on the Company's books at December 1, 2008 (the Termination Date ). At the Termination Date, the Company had \$22.8 million of deferred revenue related to the original sale of the two partially completed VIVITROL manufacturing lines to Cephalon. The Company paid Cephalon \$16.0 million to reacquire the title to these manufacturing lines and accounted for the payment as a reduction to the deferred revenue previously recognized. The remaining \$6.8 million of deferred revenue and the \$113.9 million of unearned milestone revenue were recognized in the three months ended December 31, 2008, through net collaborative profit, as the Company had no remaining performance obligations to Cephalon beyond the Termination Date, and the amounts were nonrefundable to Cephalon. The Company received \$11.0 million from Cephalon as payment to fund their share of estimated VIVITROL product losses during the one-year period following the Termination Date, and the Company is recognizing this payment as revenue through the application of a proportional performance model based on VIVITROL net product losses.

*New Accounting Pronouncements*

In November 2007, the Emerging Issues Task Force ( EITF ) of the Financial Accounting Standards Board ( FASB ) reached a final consensus on EITF Issue No. 07-1, *Accounting for Collaborative Arrangements Related to the Development and Commercialization of Intellectual Property* ( EITF No. 07-1 ). EITF No. 07-1 is effective for the Company's fiscal year beginning April 1, 2009. Adoption is on a retrospective basis to all prior periods presented for all collaborative arrangements existing as of the effective date. The Company is currently evaluating the impact of the adoption of EITF No. 07-1 on its consolidated financial statements.

In March 2008, the FASB issued SFAS No. 161, *Disclosures about Derivative Instruments and Hedging Activities* ( SFAS No. 161 ). SFAS No. 161 is intended to improve financial reporting about derivative instruments and hedging activities by requiring enhanced disclosures to enable investors to better understand their effects on an entity's financial position, financial performance and cash flows. SFAS No. 161 is effective for the Company's fiscal year beginning April 1, 2009, and the Company does not expect the adoption of this standard to have a material impact on its consolidated financial statements.

**2. COLLABORATIONS**

In November 2008, the Company and Cephalon agreed to end the collaboration for the development, supply and commercialization of certain products, including VIVITROL in the U.S., effective December 1, 2008, and the Company assumed the risks and responsibilities for the marketing and sale of VIVITROL in the U.S. The Company paid Cephalon \$16.0 million for title to two partially completed VIVITROL manufacturing lines, and the Company received \$11.0 million from Cephalon as payment to fund their share of estimated VIVITROL product losses during the one-year period following the Termination Date. As of the Termination Date, the Company is responsible for all VIVITROL profits or losses and Cephalon has no rights to royalty payments on future sales of VIVITROL. For a period of six months following the Termination Date, in order to facilitate the transfer of commercialization of VIVITROL to the Company, Cephalon, at the Company's option, performs certain transition services on behalf of the Company. Cephalon provides the Company with transition services at a full-time equivalent rate ( FTE ) agreed to by the parties.

**Table of Contents****3. COMPREHENSIVE INCOME**

Comprehensive income for the three and nine months ended December 31, 2008 and 2007 is as follows:

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

(In thousands)	Three Months Ended December 31,		Nine Months Ended December 31,	
	2008	2007	2008	2007
Net income	\$ 112,715	\$ 168,881	\$ 144,100	\$ 185,326
Unrealized losses on available-for-sale securities:				
Holding losses	(1,212)	(1,469)	(1,478)	(2,019)
Reclassification of unrealized losses to realized losses on available-for-sale securities	556	337	1,163	337
Unrealized losses on available-for-sale securities	(656)	(1,132)	(315)	(1,682)
Comprehensive income	\$ 112,059	\$ 167,749	\$ 143,785	\$ 183,644

**4. EARNINGS PER COMMON SHARE**

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

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

(In thousands)	Three Months Ended December 31,		Nine Months Ended December 31,	
	2008	2007	2008	2007
Numerator:				
Net income	\$ 112,715	\$ 168,881	\$ 144,100	\$ 185,326
Denominator:				
Weighted average number of common shares outstanding	95,316	101,703	95,246	101,676
Effect of dilutive securities:				
Stock options	446	2,159	974	2,354
Restricted stock units	56	52	178	67
Dilutive common share equivalents	502	2,211	1,152	2,421
Shares used in calculating diluted earnings per share	95,818	103,914	96,398	104,097

Stock options of 16.4 million and 11.9 million for the three months ended December 31, 2008 and 2007, respectively, and 15.4 million and 11.9 million for the nine months ended December 31, 2008 and 2007, respectively, were not included in the calculation of earnings per common share because their effects are anti-dilutive. There were 0.6 million and no restricted stock units excluded from the calculation of net income per common share for the three months ended December 31, 2008 and 2007, respectively, and less than 0.1 million and none for the nine months ended December 31, 2008 and 2007, respectively, because their effects are anti-dilutive.

**5. INVESTMENTS**

Investments consist of the following:

<b>(In thousands)</b>	<b>December 31, 2008</b>	<b>March 31, 2008</b>
Current investments:		
Available-for-sale	\$ 281,464	\$ 240,064
Long-term investments:		
Available-for-sale	74,212	114,403
Held-to-maturity	4,653	4,653
Total long-term investments	78,865	119,056
Total investments	\$ 360,329	\$ 359,120

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

The Company's available-for-sale investments are carried at fair value in the Company's condensed consolidated balance sheets and include U.S. government and agency debt securities, investment grade corporate debt securities, including asset backed debt securities and student loan backed auction rate securities, and strategic equity investments, which are investments in certain publicly traded companies. The Company's held-to-maturity securities are carried at amortized cost and include U.S. government debt securities and corporate debt securities that are restricted and held as collateral under certain letters of credit related to certain of the Company's lease agreements.

At December 31, 2008, the Company had gross unrealized gains of \$4.0 million and gross unrealized losses of \$5.8 million on its available-for-sale investments. The Company believes that the gross unrealized losses on these investments are temporary, and the Company has the intent and ability to hold these securities to recovery, which may be at maturity. For the nine months ended December 31, 2008, the Company recognized \$1.2 million in charges for other-than-temporary losses on its strategic equity investments.

At December 31, 2008, the Company had \$10.0 million in investments in auction rate securities with an unrealized loss of \$1.1 million. The securities represent the Company's investment in taxable student loan revenue bonds issued by state higher education authorities which service student loans under the Federal Family Education Loan Program. The bonds were triple A rated at the date of purchase and 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. Each of these securities had been subject to auction processes for which there had been insufficient bidders on the scheduled auction dates and the auctions subsequently failed. The Company is not able to liquidate its investments in auction rate securities until future auctions are successful, a buyer is found outside of the auction process or the bonds are redeemed by the issuer. The securities continue to pay interest at predetermined interest rates during the periods in which the auctions have failed. At December 31, 2008, the Company determined that the securities were 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 and the guarantee agencies, and the Company's intent and ability to hold each security for a period of time sufficient to allow for any anticipated recovery in fair value.

At December 31, 2008, the Company had \$7.5 million in investments in asset backed debt securities with an unrealized loss of \$0.9 million. The securities represent the Company's investment in investment grade 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 December 31, 2008, a portion of the Company's initial investment in the Meridian MTN s had been redeemed by MBIA through scheduled sinking fund redemptions at par value, and the first sinking fund redemption on the Aleutian MTN is scheduled for June 2009.

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. In June 2008, Ambac had its triple A rating reduced to Aa3 by Moody's and in November, Moody's further downgraded Ambac's rating to Baa1 with a developing outlook. Standard and Poor's ( S&P ) reduced Ambac's rating to double A in June 2008 and in August 2008, affirmed its double A rating with a negative outlook. In June 2008, MBIA was downgraded from triple A to A2 by Moody's and in September Moody's placed MBIA on review for possible downgrade. S&P reduced MBIA's rating to double A in June 2008 and in August 2008, affirmed its double A rating with a negative outlook. All downgrades were due to Ambac's and MBIA's inability to maintain triple A capital levels.



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 December 31, 2008, 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 one of the issuers and the Company's intent and ability to hold each security for a period of time sufficient to allow for any anticipated recovery in fair value or until scheduled redemption.

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

The Company also holds a warrant to purchase securities of a certain publicly held company included in its portfolio of strategic equity investments. This warrant is considered to be a derivative instrument, and at December 31, 2008 and March 31, 2008 the carrying value of the warrant was immaterial.

**6. FAIR VALUE MEASUREMENTS**

Effective April 1, 2008, the Company implemented SFAS No. 157, *Fair Value Measurements* ( SFAS No. 157 ) for its financial assets and liabilities that are re-measured and reported at fair value at each reporting period. The adoption of SFAS No. 157 did not have a material impact on the Company's financial position and results of operations. In accordance with the provisions of FASB Staff Position FAS 157-2, *Effective Date of FASB Statement No. 157* ( FSP FAS 157-2 ), the Company has elected to defer implementation of SFAS No. 157 as it relates to non-financial assets and non-financial liabilities that are recognized and disclosed at fair value in the financial statements on a nonrecurring basis until April 1, 2009. The Company is evaluating the impact, if any, this standard will have on its non-financial assets and liabilities.

SFAS No. 157 provides a framework for measuring fair value and requires expanded disclosures regarding fair value measurements. SFAS No. 157 defines fair value as the price that would be received to sell an asset or paid to transfer a liability (the exit price) in an orderly transaction between market participants at the measurement date. In determining fair value, SFAS No. 157 permits the use of various valuation approaches, including market, income and cost approaches. SFAS No. 157 establishes a hierarchy for inputs used in measuring fair value that maximizes the use of observable inputs and minimizes the use of unobservable inputs by requiring that the observable inputs be used when available. In October 2008, the FASB issued FASB Staff Position FAS 157-3 *Determining the Fair Value of a Financial Asset When the Market for that Asset is not Active* ( FSP FAS 157-3 ). FSP FAS 157-3 clarifies the application of SFAS No. 157 in a market that is not active and provides an example to illustrate key considerations in determining the fair value of a financial asset when the market for that financial asset is not active. FSP FAS 157-3 was effective for the Company's condensed consolidated financial statements for the quarter ended September 30, 2008. The adoption of this standard did not have a material impact on the consolidated financial statements.

The fair value hierarchy is broken down into three levels based on the reliability of inputs. The Company has categorized its cash, cash equivalents and investments within the hierarchy as follows:

*Level 1* - These valuations are based on a market approach using quoted prices in active markets for identical assets. Valuations of these products do not require a significant degree of judgment. Assets utilizing Level 1 inputs include investments in money market funds, U.S. government and agency debt securities, bank deposits and exchange-traded equity securities of certain publicly held companies;

*Level 2* - These valuations are based on a market approach using quoted prices obtained from brokers or dealers for similar securities or for securities for which we have limited visibility into their trading volumes. Valuations of these products do not require a significant degree of judgment. Assets utilizing Level 2 inputs consist of investments in corporate debt securities; and

*Level 3* - These valuations are based on an income approach using certain inputs that are unobservable and are significant to the overall fair value measurement. Valuations of these products require a significant degree of judgment. Assets utilizing Level 3 inputs consist of investments in auction rate securities and asset backed debt securities that are not currently trading. In addition, the Company holds a warrant in a certain publicly held company that is classified using Level 3 inputs. The carrying balance of this warrant was immaterial at December 31, 2008 and March 31, 2008.

