ALKERMES INC Form 10-Q November 07, 2008

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

(Mark One)

**DESCRIPTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934** 

For the quarterly period ended September 30, 2008

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

For the transition period from

# Commission file number 1-14131 ALKERMES, INC.

(Exact name of registrant as specified in its charter)

#### **PENNSYLVANIA**

23-2472830

(State or other jurisdiction of incorporation or organization)

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

#### 88 Sidney Street, Cambridge, MA

02139-4234

(Address of principal executive offices)

(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 b No o

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 b Accelerated filer o

Non-accelerated filer o

Smaller reporting company o

(Do not check if a smaller reporting company)

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act.): Yes o No b

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

As of November 5, 2008 94,932,052 382,632

Class
Common Stock, \$.01 par value
Non-Voting Common Stock, \$.01 par value

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## PART 1. FINANCIAL INFORMATION

#### Item 1. Condensed Consolidated Financial Statements:

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

		March 31, 2008 ds, except share are amounts)
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	\$ 68,525	\$ 101,241
Investments short-term	263,913	240,064
Receivables	36,047	47,249
Inventory	15,721	18,884
Prepaid expenses and other current assets	15,354	5,720
Total current assets	399,560	413,158
PROPERTY, PLANT AND EQUIPMENT:		
Land	301	301
Building and improvements	36,371	35,003
Furniture, fixtures and equipment	65,293	63,364
Equipment under capital lease	464	464
Leasehold improvements	33,614	33,387
Construction in progress	40,686	42,859
	176,729	175,378
Less: accumulated depreciation	(67,922)	( 62,839)
Total property, plant and equipment net	108,807	112,539
INVESTMENTS LONG-TERM	93,395	119,056
OTHER ASSETS	3,256	11,558
TOTAL ASSETS	\$ 605,018	\$ 656,311
LIABILITIES AND SHAREHOLDERS EQUITY CURRENT LIABILITIES:		
Accounts payable and accrued expenses	\$ 23,623	\$ 36,046
Unearned milestone revenue current portion	5,728	5,927
Deferred revenue current portion	298	2,227
Long-term debt current portion	2,0	47
Non-recourse RISPERDAL CONSTA secured 7% notes current portion	15,835	.,
Total current liabilities	45,484	42,020

NON-RECOURSE RISPERDAL CONSTA SECURED 7% NOTES UNEARNED MILESTONE REVENUE LONG-TERM PORTION DEFERRED REVENUE LONG-TERM PORTION OTHER LONG-TERM LIABILITIES	76,054 108,890 28,397 7,228	160,324 111,730 27,837 9,086
TOTAL LIABILITIES	266,053	350,997
COMMITMENTS AND CONTINGENCIES (Note 12) SHAREHOLDERS EQUITY: Capital stock, par value, \$0.01 per share; 4,550,000 shares authorized (includes 3,000,000 shares of preferred stock); none issued and outstanding Common stock, par value, \$0.01 per share; 160,000,000 shares authorized;		
103,912,534 and 102,977,348 shares issued; 94,912,489 and 95,099,166 shares outstanding at September 30, 2008 and March 31, 2008, respectively Non-voting common stock, par value, \$0.01 per share; 450,000 shares authorized;	1,039	1,030
382,632 shares issued and outstanding at September 30, 2008 and March 31, 2008	4	4
Treasury stock, at cost (9,000,045 and 7,878,182 shares at September 30, 2008	(	(
and March 31, 2008, respectively)	120,970)	107,322)
Additional paid-in capital	885,259	869,695
Accumulated other comprehensive loss	(1,185)	(1,526)
1	(	(
Accumulated deficit	425,182)	456,567)
TOTAL SHAREHOLDERS EQUITY	338,965	305,314
TOTAL LIABILITIES AND SHAREHOLDERS EQUITY	\$ 605,018	\$ 656,311