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

The following table presents information about the Company's assets that are measured at fair value on a recurring basis at December 31, 2008, and indicates the fair value hierarchy of the valuation techniques the Company utilized to determine such fair value:

<b>(In thousands)</b>	<b>December 31, 2008</b>	<b>Level 1</b>	<b>Level 2</b>	<b>Level 3</b>
Cash equivalents	\$ 1,163	\$ 1,163	\$	\$
U.S. government and agency debt securities	267,565	267,565		
Corporate debt securities	76,504	4,240	72,264	
Asset backed debt securities	6,607			6,607
Auction rate securities	8,858			8,858
Strategic equity investments	795	795		
<b>Total</b>	<b>\$ 361,492</b>	<b>\$ 273,763</b>	<b>\$ 72,264</b>	<b>\$ 15,465</b>

The fair values of the Company's investments in asset backed debt securities and auction rate securities are determined using certain inputs that are unobservable and significant to the overall fair value measurement. Typically, auction rate securities trade at their par value due to the short interest rate reset period and the availability of buyers or sellers of the securities at recurring auctions. However, 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 its investments in auction rate securities at December 31, 2008. The Company also used a discounted cash flow model to determine the estimated fair value of its investments in asset backed debt securities at December 31, 2008, as the asset backed debt securities are not actively trading. The assumptions used in the discounted cash flow models used to determine the estimated fair value of these securities include estimates for interest rates, timing of cash flows, expected holding periods and risk adjusted discount rates, which include a provision for default and liquidity risk. 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 inability to sell the investment in an active market, the creditworthiness of the issuer and any associated guarantees, the timing of expected future cash flows, and the expectation of the next time 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.

The following table is a rollforward of the fair value of the Company's investments in asset backed debt securities and auction rate securities whose fair value is determined using Level 3 inputs:

<b>(In thousands)</b>	<b>Fair Value</b>
Balance, April 1, 2008	\$ 18,612
Total unrealized losses included in earnings	
Total unrealized losses included in comprehensive income	(902)
Redemptions, at par value	(2,245)
<b>Balance, December 31, 2008</b>	<b>\$ 15,465</b>

In February 2007, the FASB issued SFAS No. 159, *The Fair Value Option for Financial Assets and Financial Liabilities Including an Amendment of FASB Statement No. 115* (SFAS No. 159). SFAS No. 159 permits, but does not require, entities to elect to measure selected financial instruments and certain other items at fair value. Unrealized gains and losses on items for which the fair value option has been elected are recognized in earnings at each reporting

period. The Company adopted the provisions of SFAS No. 159 on April 1, 2008 and did not elect to measure any new assets or liabilities at their respective fair values and, therefore, the adoption of SFAS No. 159 did not have an impact on its results of operations and financial position.

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

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

<b>(In thousands)</b>	<b>December 31, 2008</b>	<b>March 31, 2008</b>
Raw materials	\$ 7,699	\$ 8,373
Work in process	5,261	3,060
Finished goods	6,917	7,451
Consigned-out inventory	1,236	
Total	\$ 21,113	\$ 18,884

**8. ACCOUNTS PAYABLE AND ACCRUED EXPENSES**

Accounts payable and accrued expenses consist of the following:

<b>(In thousands)</b>	<b>December 31, 2008</b>	<b>March 31, 2008</b>
Accounts payable	\$ 5,364	\$ 7,042
Accrued compensation	9,211	11,245
Accrued interest	1,662	2,975
Accrued restructuring current portion	771	4,037
Accrued other	13,302	10,747
Total	\$ 30,310	\$ 36,046

**9. RESTRUCTURING**

In March 2008, the Company announced the decision by Eli Lilly and Company to discontinue the AIR<sup>®</sup> Insulin development program. As a result, the Company terminated approximately 150 employees and closed its commercial manufacturing facility in Chelsea, MA (the 2008 Restructuring). In connection with the 2008 Restructuring, the Company recorded net restructuring charges of \$6.9 million in the year ended March 31, 2008. At December 31, 2008, the Company had paid in cash approximately \$3.8 million in connection with the 2008 Restructuring.

Restructuring activity during the nine months ended December 31, 2008 for the 2008 Restructuring is as follows:

<b>(In thousands)</b>	<b>Facility Closure</b>	<b>Severance</b>	<b>Other Contract Losses</b>	<b>Total</b>
Balance, April 1, 2008	\$ 4,930	\$ 2,881	\$ 37	\$ 7,848
Additions		78	70	148
Payments	(725)	(2,959)	(107)	(3,791)
Other adjustments	149			149
Balance, December 31, 2008 (1)	\$ 4,354	\$	\$	\$ 4,354

- (1) At  
December 31,  
2008, the  
restructuring  
liability consists  
of \$0.8 million  
classified as  
current and  
\$3.6 million  
classified as  
long-term in the  
accompanying  
condensed  
consolidated  
balance sheets.

In June 2004, the Company and its former collaborative partner Genentech, Inc. announced the decision to discontinue commercialization of NUTROPIN DEPOT® (the 2004 Restructuring ). In connection with the 2004 Restructuring, the Company recorded charges of \$11.5 million in the year ended March 31, 2005. During the six months ended September 30, 2008, the Company paid \$0.1 million in facility closure costs and recorded an adjustment of \$0.1 million to reduce the 2004 Restructuring liability to zero. As of September 30, 2008, the 2004 Restructuring was complete.

**Table of Contents****ALKERMES, INC. AND SUBSIDIARIES****NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)****10. SHARE-BASED COMPENSATION**

Share-based compensation expense for the three and nine months ended December 31, 2008 and 2007 is as follows:

(In thousands)	Three Months Ended December 31,		Nine Months Ended December 31,	
	2008	2007	2008	2007
Cost of goods manufactured	\$ 291	\$ 319	\$ 1,148	\$ 1,279
Research and development	527	2,055	3,397	5,691
Selling, general and administrative	2,463	2,808	7,045	8,507
Total	\$ 3,281	\$ 5,182	\$ 11,590	\$ 15,477

At December 31, 2008 and March 31, 2008, \$0.2 million and \$0.3 million, respectively, of share-based compensation cost was capitalized and recorded as Inventory in the condensed consolidated balance sheets.

**11. EXTINGUISHMENT OF DEBT**

In June and July 2008, the Company purchased, in three privately negotiated transactions, \$75.0 million in principal amount of its outstanding 7% Notes for \$71.8 million. As a result of the purchases, \$95.0 million principal amount of the 7% Notes remains outstanding at December 31, 2008. The Company recorded a loss on the extinguishment of the purchased 7% Notes of \$2.0 million in the six months ended September 30, 2008, which was recorded as interest expense.

**12. 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 December 31, 2008, 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 earned income before income taxes of \$112.4 million and \$144.7 million during the three and nine months ended December 31, 2008, respectively and the Company recorded an income tax benefit of \$0.3 million and an income tax provision of \$0.6 million for the three and nine months ended December 31, 2008, respectively. This variation in the customary relationship between income earned before income taxes and the income tax provision is due to termination of the VIVITROL collaboration with Cephalon as discussed in Note 2, *Collaborations*. The Company previously recognized, for tax purposes, the milestone payments received from Cephalon under the VIVITROL collaboration. The income tax benefit and provision recorded for the three and nine months ended December 31, 2008, respectively, and the income tax provision of \$3.2 million and \$5.8 million for the three and nine months ended December 31, 2007, respectively, related to the U.S. alternative minimum tax (AMT). Included in the \$0.6 million provision for the nine months ended December 31, 2008 is a \$0.1 million estimated benefit as a result of the recently enacted *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 utilization of tax loss carryforwards is limited in the calculation of AMT and, as a result, a federal tax benefit was recorded in the three months ended December 31, 2008, and a federal tax charge was recorded in the nine months ended December 31, 2008 and in the three and nine months ended December 31, 2007. 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.

**13. 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 November 2007, Reliant Pharmaceuticals, Inc. ( Reliant ) was acquired by GlaxoSmithKline ( GSK ). Under the terms of the acquisition, the Company received \$166.9 million upon the closing of the transaction in December 2007 in exchange for the Company s investment in Series C convertible, redeemable preferred stock of Reliant. The Company is entitled to receive up to an additional \$7.7 million of funds held in escrow subject to the terms of an escrow agreement between GSK and Reliant. The escrowed funds represent the maximum potential amount of future payments that may be payable to GSK under the terms of the escrow agreement, which is effective for a period of 15 months following the closing of the transaction. The Company has not recorded a liability related to the indemnification to GSK, as the Company currently believes that it is remote that any of the escrowed funds will be needed to indemnify GSK for any losses it might incur related to the representations and warranties made by Reliant in connection with the acquisition.



**Table of Contents**

**ALKERMES, INC. AND SUBSIDIARIES**

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

**14. SEGMENT INFORMATION**

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

14

---

**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. 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. Headquartered in Cambridge, Massachusetts, we have research facilities in Massachusetts and a commercial manufacturing facility in Ohio.