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

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

	Three Months Ended September 30, 2008 2007		Six Month Septem 2008	
		nousands, excep		
REVENUES:		, -	-	
Manufacturing revenues	\$ 33,039	\$ 24,137	\$ 71,649	\$ 55,654
Royalty revenues	8,439	7,348	17,020	14,330
Research and development revenue under collaborative				
arrangements	5,252	21,206	36,702	44,656
Net collaborative profit	581	5,909	1,932	12,898
Total revenues	47,311	58,600	127,303	127,538
EXPENSES:				
Cost of goods manufactured	12,071	9,218	26,385	19,363
Research and development	19,710	28,317	41,971	60,936
Selling, general and administrative	11,679	14,487	23,605	29,887
Total expenses	43,460	52,022	91,961	110,186
OPERATING INCOME	3,851	6,578	35,342	17,352
OTHER (EXPENSE) INCOME:				
Interest income	2,693	4,246	6,309	8,648
Interest expense	(4,243)	(4,077)	(8,469)	(8,150)
Other (expense) income	(666)	1,151	(830)	1,177
Total other (expense) income	(2,216)	1,320	(2,990)	1,675
INCOME BEFORE INCOME TAXES	1,635	7,898	32,352	19,027
INCOME TAX (BENEFIT) PROVISION	(63)	200	967	2,582
NET INCOME	\$ 1,698	\$ 7,698	\$ 31,385	\$ 16,445
EARNINGS PER COMMON SHARE:				
BASIC	\$ 0.02	\$ 0.08	\$ 0.33	\$ 0.16
DILUTED	\$ 0.02	\$ 0.07	\$ 0.32	\$ 0.16
WEIGHTED AVERAGE NUMBER OF COMMON SHARES OUTSTANDING:				
BASIC	95,637	101,595	95,211	101,663
DILUTED	97,356	104,315	96,729	104,446

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

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

	Six Months Ended September 30,		
	2008	2007	
	(In thou	ısands)	
CASH FLOWS FROM OPERATING ACTIVITIES:			
Net income	\$ 31,385	\$ 16,445	
Adjustments to reconcile net income to cash flows from operating activities:			
Share-based compensation	8,309	10,295	
Depreciation	4,901	6,114	
Other non-cash charges	2,564	2,187	
Loss on the purchase of the 7% Notes	1,989		
Change in fair value of warrants		(1,426)	
Changes in assets and liabilities:			
Receivables	2,251	10,939	
Inventory, prepaid expenses and other assets	890	(8,116)	
Accounts payable and accrued expenses	(10,785)	(20,707)	
Unearned milestone revenue	(3,039)	(8,101)	
Deferred revenue	2,092	2,086	
Other liabilities	(1,363)	(155)	
Cash flows from operating activities	39,194	9,561	
CASH FLOWS FROM INVESTING ACTIVITIES:			
Purchases of property, plant and equipment	(3,567)	(14,609)	
Sales of property, plant and equipment	7,717		
Purchases of investments	(462,412)	(291,480)	
Sales and maturities of investments	463,959	293,861	
Cash flows from investing activities	5,697	(12,228)	
CASH FLOWS FROM FINANCING ACTIVITIES:			
Proceeds from issuance of common stock	7,221	9,122	
Excess tax benefit from stock options	74	108	
Payment of debt	(47)	(644)	
Purchase of non-recourse RISPERDAL CONSTA secured 7% notes	(71,775)		
Purchase of treasury stock	(13,080)		
Cash flows from financing activities	(77,607)	8,586	
NET (DECREASE) INCREASE IN CASH AND CASH EQUIVALENTS	(32,716)	5,919	
CASH AND CASH EQUIVALENTS Beginning of period	101,241	80,500	
CASH AND CASH EQUIVALENTS End of period	\$ 68,525	\$ 86,419	
SUPPLEMENTAL CASH FLOW DISCLOSURE:			

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Cash paid for interest	\$ 6,662	\$ 5,999
Cash paid for income taxes	\$ 435	\$ 980
Non-cash investing and financing activities:		
Purchased capital expenditures included in accounts payable and accrued expenses	\$ 233	\$ 246
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	\$ 568	\$ 924

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

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# ALKERMES, INC. AND SUBSIDIARIES NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED) 1. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

#### **Basis of Presentation**

The accompanying condensed consolidated financial statements of Alkermes, Inc. (the Company or Alkermes ) for the three and six months ended September 30, 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 of America (commonly referred to as GAAP ). In the opinion of management, the condensed consolidated financial statements include all adjustments, which are of a normal recurring nature, that are necessary to present fairly the results of operations for the reported periods.