**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 and 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 countries in 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; the successful continuation of development activities for our programs, including exenatide once weekly, a four-week formulation of RISPERDAL CONSTA, VIVITROL for opiate dependence, ALKS 27, ALKS 29 and ALKS 33; the timeline for the NDA submission for exenatide once weekly; the successful manufacture of our products and product candidates, including RISPERDAL CONSTA and VIVITROL, by us at a commercial scale, and the successful manufacture of exenatide once weekly by Amylin Pharmaceuticals, Inc. ( Amylin ); and our building a successful commercial infrastructure for VIVITROL. 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 and VIVITROL in sufficient quantities and with sufficient yields to meet our partners' requirements or to add additional production capacity for RISPERDAL CONSTA and VIVITROL, or unexpected events could interrupt manufacturing operations at our RISPERDAL CONSTA and VIVITROL manufacturing facility, which is the sole source of supply for these products; (iii) we may be unable to develop the commercial capabilities, and/or infrastructure, necessary to successfully commercialize VIVITROL; (iv) Cilag may be unable to receive approval for VIVITROL for the treatment of opioid dependence in Russia and for the treatment of alcohol and opioid dependence in the other countries in the CIS; (v) Cilag may be unable to successfully commercialize VIVITROL; (vi) third party payors may not cover or reimburse VIVITROL; (vii) we may be unable to scale-up and manufacture our product candidates commercially or economically; (viii) we may not be able to source raw materials for our production processes from third parties; (ix) Amylin may not be able to successfully operate the manufacturing facility for exenatide once weekly and the U.S. Food and Drug Administration ( FDA ) may not find the product produced in the Amylin facility comparable to the product used in the pivotal clinical study which was produced in our facility; (x) 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; (xi) we rely on our partners to determine the regulatory and marketing strategies for RISPERDAL CONSTA, including the four-week formulation of RISPERDAL CONSTA currently being developed by us, and our other partnered, non-proprietary programs; (xii) 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; (xiii) 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; (xiv) clinical trials may take more time or consume more resources than initially envisioned; (xv) results of earlier clinical trials may not necessarily be predictive of the safety and efficacy results in larger clinical trials; (xvi) our product candidates could be ineffective or unsafe during

**Table of Contents**

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; (xvii) after the completion of clinical trials for our product candidates, including exenatide once weekly, or after the submission for marketing approval of such product candidate, 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 product to receive marketing approval; (xviii) 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; (xix) technological change in the biotechnology or pharmaceutical industries could render our products and/or product candidates obsolete or non-competitive; (xx) difficulties or set-backs in obtaining and enforcing our patents and difficulties with the patent rights of others could occur; (xxi) we may incur losses in the future; (xxvi) 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; (xxii) we may not be able to liquidate or otherwise recoup our investments in our 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 unique formulation expertise and drug development technologies to develop, both with partners and on our own, innovative and competitively advantaged drug products that enhance patient outcomes in major therapeutic areas. We develop our own proprietary therapeutics by applying our innovative formulation expertise and drug development capabilities to create new pharmaceutical products. In addition, we enter into select collaborations with pharmaceutical and biotechnology companies to develop significant new product candidates, based on existing drugs and incorporating our technologies. Each of these approaches is discussed in more detail below.

**Product Developments*****RISPERDAL CONSTA***

RISPERDAL CONSTA is a long-acting formulation of risperidone, a product of Janssen, and is the first and only long-acting, FDA-approved atypical antipsychotic. The medication uses our proprietary Medisorb® technology to deliver and maintain therapeutic medication levels in the body through just one injection every two weeks. Schizophrenia is a brain disorder characterized by disorganized thinking, delusions and hallucinations. Studies have demonstrated that as many as 75 percent of patients with schizophrenia have difficulty taking their oral medication on a regular basis, which can lead to worsening of symptoms. Clinical data has shown that treatment with RISPERDAL CONSTA may lead to improvements in symptoms, sustained remission and decreases in hospitalization. RISPERDAL CONSTA is marketed by Janssen and is exclusively manufactured by us. RISPERDAL CONSTA was first approved by regulatory authorities in the United Kingdom ( UK ) and Germany in August 2002 and the FDA in October 2003. RISPERDAL CONSTA is approved in approximately 85 countries and marketed in approximately 60 countries, and Janssen continues to launch the product around the world.

In April 2008, we announced that our partner, Johnson & Johnson Pharmaceutical Research & Development, L.L.C. ( J&JPRD ), submitted a Supplemental New Drug Application ( sNDA ) for RISPERDAL CONSTA to the FDA seeking approval for adjunctive maintenance treatment to delay the occurrence of mood episodes in patients with frequently relapsing bipolar disorder ( FRBD ). FRBD is defined as four or more manic or depressive episodes in the previous year that require a doctor's care. The condition may affect 10 to 20 percent of the estimated 27 million people world-wide with bipolar disorder.

In May 2008, the results of a study sponsored by Janssen were presented at the American Psychiatric Association ( APA ) 161st Annual Meeting in Washington D.C. This 24 - month, open-label, active-controlled, international study investigated whether treatment with Risperidone Long-Acting Injection ( RLAI ), compared with oral quetiapine when

tested in a routine care setting within general psychiatric services, had an effect on long-term efficacy maintenance as measured by time to relapse in patients with schizophrenia. The results demonstrated that the average relapse-free time was significantly longer in patients treated with RLAI (607 days) compared to quetiapine (533 days) ( $p < 0.0001$ ). Furthermore, over the 24 - month treatment period, relapse occurred in 16.5 percent of patients treated with RLAI and 31.3 percent in the quetiapine treatment arm.

**Table of Contents**

In July 2008, we announced that our partner J&JPRD submitted a sNDA for RISPERDAL CONSTA to the FDA for approval as monotherapy in the maintenance treatment of bipolar I disorder to delay the time to occurrence of mood episodes in adults. Bipolar disorder is a brain disorder that causes unusual shifts in a person's mood, energy and ability to function. Characterized by debilitating mood swings, from extreme highs (mania) to extreme lows (depression), bipolar I disorder affects an estimated 5.7 million, or 2.6 percent, of the American adult population in any given year.

In October 2008, the FDA approved the deltoid muscle of the arm as a new injection site for RISPERDAL CONSTA. RISPERDAL CONSTA was previously approved as a gluteal injection only.

In January 2009, we announced that J&JPRD initiated a phase 1, single-dose, open-label study of a four-week formulation of RISPERDAL CONSTA for the treatment of schizophrenia. The study is designed to assess the pharmacokinetics, safety and tolerability of a gluteal injection of this risperidone formulation in approximately 26 patients diagnosed with chronic, stable schizophrenia.

**VIVITROL**

We developed VIVITROL, an extended-release Medisorb formulation of naltrexone, for the treatment of alcohol dependence in patients who are able to abstain from drinking in an outpatient setting and are not actively drinking prior to treatment initiation. Alcohol dependence is a serious and chronic brain disease characterized by cravings for alcohol, loss of control over drinking, withdrawal symptoms and an increased tolerance for alcohol. Adherence to medication is particularly challenging with this patient population. In clinical trials, when used in combination with psychosocial support, VIVITROL was shown to reduce the number of drinking days and heavy drinking days and to prolong abstinence in patients who abstained from alcohol the week prior to starting treatment. Each injection of VIVITROL provides medication for one month and alleviates the need for patients to make daily medication dosing decisions. VIVITROL was approved by the FDA in April 2006 and was launched in June 2006.

In April 2007, we submitted a Marketing Authorization Application ( MAA ) for VIVITROL for the treatment of alcohol dependence to regulatory authorities in the UK and Germany based on the single pivotal clinical study used to register VIVITROL in the U.S. In July 2008, based on feedback from the UK health authorities that data from a single study would not be sufficient to register VIVITROL in the UK and Germany, we withdrew the MAA.

In December 2007, we entered into an exclusive agreement with Cilag to commercialize VIVITROL for the treatment of alcohol dependence and opioid dependence in Russia and other countries in the CIS. In August 2008, we announced that Cilag received approval from the Russian regulatory authority to market VIVITROL for the treatment of alcohol dependence. Janssen-Cilag, an affiliate company of Cilag, will commercialize VIVITROL. We retain exclusive development and marketing rights to VIVITROL in all markets outside Russia and other countries in the CIS. We are responsible for manufacturing VIVITROL and will receive manufacturing fees and royalties based on product sales.

In June 2008, we initiated a randomized, multi-center registration study of VIVITROL in Russia for the treatment of opioid dependence. The multi-center study is designed to assess the efficacy and safety of VIVITROL in approximately 200 patients diagnosed with opioid dependence. The clinical data from this study may form the basis of a sNDA to the FDA for VIVITROL for the treatment of opioid dependence, a chronic brain disease.

In November 2008, we and Cephalon agreed to end the collaboration for the development, supply and commercialization of certain products, including VIVITROL in the U.S., effective December 1, 2008 (the Termination Date ), and we assumed the risks and responsibilities for the marketing and sale of VIVITROL in the U.S. We paid Cephalon \$16.0 million for title to two partially completed VIVITROL manufacturing lines, and we received \$11.0 million from Cephalon as payment to fund their share of estimated VIVITROL product losses during the one-year period following the Termination Date. As of the Termination Date, Cephalon is no longer responsible for the marketing and sale of VIVITROL in the U.S., and we are responsible for all VIVITROL profits or losses. Cephalon has no rights to royalty payments on future sales of VIVITROL. For a period of six months following the Termination Date, in order to facilitate the transfer of commercialization of VIVITROL to us, Cephalon, at our option, performs certain transition services on our behalf. Cephalon provides us with transition services at a full-time equivalent rate ( FTE ) agreed to by the parties.



**Table of Contents*****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) which 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 sulfonylurea; two commonly used oral diabetes medications. In December 2006, the FDA approved BYETTA as an add-on therapy for people with type 2 diabetes unable to achieve adequate glucose control on thiazolidinedione, a class of diabetes medications. Amylin has an agreement with Eli Lilly and Company (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 June 2008, we, Amylin and Lilly announced positive results from a 52-week, open-label clinical study (DURATION-1 study) that showed the durable efficacy of exenatide once weekly. At 52 weeks, patients taking exenatide once weekly showed an average A1C improvement of 2 percent and an average weight loss of 9.5 pounds. The study also showed that patients who switched from BYETTA injection after 30 weeks to exenatide once weekly experienced additional improvements in A1C and fasting plasma glucose. 74 percent of all patients in the study achieved an endpoint of A1C of 7 percent or less at 52 weeks. Exenatide once weekly was well tolerated, with no major hypoglycemia events regardless of background therapy and nausea was predominantly mild and transient.

In November 2008, we announced that Amylin had received feedback from the FDA that the data it submitted from its *in vitro in vivo* correlation studies to demonstrate comparability between exenatide once weekly manufactured by us in our facility, and used in previous clinical studies, and exenatide once weekly manufactured on a commercial scale in Amylin's Ohio facility did not meet FDA requirements. In December 2008, the FDA indicated that the ongoing extension of the DURATION-1 study is appropriate to use as the basis for demonstrating comparability between intermediate-scale clinical trial material made in our manufacturing facility and the commercial-scale drug product made at Amylin's manufacturing facility. The DURATION-1 study is ongoing and results are expected in early calendar 2009. The collaboration is planning to submit an NDA to the FDA by the end of the first half of calendar 2009. Additional studies designed to demonstrate the superiority of exenatide once weekly are ongoing.

***ALKS 29***

We are developing ALKS 29, an oral compound for the treatment of alcohol dependence. In July 2007, we announced positive preliminary results from a phase 1/2 multi-center, randomized, double-blind, placebo-controlled, eight-week study that was designed to assess the efficacy and safety of ALKS 29 in approximately 150 alcohol dependent patients. In the study, ALKS 29 was generally well tolerated and led to both a statistically significant increase in the percent of days abstinent and a decrease in drinking compared to placebo when combined with psychosocial therapy. The study endpoints included the percent of days abstinent, percent of heavy drinking days and number of drinks per day. Heavy drinking was defined as five or more drinks per day for men and four or more drinks per day for women.