These financial statements should be read in conjunction with the Company s audited consolidated financial statements and notes thereto which are contained in the Company s Annual Report on Form 10-K for the year ended March 31, 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 RISPERDA® 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.

#### **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 Statement of Financial Accounting Standards (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.

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# ALKERMES, INC. AND SUBSIDIARIES NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued) 2. COMPREHENSIVE INCOME

Comprehensive income for the three and six months ended September 30, 2008 and 2007 is as follows:

	Three Mor Septem		Six Months Ended September 30,		
(In thousands)	2008	2007	2008	2007	
Net income	\$ 1,698	\$ 7,698	\$ 31,385	\$ 16,445	
Unrealized gains (losses) on available-for-sale securities:					
Holding losses	(61)	(25)	(266)	(550)	
Reclassification of unrealized losses to realized losses on available-for-sale securities	559		607		
Unrealized gains (losses) on available-for-sale securities	498	(25)	341	(550)	
Comprehensive income	\$ 2,196	\$ 7,673	\$31,726	\$ 15,895	

#### 3. 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 stock awards.

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

		onths Ended nber 30,	Six Months Ended September 30,		
(In thousands)	2008	2007	2008	2007	
Numerator:					
Net income	\$ 1,698	\$ 7,698	\$ 31,385	\$ 16,445	
Denominator:					
Weighted average number of common shares					
outstanding	95,637	101,595	95,211	101,663	
Effect of dilutive securities:					
Stock options	1,479	2,371	1,329	2,451	
Restricted stock awards	240	349	189	332	
Dilutive common share equivalents	1,719	2,720	1,518	2,783	
Shares used in calculating diluted earnings per common					
share	97,356	104,315	96,729	104,446	

Stock options of 13.4 million and 10.3 million for the three months ended September 30, 2008 and 2007, respectively, and 13.9 million and 11.8 million for the six months ended September 30, 2008 and 2007, respectively, were not included in the calculation of net income per common share because their effects are anti-dilutive. There were 0.1 million and no restricted stock units excluded from the calculation of net income per common share for the three and months ended September 30, 2008 and 2007, respectively, and none for the six months ended September 30, 2008 and 2007 because their effects are anti-dilutive.

#### 4. INVESTMENTS

At September 30, 2008 and March 31, 2008, the Company held investments of \$352.6 million and \$354.5 million, respectively, of which \$88.7 million and \$114.4 million are long-term, respectively, which were classified as available-for-sale and are carried at fair value in the Company's condensed consolidated balance sheets. These investments include United States (U.S.) government debt securities, U.S. agency debt securities, municipal debt securities, investment grade corporate debt securities, including asset backed debt securities, student loan backed auction rate securities and strategic equity investments.

At September 30, 2008 and March 31, 2008, the Company held investments of \$4.7 million, which were classified as long-term, held-to-maturity securities and were carried at amortized cost. These investments include

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

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 September 30, 2008, the Company had gross unrealized gains of \$2.3 million and gross unrealized losses of \$3.5 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 six months ended September 30, 2008, the Company recognized \$0.6 million in charges for other-than-temporary losses on its strategic equity investments.