In December 2008, we initiated a phase 1, open-label crossover study of ALKS 29, which is designed to assess the pharmacokinetics, safety and tolerability of ALKS 29 compared to an oral control. We expect to report top-line results from the study in the first half of calendar 2009.

***ALKS 27***

Using our AIR® pulmonary technology, we are independently developing an inhaled trospium product for the treatment of chronic obstructive pulmonary disease (COPD). COPD is a serious, chronic disease characterized by a gradual loss of lung function. Last year, we reported positive clinical data from a phase 2a study showing that single doses of ALKS 27 demonstrated a rapid onset of action and produced a significant improvement in lung function compared to placebo. We are manufacturing clinical trial material for a phase 2 dose ranging study expected to start in the first quarter of calendar 2009.

***ALKS 33***



ALKS 33 is a novel opioid modulator, identified from the library of compounds in-licensed from Rensselaer Polytechnic Institute ( RPI ). These compounds represent an opportunity for us to develop important therapeutics for a broad range of diseases and medical conditions, including addiction, pain and other central nervous system disorders. In July 2008, we announced positive preclinical results for three proprietary molecules targeting opioid receptors, including ALKS 33. The study results included efficacy data from an

**Table of Contents**

ethanol drinking behavior model in rodents, a well-characterized model for evaluating the effects of potential therapeutics targeting opioid receptors. Results showed that single, oral doses of our novel molecules significantly reduced the ethanol drinking behavior in rodents, with an average reduction from baseline ranging from 35 percent to 50 percent for the proprietary molecules compared to 10 percent for the naltrexone control arm (P less than 0.05). Details from an evaluation of the *in vivo* pharmacology, pharmacokinetics and *in vitro* metabolism were also presented. Data showed that the molecules have improved metabolic stability compared to the naltrexone control arm when cultured with human hepatocytes (liver cells), suggesting that they are not readily metabolized by the liver, a unique advantage over existing oral therapies for addiction. Pharmacokinetic results showed that the oral bioavailability of ALKS 33 was significantly greater than that of the active control.

In December 2008, we initiated a phase 1 randomized, double-blind, placebo-controlled study for ALKS 33 in approximately 16 healthy volunteers. The study is designed to assess the pharmacokinetics, safety and tolerability of ALKS 33 following single oral administration at escalating dose levels. Initiation of this trial is based on recent data from preclinical studies that showed ALKS 33 demonstrated statistically superior oral efficacy compared to naltrexone. We expect to report top-line results from the study in the first half of calendar 2009.

**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 the 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. Except as noted in this section, refer to Part II, Item 7 of our Annual Report on Form 10-K for the year ended March 31, 2008 in the Critical Accounting Policies section for a discussion of our critical accounting policies and estimates.

**Product Revenue Recognition** On December 1, 2008, we became responsible for the marketing and sale of VIVITROL in the U.S. We recognize revenue from the sale of VIVITROL upon delivery, when title and associated risk of product loss has passed to the customer, and collectibility is reasonably assured. Due to the expected introduction of a return policy, and as we do not have history to allow us to estimate returns, we defer the recognition of revenue on shipments of VIVITROL to our customers until the product has left the distribution channel. We estimate product shipments out of the distribution channel through data provided by external sources, including information as to inventory levels provided by our wholesalers, specialty distributor and specialty pharmacies, as well as prescription information. In order to match the cost of goods related to products shipped to customers with the associated revenue, we are deferring the recognition of the cost of goods to the period in which the associated revenue will be recognized.

**Financial Highlights Three and Nine Months Ended December 31, 2008**

Net income for the three months ended December 31, 2008 was \$112.7 million, or \$1.18 per common share basic and diluted, as compared to net income of \$168.9 million, or \$1.66 per common share basic and \$1.63 per common share diluted, for the three months ended December 31, 2007. Net income for the nine months ended December 31, 2008 was \$144.1 million, or \$1.51 per common share basic and \$1.49 per common share diluted, as compared to net income of \$185.3 million, or \$1.82 per common share basic and \$1.78 per common share diluted, for the nine months ended December 31, 2007.

In connection with the termination of the VIVITROL collaboration with Cephalon, we recognized \$120.7 million of previously deferred and unearned milestone revenue as net collaborative profit in the three months ended December 31, 2008.

Worldwide sales of RISPERDAL CONSTA by Janssen were \$318.8 million and \$999.5 million for the three and nine months ended December 31, 2008, respectively, as compared to \$295.1 million and \$867.4 million for the three and nine months ended December 31, 2007, respectively.

**Table of Contents****Results of Operations****Revenues**

(In millions)	Three Months Ended December 31,			Nine Months Ended December 31,		
	2008	2007	Change	2008	2007	Change
Manufacturing revenues:						
RISPERDAL CONSTA	\$ 21.3	\$ 12.9	\$ 8.4	\$ 88.0	\$ 66.1	\$ 21.9
VIVITROL	(0.8)	1.4	(2.2)	4.2	3.9	0.3
Total manufacturing revenues	20.5	14.3	6.2	92.2	70.0	22.2
Royalty revenues	8.0	7.4	0.6	25.0	21.7	3.3
Research and development revenue under collaborative arrangements	3.8	24.0	(20.2)	40.4	68.6	(28.2)
Net collaborative profit	123.4	5.1	118.3	125.4	18.0	107.4
Total revenues	\$ 155.7	\$ 50.8	\$ 104.9	\$ 283.0	\$ 178.3	\$ 104.7

**Manufacturing Revenues**

Under our manufacturing and supply agreement with Janssen, we earn manufacturing revenues when RISPERDAL CONSTA 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 nine months ended December 31, 2008 and 2007, 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 during the fiscal year ending March 31, 2009.

The increase in RISPERDAL CONSTA manufacturing revenues for the three and nine months ended December 31, 2008, as compared to the three and nine months ended December 31, 2007, was primarily due to a 95% and 29% increase in units shipped to Janssen, respectively, and to unit net sales price increases. Shipments of RISPERDAL CONSTA were lower in the three and nine months ended December 31, 2007 as Janssen was managing its product inventory due in part to increased efficiencies and reliability in our RISPERDAL CONSTA manufacturing process. For the three months ended December 31, 2008, the increase in the unit net sales price was partially offset by an overall strengthening of the U.S. dollar in relation to the foreign currencies of the countries in which the product was sold. For the nine months ended December 31, 2008, the increase in the unit net sales price was due in part to an overall weakening in the exchange ratio of the U.S. dollar in relation to the foreign currencies of the countries in which the product was sold. See Part I, Item 3. Quantitative and Qualitative Disclosures about Market Risk for information on foreign currency exchange rate risk related to RISPERDAL CONSTA revenues.

In connection with the termination of the VIVITROL collaboration with Cephalon, we assumed title to certain VIVITROL inventory which we had previously sold to Cephalon prior to the termination. In the three months ended December 31, 2008, we reduced manufacturing revenues by \$(0.8) million to reverse the previous sale of this inventory to Cephalon. VIVITROL manufacturing revenues for the three months ended December 31, 2007 consisted entirely of product shipped to Cephalon. For the nine months ended December 31, 2008, VIVITROL manufacturing revenues consisted of \$2.8 million of billings to Cephalon for failed product batches, \$0.7 million of net shipments of VIVITROL to Cephalon, \$0.3 million related to manufacturing profit on VIVITROL, which equals a 10% markup on VIVITROL cost of goods manufactured, all occurring prior to the termination of the VIVITROL collaboration; and \$0.4 million of shipments of VIVITROL to Janssen-Cilag to support commercialization of VIVITROL in Russia. For the nine months ended December 31, 2007, VIVITROL manufacturing revenues consisted of \$2.2 million of billings

to Cephalon for idle capacity costs, \$1.4 million of shipments of VIVITROL to Cephalon and \$0.3 million related to manufacturing profit on VIVITROL, which equals a 10% markup on VIVITROL cost of goods manufactured. Due to the termination of the VIVITROL collaboration with Cephalon, we expect a decrease in VIVITROL manufacturing revenues after December 31, 2008 as we will earn manufacturing revenues only on VIVITROL sold to Janssen-Cilag for sale in Russia.

Prior to the termination of the VIVITROL collaboration with Cephalon, gross sales of VIVITROL by Cephalon were \$3.1 million and \$12.6 million for the three and nine months ended December 31, 2008, respectively, and \$5.0 million and \$13.7 million for the three and nine months ended December 31, 2007, respectively. We began selling VIVITROL in the U.S. on December 1, 2008 upon the termination of the VIVITROL collaboration with Cephalon and had gross shipments of \$1.6 million made primarily to

**Table of Contents**

pharmaceutical wholesalers, specialty pharmacies and distributors. We defer the recognition of revenue on shipments of VIVITROL to our customers until the product has left the distribution channel. We estimate product shipments out of the distribution channel through data provided by external sources, including information on inventory levels provided by our wholesalers, distributors and specialty pharmacies as well as prescription information.

*Royalty Revenues*

Royalty revenues for the three and nine months ended December 31, 2008 and 2007 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. Royalty revenues for the three and nine months ended December 31, 2008 were based on RISPERDAL CONSTA sales of \$318.8 million and \$999.5 million, respectively. Royalty revenues for the three and nine months ended December 31, 2007 were based on RISPERDAL CONSTA sales of \$295.1 million and \$867.4 million, respectively. For the three months ended December 31, 2008, the increase in sales was partially offset by an overall strengthening of the U.S. dollar in relation to the foreign currencies of the countries in which the product was sold. For the nine months ended December 31, 2008, the increase sales was due in part to an overall weakening of the U.S. dollar in relation to the foreign currencies of the countries in which the product was sold. See Part I, Item 3. Quantitative and Qualitative Disclosures about Market Risk for information on foreign currency exchange rate risk related to RISPERDAL CONSTA revenues.

*Research and Development Revenue Under Collaborative Arrangements*

The decrease in research and development revenue under collaborative arrangements ( R&D revenue ) for the three months ended December 31, 2008, as compared to the three months ended December 31, 2007, was primarily due to the termination of the AIR Insulin development program in March 2008 and reductions in revenues earned under the exenatide once weekly development program, partially offset by increased revenues earned on the four-week RISPERDAL CONSTA development program. The decrease in R&D revenue for the nine months ended December 31, 2008, as compared to the nine months ended December 31, 2007, was due to the termination of the AIR Insulin development program, reductions in revenues earned under the exenatide once weekly development program and the termination of the AIR parathyroid hormone ( PTH ) development program in the quarter ended September 30, 2007, partially offset by increased revenues earned on the four-week RISPERDAL CONSTA development program.

In June 2008, we entered into an agreement with Eli Lilly and Company ( Lilly ) in connection with the termination of the development and license agreements and supply agreement for the development of AIR Insulin (the AIR Insulin Termination Agreement ). Under the AIR Insulin Termination Agreement, we received \$40.0 million in cash as payment for all services we had performed through the date of the AIR Insulin Termination Agreement. We previously recognized \$14.5 million of this payment as R&D revenue in the year ended March 31, 2008 and recognized \$25.5 million of this payment as R&D revenue in the three months ended June 30, 2008. Revenues from the AIR Insulin development program totaled \$10.9 million and \$36.8 million for the three and nine months ended December 31, 2007, respectively. We do not expect to record any material amounts of revenue from the AIR Insulin development program in the future.

The decrease in the revenues earned under the exenatide once weekly development program was due to reduced activity as the program nears the anticipated date of submission of the NDA to the FDA. Revenues from the exenatide once weekly development program totaled \$1.5 million and \$9.3 million for the three and nine months ended December 31, 2008, as compared to \$12.5 million and \$24.9 million for the three and nine months ended December 31, 2007. We also saw a decline in revenues during the nine months ended December 31, 2008, as compared to the nine months ended December 31, 2007, due to the termination of the AIR PTH development program during the three months ended September 30, 2007. This decline was partially offset by revenues earned on the four-week RISPERDAL CONSTA development program.

**Table of Contents***Net Collaborative Profit*

Net collaborative profit for the three and nine months ended December 31 consists of the following:

(In millions)	Three Months Ended December 31,		Nine Months Ended December 31,	
	2008	2007	2008	2007
Milestone revenue cost recovery	\$	\$	\$	\$
Milestone revenue license	0.8	1.3	3.5	5.3
Total milestone revenue cost recovery and license	0.8	1.3	3.5	9.2
Net payments from Cephalon	0.7	3.8		8.8
VIVITROL losses funded by Cephalon, post termination	1.2		1.2	
Recognition of deferred and unearned milestone revenue due to termination of VIVITROL collaboration	120.7		120.7	
Net collaborative profit	\$ 123.4	\$ 5.1	\$ 125.4	\$ 18.0

Prior to the termination of the VIVITROL collaboration, Cephalon had paid us an aggregate of \$274.6 million in non-refundable milestone payments and we were responsible to fund the first \$124.6 million of cumulative net losses incurred on VIVITROL (the cumulative net loss cap). VIVITROL reached the cumulative net loss cap in April 2007, at which time Cephalon became responsible to fund all net losses incurred on VIVITROL through December 31, 2007. Beginning January 1, 2008, all net losses incurred on VIVITROL within the collaboration were divided between us and Cephalon in approximately equal shares. For the three and nine months ended December 31, 2008, we recognized no milestone revenue cost recovery, as VIVITROL had reached the cumulative loss cap prior to these reporting periods. Milestone revenue license, related to the license provided to Cephalon to commercialize VIVITROL and was being recognized on a straight-line basis over 10 years, at approximately \$5.2 million per year. Net payments from Cephalon were received based upon the sharing of VIVITROL costs and losses incurred during the reporting periods.

Upon the termination of the VIVITROL collaboration with Cephalon, we received \$11.0 million from Cephalon to fund their share of VIVITROL product losses during the one-year period following the Termination Date. We recorded the \$11.0 million as deferred revenue and are recognizing it as revenue through the application of a proportional performance model based on VIVITROL net product losses. In the three months ended December 31, 2008, we recognized \$1.2 million of revenue under proportional performance. In addition, we recognized \$120.7 million of net collaborative profit, consisting of \$113.9 million of unearned milestone revenue that existed at the Termination Date and \$6.8 million of deferred revenue. At the Termination Date, we had \$22.8 million of deferred revenue related to the original sale of the two partially completed VIVITROL manufacturing lines to Cephalon. We paid Cephalon \$16.0 million to acquire the title to these manufacturing lines and accounted for the payment as a reduction to deferred revenue. The remaining \$6.8 million of deferred revenue and the \$113.9 million of unearned milestone revenue were recognized in the three months ended December 31, 2008, as we had no remaining performance obligations to Cephalon and the amounts were nonrefundable. We do not expect to recognize any further net collaborative profit after the \$11.0 million payment has been fully recognized as revenue, which we expect to occur in fiscal year 2010.

*Expenses*

(In millions)	Three Months Ended December 31,			Nine Months Ended December 31,		
	2008	2007	Change	2008	2007	Change
Cost of goods sold:						
RISPERDAL CONSTA	\$ 5.0	\$ 5.9	\$ 0.9	\$ 24.0	\$ 23.0	\$ (1.0)

Edgar Filing: ALKERMES INC - Form 10-Q

VIVITROL	0.5	1.6	1.1	7.9	3.9	(4.0)
Total cost of goods sold	5.5	7.5	2.0	31.9	26.9	(5.0)
Research and development	22.7	30.4	7.7	64.6	91.3	26.7
Selling, general and administrative	14.6	15.2	0.6	38.2	45.1	6.9
Total expenses	\$ 42.8	\$ 53.1	\$ 10.3	\$ 134.7	\$ 163.3	\$ 28.6

*Cost of Goods Sold*

**Table of Contents**

RISPERDAL CONSTA cost of goods sold for the three months ended December 31, 2008 decreased, as compared to the three months ended December 31, 2007, due to a decrease in the unit cost of RISPERDAL CONSTA shipped, partially offset by an increase in the number of units shipped. The increase in RISPERDAL CONSTA cost of goods sold for the nine months ended December 31, 2008, as compared to the nine months ended December 31, 2007, was due to an increase in units of RISPERDAL CONSTA shipped to Janssen, partially offset by a decrease in the unit cost of RISPERDAL CONSTA shipped.

VIVITROL cost of goods sold for the three months ended December 31, 2008 consisted of \$1.0 million of expense related to the restart of the VIVITROL manufacturing line following a planned manufacturing shutdown, \$0.2 million of cost for failed product batches, offset by a reduction in cost of goods sold due to the reversal of prior sales of VIVITROL to Cephalon of \$0.7 million in connection with the termination of the VIVITROL collaboration with Cephalon. Cost of goods sold for VIVITROL for the three months ended December 31, 2007 consisted of \$1.1 million for shipments of VIVITROL to Cephalon and \$0.5 million for idle capacity costs, which consisted of current period manufacturing costs related to underutilized VIVITROL manufacturing capacity.

VIVITROL cost of goods sold for the nine months ended December 31, 2008 consisted of \$3.6 million of expense related to the restart of the VIVITROL manufacturing line following a planned shutdown, \$3.4 million of cost for failed batches, \$1.3 million for shipments of VIVITROL to Cephalon, and \$0.3 million of shipments to Janssen-Cilag to support the commercialization of VIVITROL in Russia. These costs were partially offset by the reversal of prior sales of VIVITROL to Cephalon of \$0.7 million. Cost of goods sold for VIVITROL for the nine months ended December 31, 2007 consisted of \$1.1 million for shipments of VIVITROL to Cephalon and \$2.8 million for idle capacity costs, which consisted of current period manufacturing costs related to underutilized VIVITROL manufacturing capacity.

*Research and Development*

The decrease in research and development expenses for the three months ended December 31, 2008, as compared to the three months ended December 31, 2007, was primarily due to the termination of the AIR Insulin development program in March 2008, and reductions in costs on the exenatide once weekly development program as the program nears the anticipated date of submission of the NDA to the FDA. These reductions were partially offset by increased costs on the ALKS 29 and ALKS 33 programs, which began phase 1 clinical trials in the three months ended December 31, 2008, costs related to the four-week RISPERDAL CONSTA development program, which began phase 1 clinical trials in January 2009, and the VIVITROL opioid dependence development program, in which a multi-center registration study was initiated in June 2008.

The decrease in research and development expenses for the nine months ended December 31, 2008, as compared to the nine months ended December 31, 2007, was primarily due to the termination of the AIR Insulin development program in March 2008, the termination of the AIR PTH development program in the quarter ended September 30, 2007 and reductions in costs on the exenatide once weekly development program. These reductions were partially offset by increased costs on the ALKS 29, ALKS 33, four-week RISPERDAL CONSTA and the VIVITROL opioid dependence development programs.

A significant portion of our research and development expenses (including laboratory supplies, travel, dues and subscriptions, recruiting costs, temporary help costs, consulting costs and allocable costs such as occupancy and depreciation) are not tracked by project as they benefit multiple projects or our technologies in general. Expenses incurred to purchase specific services from third parties to support our collaborative research and development activities are tracked by project and are reimbursed to us by our partners. We generally bill our partners under collaborative arrangements using a negotiated full-time equivalent ( 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*



The decrease in selling, general and administrative expenses for the three months ended December 31, 2008, as compared to the three months ended December 31, 2007, was primarily due to a decrease in share-based compensation expense, consulting expense and IT-related expenses, partially offset by increased sales and marketing expenses in December 2008 related to VIVITROL. The decrease in selling, general and administrative expenses for the nine months ended December 31, 2008, as compared to the nine months ended December 31, 2007, was primarily due to a decrease in personnel related costs, including share-based compensation expense, professional fees and taxes, partially offset by the increased sales and marketing expenses related to VIVITROL.

**Table of Contents****Other (Expense) Income**

(In millions)	Three Months Ended			Nine Months Ended		
	December 31,			December 31,		
	2008	2007	Change	2008	2007	Change
Interest income	\$ 2.6	\$ 4.3	\$ (1.7)	\$ 8.9	\$ 12.9	\$ (4.0)
Interest expense	(2.4)	(4.1)	1.7	(10.9)	(12.2)	1.3
Other (expense) income	(0.7)	(0.4)	(0.3)	(1.5)	0.8	(2.3)
Gain on sale of investment in Reliant Pharmaceuticals, Inc.		174.6	(174.6)		174.6	(174.6)
Total other (expense) income	\$ (0.5)	\$ 174.4	\$ (174.9)	\$ (3.5)	\$ 176.1	\$ (179.6)

**Interest income**

The decrease in interest income for the three and nine months ended December 31, 2008, as compared to the three and nine months ended December 31, 2007, was due to lower interest rates earned during the comparable periods, partially offset by a higher average balance of cash and investments. We expect our interest earnings to decrease as compared to prior periods due to a general reduction in interest rates.

**Interest expense**

The decrease in interest expense for the three months ended December 31, 2008, as compared to December 31, 2007, was a result of the purchase of \$75.0 million in principal amount of our non-recourse RISPERDAL CONSTA secured 7% notes (the 7% Notes ) in three privately negotiated transactions in June and July 2008. The decrease in interest expense for the nine months ended December 31, 2008, as compared to December 31, 2007, was due to reduced interest expense due to the repurchase of the 7% Notes, partially offset by an aggregate of \$2.0 million in debt extinguishment charges related to the 7% Notes repurchases, which were recorded as interest expense in June and July 2008. We expect our interest expense to decrease as compared to prior periods due to the decrease in our borrowings.

**Other (expense) income**

The increase in other expense for the three months ended December 31, 2008, as compared to the three months ended December 31, 2007, was primarily due to increased charges for other-than-temporary impairments on our investments in the common stock of certain publicly held companies. Other expense during the nine months ended December 31, 2008 consisted primarily of charges for other-than-temporary impairments on our investments in the common stock of certain publicly held companies, compared to other income during the nine months ended December 31, 2007, which consisted primarily of income recognized on the changes in the fair value of our investments in warrants of certain publicly held companies, partially offset by other-than-temporary impairment charges on our investments in the common stock of certain publicly held companies.

**Gain on sale of investment in Reliant Pharmaceuticals, Inc.**

The gain on sale of investment in Reliant Pharmaceuticals, Inc. ( Reliant ), for the three and nine months ended December 31, 2007 is due to the purchase of Reliant by GlaxoSmithKline ( GSK ) in November 2007. Under the terms of the acquisition, we received \$166.9 million upon the closing of the transaction in December 2007 in exchange for our investment in Series C convertible, redeemable preferred stock of Reliant. In March 2009, we are entitled to receive up to an additional \$7.7 million of funds held in escrow subject to the terms of an escrow agreement between GSK and Reliant.

**Income Taxes**

(In millions)	Three Months Ended			Nine Months Ended		
	December 31,			December 31,		
	2008	2007	Change	2008	2007	Change
Income tax (benefit) provision	\$ (0.3)	\$ 3.2	\$ 3.5	\$ 0.6	\$ 5.8	\$ 5.2



**Table of Contents**

We earned income before income taxes of \$112.4 million and \$144.7 million during the three and nine months ended December 31, 2008, respectively, and we recorded an income tax benefit of \$0.3 million and an income tax provision of \$0.6 million for the three and nine months ended December 31, 2008, respectively. This variation is due to the termination of the VIVITROL collaboration with Cephalon. We previously recognized, for tax purposes, the milestone payments received from Cephalon under the VIVITROL collaboration. The income tax benefit and provision recorded for the three and nine months ended December 31, 2008, respectively, and the income tax provision of \$3.2 million and \$5.8 million for the three and nine months ended December 31, 2007, respectively, related to the U.S. alternative minimum tax ( AMT ). Included in the \$0.6 million provision for the nine months ended December 31, 2008 is a \$0.1 million estimated benefit as a result of the recently enacted *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 utilization of tax loss carryforwards is limited in the calculation of AMT and, as a result, a federal tax benefit was recorded in the three months ended December 31, 2008, and a federal tax charge was recorded in the nine months ended December 31, 2008 and in the three and nine months ended December 31, 2007. 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.

**Liquidity and Capital Resources**

Our financial condition is summarized as follows:

<b>(In millions)</b>	<b>December 31, 2008</b>	<b>March 31, 2008</b>
Cash and cash equivalents	\$ 63.3	\$ 101.2
Investments short-term	281.4	240.1
Investments long-term	78.9	119.1
Total cash, cash equivalents and investments	\$ 423.6	\$ 460.4
Working capital	\$ 341.7	\$ 371.1
Outstanding borrowings current and long-term	\$ 92.4	\$ 160.4

**Operating Activities**

Cash provided by operating activities was \$43.2 million and \$28.0 million for the nine months ended December 31, 2008 and 2007, respectively. The increase in cash flows from operating activities in the nine months ended December 31, 2008, as compared to the nine months ended December 31, 2007, was primarily due to the \$40.0 million we received from Lilly related to the AIR Insulin Termination Agreement, of which \$25.5 million was recognized as revenue in the first quarter of fiscal 2009, and a net reduction in working capital accounts.

**Investing Activities**

Cash provided by investing activities was \$0.9 million and \$231.3 million for the nine months ended December 31, 2008 and 2007, respectively. The decrease in cash provided by investing activities in the nine months ended December 31, 2008, as compared to the nine months ended December 31, 2007, was due to the \$166.9 million we received from the sale of our investment in Reliant and \$82.1 million in net sales of investments in the nine months ended December 31, 2007, partially offset by reduced purchases of property, plant and equipment.

**Financing Activities**

Cash used in financing activities was \$82.1 million and \$18.9 million in the nine months ended December 31, 2008 and 2007, respectively. The increase in cash used in financing activities in the nine months ended December 31, 2008, as compared to the nine months ended December 31, 2007, was due to the purchase of \$75.0 million principal amount of our non-recourse RISPERDAL CONSTA 7% notes (the 7% Notes ) for \$71.8 million during the nine months ended

December 31, 2008, partially offset by a \$9.7 million decrease in the amount of treasury stock purchased under our publicly announced share repurchase programs.

We invest in short-term and long-term investments consisting of U.S. government and agency debt securities, investment grade corporate debt securities, including asset backed debt securities, and student loan backed auction rate securities issued by major financial institutions in accordance with our documented corporate policies. Our investment objectives are, first, to assure liquidity

**Table of Contents**

and conservation of capital and, second, to obtain investment income. At December 31, 2008, we had gross unrealized gains of \$4.0 million and gross unrealized losses of \$5.8 million in our investment portfolio. We performed an analysis of our investments with unrealized losses at December 31, 2008 for impairment and determined that they are temporarily impaired and consist primarily of investments in corporate debt securities, including asset backed debt securities and student loan backed auction rate securities. We determined that we had an other-than-temporary impairment of \$0.6 million attributed to investments in the common stock of certain collaborative partners. Temporary impairments are unrealized and are recorded in accumulated other comprehensive income, a component of shareholders' equity. Other-than-temporary impairments are realized and recorded in our condensed consolidated statements of income.

At December 31, 2008, we have classified \$74.2 million of our available-for-sale investments in securities with temporary losses of \$5.8 million as Investments - Long-Term in the accompanying condensed consolidated balance sheet, as we believe the recovery of the losses will extend beyond one year and we have the intent and ability to hold the investments to recovery, which may be maturity.

On April 1, 2008, we implemented SFAS No. 157, *Fair Value Measurements* ( SFAS No. 157 ) for our financial assets and liabilities that are re-measured and reported at fair value at each reporting period. SFAS No. 157 provides a framework for measuring fair value and requires expanded disclosures regarding fair value measurements. SFAS No. 157 defines fair value as the price that would be received to sell an asset or paid to transfer a liability (the exit price ) in an orderly transaction between market participants at the measurement date. In determining fair value, SFAS No. 157 permits the use of various valuation approaches, including market, income and cost approaches. SFAS No. 157 establishes a hierarchy for inputs used in measuring fair value that maximizes the use of observable inputs and minimizes the use of unobservable inputs by requiring that the observable inputs be used when available.

The fair value hierarchy is broken down into three levels based on the reliability of inputs. We have categorized our cash, cash equivalents and investments within the hierarchy as follows:

*Level 1* - These valuations are based on a market approach using quoted prices in active markets for identical assets. Valuations of these products do not require a significant degree of judgment. Assets utilizing Level 1 inputs include investments in money market funds, U.S. government debt securities, U.S. agency debt securities, municipal debt securities, bank deposits and exchange-traded equity securities of certain publicly held companies;

*Level 2* - These valuations are based on a market approach using quoted prices obtained from brokers or dealers for similar securities or for securities for which we have limited visibility into their trading volumes. Valuations of these products do not require a significant degree of judgment. Assets utilizing Level 2 inputs consist of investments in corporate debt securities; and

*Level 3* - These valuations are based on an income approach using certain inputs that are unobservable and are significant to the overall fair value measurement. Valuations of these products require a significant degree of judgment. Assets utilizing Level 3 inputs consist of investments in auction rate securities and asset backed debt securities that are not currently trading. In addition, we hold warrants in certain publicly held companies that are classified using Level 3 inputs. The carrying balance of these warrants was immaterial at December 31, 2008 and March 31, 2008.

Our investments in auction rate securities have a cost of \$10.0 million and invest in taxable student loan revenue bonds issued by state higher education authorities which service student loans under the Federal Family Education Loan Program. The bonds were triple A rated at the date of purchase and 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. Each of these securities had been subject to auction processes for which there had been insufficient bidders on the scheduled auction dates and the auctions subsequently failed. We are not able to liquidate our investments in auction rate securities until future auctions are successful, a buyer is found outside of the auction process or the notes are redeemed by the issuer. The securities continue to pay interest at predetermined interest rates during the periods in which the auctions have failed.

Typically, auction rate securities trade at their par value due to the short interest rate reset period and the availability of buyers or sellers of the securities at recurring auctions. However, since the security auctions have failed

and fair value cannot be derived from quoted prices, we used a discounted cash flow model to determine the estimated fair value of the securities at December 31, 2008. Our 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 any associated guarantees, the timing of expected future cash flows, and the expectation of the next time 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 us. Based upon this methodology, we have recorded an unrealized loss related to our

**Table of Contents**

investments in auction rate securities of approximately \$1.1 million to accumulated other comprehensive income at December 31, 2008. We believe there are several significant assumptions that are utilized in our valuation analysis, the two most critical of which are the discount rate, which includes a provision for default and liquidity risk, and the average expected term.

At December 31, 2008, we 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, financial condition and near term prospects of the issuers and our intent and ability to hold each security for a period of time sufficient to allow for any anticipated recovery in fair value. We do not expect the estimated fair value of these securities to decrease significantly in the future unless credit market conditions continue to deteriorate significantly.

Our investments in asset backed debt securities have a cost of \$7.5 million and consist of investment grade medium term floating rate notes ( MTN ) of Aleutian Investments, LLC ( Aleutian ) and Meridian Funding Company, LLC ( Meridian ), which are qualified special purpose entities ( QSPE ) 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 a sinking fund redemption feature 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 December 31, 2008, a substantial portion of our initial investment in the Meridian MTN s had been redeemed by MBIA through scheduled sinking fund redemptions at par value, and the first sinking fund redemption on the Aleutian MTN is scheduled for June 2009.

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. In June 2008, Ambac had its triple A rating reduced to Aa3 by Moody s and in November, Moody s further downgraded Ambac s rating to Baa1 with a developing outlook. Standard and Poor s ( S&P ) reduced Ambac s rating to double A in June 2008 and in August 2008, affirmed its double A rating with a negative outlook. In June 2008, MBIA was downgraded from triple A to A2 by Moody s and in September Moody s placed MBIA on review for possible downgrade. S&P reduced MBIA s rating to double A in June 2008 and in August 2008, affirmed its double A rating with a negative outlook. All downgrades were due to Ambac s and MBIA s inability to maintain triple A capital levels.

We may not be able to liquidate our investment in these securities before the scheduled redemptions or until trading in the securities resumes in the credit markets, which may not occur. Because the MTN s are not actively trading in the credit markets and fair value cannot be derived from quoted prices, we used a discounted cash flow model to determine the estimated fair value of the securities at December 31, 2008. Our 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. Based upon this methodology, we have an unrealized loss related to these asset backed debt securities of approximately \$0.9 million in accumulated other comprehensive income at December 31, 2008. We believe there are several significant assumptions that are utilized in our valuation analysis, the two most critical of which are the discount rate, which includes a provision for default and liquidity risk, and the average expected term.

At December 31, 2008, we 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 one of the issuers and our intent and ability to hold each security for a period of time sufficient to allow for any anticipated recovery in fair value or until scheduled redemption. We do not expect the estimated fair value of these securities to decrease significantly in the future unless credit market conditions continue to deteriorate significantly or the credit ratings of the issuers are further downgraded.

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. We believe that our current cash and cash equivalents and

**Table of Contents**

short-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.

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

***Borrowings***

At December 31, 2008, our borrowings consisted of our 7% Notes, which had a carrying value of \$92.4 million. We are currently making interest payments on the 7% Notes, with principal payments scheduled to begin in April 2009. In June and July 2008, in three separate privately negotiated transactions, we purchased an aggregate total of \$75.0 million principal amount of the 7% Notes for \$71.8 million. We recorded a loss on the extinguishment of the notes of \$2.0 million during the nine months ended December 31, 2008. As a result of the purchases, \$95.0 principal amount of the 7% Notes remains outstanding, and we will save approximately \$9.5 million in interest payments over the remaining life of the 7% notes.

***Capital Requirements***

We may continue to pursue opportunities to obtain additional financing in the future. Such financing may be sought through various sources, including debt and equity offerings, corporate collaborations, bank borrowings, arrangements relating to assets or other financing methods or structures. The source, timing and availability of any financings will depend on market conditions, interest rates and other factors. Our future capital requirements will also depend on many factors, including continued scientific progress in our research and development programs (including our proprietary product candidates), the size of these programs, progress with preclinical testing and clinical trials, the time and costs involved in obtaining regulatory approvals, the costs involved in filing, prosecuting and enforcing patent claims, the presence of competing technologies and the occurrence of market developments, the establishment of additional collaborative arrangements, the cost of manufacturing facilities and of commercialization activities and arrangements and the cost of product in-licensing and any possible acquisitions and, for any current or future proprietary products, the sales, marketing and promotion expenses associated with marketing such products. We may from time to time seek to retire or purchase our outstanding debt through cash purchases and/or exchanges for equity securities, in open market purchases, privately negotiated transactions or otherwise. Such repurchases or exchanges, if any, will depend on prevailing market conditions, our liquidity requirements, contractual restrictions and other factors. The amounts involved may be material.

We may need to raise substantial additional funds for longer-term product development, including development of our proprietary product candidates, regulatory approvals and manufacturing and sales and marketing activities that we might undertake in the future. There can be no assurance that additional funds will be available on favorable terms, if at all. If adequate funds are not available, we may be required to curtail significantly one or more of our research and development programs and/or obtain funds through arrangements with collaborative partners or others that may require us to relinquish rights to certain of our technologies, product candidates or future products.

Capital expenditures are expected in the range from \$2.5 million to \$3.5 million for the year ending March 31, 2009.

***Contractual Obligations***

With the exception of the repurchases of our 7% Notes, discussed above under Borrowings, and in Note 11 to the accompanying condensed consolidated financial statements, the contractual cash obligations disclosed in our Annual Report on Form 10-K for the year ended March 31, 2008 have not changed materially since the date of that report.

***Off-Balance Sheet Arrangements***

As of December 31, 2008, we were not a party to any off-balance sheet arrangements that have, or are reasonably likely to have, a current or future effect on our financial condition, changes in financial condition, revenue or expenses, results of operations, liquidity, capital expenditures or capital resources material to investors.

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

We hold financial instruments in our investment portfolio that are sensitive to market risks. Our investment portfolio, excluding warrants and equity securities we hold in connection with our collaborations and licensing activities, is used to preserve capital until it is required to fund operations. Our held-to-maturity investments are restricted and are held as collateral under certain letters of credit



**Table of Contents**

related to our lease agreements. Our short-term and long-term investments consist of U.S. government debt securities, U.S. agency debt securities, municipal debt securities, investment grade corporate debt securities, including asset backed debt securities, and auction rate securities. These debt securities are: (i) classified as available-for-sale; (ii) recorded at fair value; and (iii) subject to interest rate risk, and could decline in value if interest rates increase. Fixed rate interest securities may have their market value adversely impacted by a rise in interest rates, while floating rate securities may produce less income than expected if interest rates fall. Due in part to these factors, our future investment income may fall short of expectation due to a fall in interest rates or we may suffer losses in principal if we are forced to sell securities that decline in the market value due to changes in interest rates. However, because we classify our investments in debt securities as available-for-sale, no gains or losses are recognized due to changes in interest rates unless such securities are sold prior to maturity or declines in fair value are determined to be other-than-temporary. Should interest rates fluctuate by 10%, our interest income would change by approximately \$1.2 million over an annual period. Due to the conservative nature of our short-term and long-term investments and our investment policy, we do not believe that we have a material exposure to interest rate risk. Although our investments are subject to credit risk, our investment policies specify credit quality standards for our investments and limit the amount of credit exposure from any single issue, issuer or type of investment.

Our investments that are subject to the greatest credit risk at this time are our investments in asset backed debt securities and auction rate securities. Holding all other factors constant, if we were to increase the discount rate utilized in our valuation analysis of the asset backed debt securities and auction rate securities by 50 basis points (one-half of a percentage point), this change would have the effect of reducing the fair value of these investments by approximately \$0.4 million and \$0.1 million at December 31, 2008, respectively. Similarly, holding all other factors constant, if we were to assume that the expected term of the asset backed debt securities was the full contractual maturity, which could be through calendar year 2012, this change would have the effect of reducing the fair value of these securities by approximately \$0.7 million at December 31, 2008. As it relates to auction rate securities, holding all other factors constant, if we were to increase the average expected term utilized in our fair value analysis by one year, this change would have the effect of reducing the fair value of these securities by approximately \$0.3 million at December 31, 2008.

We also hold warrants to purchase the equity securities of certain publicly held companies that are considered derivative instruments and are recorded at fair value. These securities are sensitive to changes in interest rates. Interest rate changes would result in a change in the fair value of warrants due to the difference between the market interest rate and the rate at the date of purchase. A 10% increase or decrease in market interest rates would not have a material impact on our consolidated financial statements.

At December 31, 2008, the fair value of our 7% Notes approximated the carrying value. The interest rate on these notes are fixed and therefore not subject to interest rate risk.

**Foreign Currency Exchange Rate Risk**

The manufacturing and royalty revenues we receive on RISPERDAL CONSTA are a percentage of the net sales made by our collaborative partner, Janssen. A majority of these sales are made in foreign countries and are denominated in foreign currencies. The manufacturing and royalty payments on these foreign sales is calculated initially in the foreign currency in which the sale is made and is then converted into U.S. dollars to determine the amount that Janssen pays us for manufacturing and royalty revenues. Fluctuations in the exchange ratio of the U.S. dollar and these foreign currencies will have the effect of increasing or decreasing our manufacturing and royalty revenues even if there is a constant amount of sales in foreign currencies. For example, if the U.S. dollar weakens against a foreign currency, then our manufacturing and royalty revenues will increase given a constant amount of sales in such foreign currency.

The impact on our manufacturing and royalty revenues from foreign currency exchange rate risk is based on a number of factors, including the exchange rate (and the change in the exchange rate from the prior period) between a foreign currency and the U.S. dollar, and the amount of RISPERDAL CONSTA sales by Janssen that are denominated in foreign currencies. For the nine months ended December 31, 2008, an average 10% strengthening of the U.S. dollar relative to the currencies in which RISPERDAL CONSTA is sold, would have resulted in our manufacturing and royalty revenues being reduced by approximately \$7.5 million and \$1.6 million, respectively. We do not currently

hedge our foreign currency exchange rate risk.

**Item 4. Controls and Procedures**

**(a) Evaluation of Disclosure Controls and Procedures**

We have carried out an evaluation, under the supervision and the participation of our management, including our principal executive officer and principal financial officer, of the effectiveness of the design and operation of our disclosure controls and

**Table of Contents**

procedures (as defined in Rule 13a-15(e) under the Securities Exchange Act of 1934, as amended, or the Securities Exchange Act) at December 31, 2008. Based upon that evaluation, our principal executive officer and principal financial officer concluded that, at December 31, 2008, our disclosure controls and procedures are effective in providing reasonable assurance that (a) the information required to be disclosed by us in the reports that we file or submit under the Securities Exchange Act is recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission's (SEC) rules and forms, and (b) such information is accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate to allow timely decisions regarding required disclosure. In designing and evaluating our disclosure controls and procedures, our management recognized that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives, and our management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

***(b) Change in Internal Control over Financial Reporting***

During the period covered by this report, there have been no changes in our internal control over financial reporting that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

**Table of Contents**

**PART II. OTHER INFORMATION**

**Item 1. *Legal Proceedings***

Please see the Legal Proceedings section of our Annual Report on Form 10-K for the year ended March 31, 2008 for more information on litigation to which we are a party.

**Item 1A. *Risk Factors***

The following risk factors are added to those included in our Annual Report on Form 10-K for the year ended March 31, 2008 as well as those included in our Quarterly Report on Form 10-Q for the quarter ended September 30, 2008 which are hereby incorporated by reference.

*VIVITROL may not be successfully marketed and sold by Alkermes and may not generate significant revenues*

In November 2008, we ended our collaboration with Cephalon related to VIVITROL. As part of the termination, we assumed all risks and responsibilities associated with the marketing and sale of VIVITROL. The revenues from the sale of VIVITROL have not been and may not become significant and will depend on numerous factors including but not limited to those specified below.

We have little experience with the commercialization of pharmaceutical products, including the marketing and sale of prescription drugs. We must build an infrastructure to support the sales and marketing of VIVITROL, including integrating members of the Cephalon sales force with our existing field force to build our own sales force, building a distribution and expanded commercial infrastructure and providing various support services for the sales force. Our ability to realize significant revenues from the marketing and sales activities associated with VIVITROL depends on our ability to retain qualified sales personnel for the sale and marketing of VIVITROL. We must also be able to attract new qualified sales personnel as needed to support potential sales growth and competition for qualified sales personnel is intense. Any failure to attract and retain qualified sales personnel now and in the future, could impair our ability to maintain sales levels and/or support potential future sales growth.

We are responsible for the entire supply chain and distribution network for VIVITROL. We have limited experience in managing a complex, cGMP supply chain and pharmaceutical product distribution network. The manufacture of products and product components, packaging, storage and distribution of our products require successful coordination among ourselves and multiple third party providers. Issues with third parties who are part of our supply chain, including but not limited to suppliers, third party logistics

**Table of Contents**

providers, distributors, wholesalers, and specialty pharmacies may have a material adverse effect on our business, results of operations and financial condition. Our inability to coordinate these efforts, the lack of capacity available from third parties or any other problems with third party operators could cause a delay in shipment of saleable products; a recall of products previously shipped or an impairment of our ability to supply products at all. These setbacks could increase our costs, cause us to lose revenue or market share and damage our reputation.

*Sales of our products are dependent, in part, on the availability of reimbursement from third-party payors such as federal and state government agencies under programs such as Medicare and Medicaid, and private insurance plans.*

There have been, there are, and we expect there will continue to be, state and federal legislative and/or administrative proposals that could limit the amount that state or federal governments will pay to reimburse the cost of pharmaceutical products. Legislative or administrative acts that reduce reimbursement for our products could adversely affect our business. Third party payors continually attempt to contain or reduce the cost of health care by challenging the prices charged for medical products and services. We may not be able to sell VIVITROL profitably if reimbursement is unavailable or coverage is limited in scope or amount.

In addition, private insurers, such as managed care organizations, may adopt their own coverage restrictions or demand price concessions in response to legislation or administrative action. Reduction in reimbursement for our products could have a material adverse effect on our results of operations. Also, the increasing emphasis on managed care in the U.S. may put increased pressure on the price and usage of our products, which may adversely affect product sales. We cannot predict the availability or amount of reimbursement for VIVITROL and current reimbursement policies may change at any time.

If reimbursement for VIVITROL changes adversely, health care providers may limit how much or under what circumstances they will prescribe or administer VIVITROL, which could reduce use of VIVITROL or cause us to reduce the price of our product.

Additionally, we have assumed all of the risks and responsibilities associated with the additional development of VIVITROL, including regulatory approval and costs. We are currently conducting a randomized, multi-center registration study of VIVITROL in Russia for the treatment of opioid dependence. Clinical data from this study will form the basis of a sNDA to the FDA for VIVITROL for the treatment of opioid dependence. However, there is no assurance that the data from this study or any clinical or preclinical data will be sufficient to gain regulatory approval of VIVITROL for opioid dependence in the U.S. or other countries. Approval of VIVITROL for alcohol dependence in countries outside of the U.S., except for Russia and other countries in the CIS, and approval of VIVITROL for other indications in the U.S. and countries outside of the U.S. will depend on our sponsoring such efforts ourselves, including conducting additional clinical studies, which can be very costly, or entering into co-development, co-promotion or sales and marketing agreements with collaborators.

*Our customer base for VIVITROL is highly concentrated.*

Our principal customers for VIVITROL are wholesale drug distributors. These customers comprise a significant part of the distribution network for pharmaceutical products in the U.S. Three large wholesale distributors, Cardinal Health, Inc., McKesson Corporation and AmerisourceBergen Corporation, control a significant share of this network. Fluctuations in the buying patterns of these customers, which may result from seasonality, wholesaler buying decisions or other factors outside of our control, could significantly affect the level of our net sales on a period-to-period basis. The impact on net sales could have a material impact on our financial condition, cash flows and results of operations.

In an effort to combat the fluctuations in the buying patterns and the potential harm to our financial condition, we intend to enter into wholesaler distribution service agreements, ( DSAs ), with our three largest wholesale drug distributors. Under the DSAs, we would pay the wholesalers a fee to maintain certain minimum inventory levels that gradually decline over several quarters. We believe it is beneficial to enter into DSAs to establish specified levels of product inventory to be maintained by our wholesalers and to obtain more precise information as to the level of our product inventory available throughout the product distribution channel. We cannot be certain that the DSAs will be effective in limiting speculative purchasing activity, that there will not be a future drawdown of inventory as a result of declining minimum inventory requirements, or otherwise, or that the inventory level data provided through our DSAs are accurate. If speculative purchasing does occur, if the wholesalers significantly decrease their





**Table of Contents**

inventory levels, or if inventory level data provided through DSAs is inaccurate, our business, financial condition, cash flows and results of operations may also be adversely affected.

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

A summary of our stock repurchase activity for the three months ended December 31, 2008 is as follows:

<b>Period</b>	<b>Total Number of Shares Purchased (a)</b>	<b>Average Price Paid per Share</b>	<b>Total Number of Shares Purchased as Part of a Publicly Announced Program (a)</b>	<b>Approximate Dollar Value of Shares that May Yet be Purchased Under the Program  (in millions)</b>
October 1 through October 31				108.6
November 1 through November 30				108.6
December 1 through December 31	487,300	9.99	487,300	\$ 103.7
<b>Total</b>	<b>487,300</b>	<b>\$ 9.99</b>	<b>487,300</b>	

(a) In November 2007, 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. The repurchase program has no set expiration date and may be suspended or discontinued at any time. We publicly

announced the share repurchase program in our press release dated November 21, 2007. In June 2008, the 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. We publicly announced the expansion of the repurchase program in our press release dated June 16, 2008.

In addition to the stock repurchases above, during the three and nine months ended December 31, 2008, we acquired, by means of net share settlements, 16,339 and 51,871 shares of Alkermes common stock, at an average price of \$8.55 and \$11.39 per share, respectively, related to the vesting of employee stock awards to satisfy withholding tax obligations. In addition, during the nine months ended December 31, 2008, we acquired 9,176 shares of Alkermes common stock, at an average price of \$12.66 per share, tendered by employees as payment of the exercise price of stock options granted under our equity compensation plans.

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

We held our annual meeting of shareholders on October 7, 2008. The following proposals were voted upon at the meeting:

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

Nominee	Votes For	Authority Withheld
Floyd E. Bloom	74,430,211	15,422,831
Robert A. Breyer	73,993,424	15,859,618
Geraldine Henwood	74,755,604	15,097,438
Paul J. Mitchell	73,167,273	16,685,769
Richard F. Pops	73,985,663	15,867,379
Alexander Rich	72,842,293	17,010,749
David A. Broecker	74,183,909	15,669,133
Mark B. Skaletsky	72,838,407	17,014,635

Edgar Filing: ALKERMES INC - Form 10-Q

Michael A. Wall	69,941,022	19,912,020
David W. Anstice	88,613,546	1,239,496

2. A proposal to approve the Alkermes 2008 Stock Option and Incentive Plan was approved with 57,876,227 votes for, 23,164,456 votes against, 74,496 abstentions and 8,737,863 broker non-votes.

**Table of Contents**

3. A proposal to ratify PricewaterhouseCoopers LLP as our independent registered public accountants for fiscal year 2009 was approved with 88,932,454 votes for, 854,501 votes against and 66,087 abstentions.

**Item 5. Other Information**

The Company's policy governing transactions in its securities by its directors, officers and employees permits its officers, directors and employees to enter into trading plans in accordance with Rule 10b5-1 under the Exchange Act. During the three months ended December 31, 2008, Mr. Floyd E. Bloom, a director of the Company, and Mr. Gordon G. Pugh, an executive officer of the Company, each entered into a trading plan in accordance with Rule 10b5-1 and the Company's policy governing transactions in its securities by its directors, officers and employees. The Company undertakes no obligation to update or revise the information provided herein, including for revision or termination of an established trading plan.

**Item 6. Exhibits**

- (a) List of Exhibits:

**Exhibit**

**No.**

- |      |   |
|------|---|
| 10.1 | Alkermes, Inc., 2008 Stock Option and Incentive Plan (incorporated by reference to Exhibit 10.1 to the Registrant's Report on Form 8-K filed on October 7, 2008).   |
| 10.2 | Alkermes, Inc. 2008 Stock Option and Incentive Plan, Stock Option Award Certificate (Incentive Stock Option) (incorporated by reference to Exhibit 10.2 to the Registrant's Report on Form 8-K filed on October 7, 2008).   |
| 10.3 | Alkermes, Inc. 2008 Stock Option and Incentive Plan, Stock Option Award Certificate (Non-Qualified Option) (incorporated by reference to Exhibit 10.3 to the Registrant's Report on Form 8-K filed on October 7, 2008).   |
| 10.4 | Alkermes, Inc. 2008 Stock Option and Incentive Plan, Stock Option Award Certificate (Non-Employee Director) (incorporated by reference to Exhibit 10.4 to the Registrant's Report on Form 8-K filed on October 7, 2008).  |
| 10.5 | Amendment to Employment Agreement by and between Alkermes, Inc. and Richard F. Pops (incorporated by reference to Exhibit 10.5 to the Registrant's Report on Form 8-K filed on October 7, 2008).  |
| 10.6 | Amendment to Employment Agreement by and between Alkermes, Inc. and David A. Broecker (incorporated by reference to Exhibit 10.6 to the Registrant's Report on Form 8-K filed on October 7, 2008).  |
| 10.7 | Form of Amendment to Employment Agreement by and between Alkermes, Inc. and each of each of Kathryn L. Biberstein, Elliot W. Ehrich, M.D., James M. Frates, Michael J. Landine, Gordon G. Pugh (incorporated by reference to Exhibit 10.7 to the Registrant's Report on Form 8-K filed on October 7, 2008). |
| 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).  |

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

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

Date: February 9, 2009

**Table of Contents**

**EXHIBIT INDEX**

**Exhibit**

**No.**

- 10.1 Alkermes, Inc., 2008 Stock Option and Incentive Plan (incorporated by reference to Exhibit 10.1 to the Registrant's Report on Form 8-K filed on October 7, 2008).
- 10.2 Alkermes, Inc. 2008 Stock Option and Incentive Plan, Stock Option Award Certificate (Incentive Stock Option) (incorporated by reference to Exhibit 10.2 to the Registrant's Report on Form 8-K filed on October 7, 2008).
- 10.3 Alkermes, Inc. 2008 Stock Option and Incentive Plan, Stock Option Award Certificate (Non-Qualified Option) (incorporated by reference to Exhibit 10.3 to the Registrant's Report on Form 8-K filed on October 7, 2008).
- 10.4 Alkermes, Inc. 2008 Stock Option and Incentive Plan, Stock Option Award Certificate (Non-Employee Director) (incorporated by reference to Exhibit 10.4 to the Registrant's Report on Form 8-K filed on October 7, 2008).
- 10.5 Amendment to Employment Agreement by and between Alkermes, Inc. and Richard F. Pops (incorporated by reference to Exhibit 10.5 to the Registrant's Report on Form 8-K filed on October 7, 2008).
- 10.6 Amendment to Employment Agreement by and between Alkermes, Inc. and David A. Broecker (incorporated by reference to Exhibit 10.6 to the Registrant's Report on Form 8-K filed on October 7, 2008).
- 10.7 Form of Amendment to Employment Agreement by and between Alkermes, Inc. and each of each of Kathryn L. Biberstein, Elliot W. Ehrich, M.D., James M. Frates, Michael J. Landine, Gordon G. Pugh (incorporated by reference to Exhibit 10.7 to the Registrant's Report on Form 8-K filed on October 7, 2008).
- 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).