At September 30, 2008, the Company had \$10.0 million in investments in auction rate securities with an unrealized loss of \$0.7 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 September 30, 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 September 30, 2008, the Company had \$8.2 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 September 30, 2008, a substantial portion of the Company s initial investment in the Meridian MTN s had been redeemed by MBIA though 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 double A by Standard and Poor s ( S&P ), and MBIA was downgraded from triple A to A2 by Moody s and double A by S&P. Both downgrades were due to Ambac s and MBIA s inability to maintain triple A capital levels. In August 2008, S&P affirmed its double A ratings of Ambac and MBIA with negative outlook. In September 2008, Moody s placed Ambac and MBIA on review for possible downgrade. In November 2008, Moody s announced that it had downgraded Ambac s rating to Baa1 with a developing outlook.

The Company may not be able to liquidate its investment in these securities before the scheduled redemptions or until trading in the securities resumes in the credit markets, which may not occur. At September 30, 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.

The Company also has warrants to purchase securities of certain publicly held companies included in its portfolio of strategic equity investments. These warrants are considered to be derivative instruments and at September 30, 2008 and March 31, 2008, the warrants had carrying values of less than \$0.1 million.

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# ALKERMES, INC. AND SUBSIDIARIES NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued) 5. 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 is effective for the Company s condensed consolidated financial statements for the three and six months 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 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;
- 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 warrants in certain publicly held companies that are classified using Level 3 inputs. The carrying balance of these warrants was immaterial at September 30, 2008 and March 31, 2008.

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

The following table presents information about the Company s assets and liabilities that are measured at fair value on a recurring basis at September 30, 2008, and indicates the fair value hierarchy of the valuation techniques the Company utilized to determine such fair value:

						gnificant Other	Sig	nificant
	Quoted Prices in September Active Markets		in	Observable Inputs		Unobservable Inputs		
			Markets					
(In thousands)		2008	(	Level 1)	(I	Level 2)	(I	Level 3)
Assets:								
Cash equivalents	\$	7,025	\$	7,025	\$		\$	
U.S. government and agency and municipal								
debt securities		250,231		250,231				
Corporate debt securities		89,107		4,240		84,867		
Asset backed debt securities		7,283		,		,		7,283
Auction rate securities		9,272						9,272
Strategic equity investments		1,414		1,414				>,272
Total	\$	364,332	\$	262,910	\$	84,867	\$	16,555

The fair values of the Company s cash equivalents and investments in U.S. government and agency and municipal debt securities, and corporate debt securities are determined through observable market sources. The Company s strategic equity investments are investments in certain publicly traded companies whose fair value is readily determinable.

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 September 30, 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 September 30, 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:

**Fair Value** 

#### (In thousands)

Balance, April 1, 2008	\$ 18,612
Total unrealized losses included in earnings	
Total unrealized losses included in comprehensive income	(468)
Redemptions	(1,589)
Balance, September 30, 2008	\$ 16,555

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

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#### ALKERMES, INC. AND SUBSIDIARIES

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

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.

The carrying amounts reflected in the Company s condensed consolidated balance sheets for cash and cash equivalents, receivables, other current assets, accounts payable and accrued expenses approximate fair value due to their short-term durations.

#### 6. INVENTORY

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

	September					
	30,	March 31,				
(In thousands)	2008	2008				
Raw materials	\$ 8	8,338 \$ 8,373				
Work in process	2	2,215 3,060				
Finished goods	5	5,168 7,451				
Total	\$ 15	5,721 \$ 18,884				

#### 7. ACCOUNTS PAYABLE AND ACCRUED EXPENSES

Accounts payable and accrued expenses consist of the following:

	September					
		30,	M	arch 31,		
(In thousands)		2008		2008		
Accounts payable	\$	5,019	\$	7,042		
Accrued compensation		8,255		11,245		
Accrued interest		1,750		2,975		
Accrued restructuring current portion		804		4,037		
Accrued other		7,795		10,747		
Total	\$	23,623	\$	36,046		

#### 8. RESTRUCTURING

In March 2008, the Company announced the decision by Eli Lilly and Company to discontinue the AIR® 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 September 30, 2008, the Company had paid in cash approximately \$3.5 million in connection with the 2008 Restructuring.

Restructuring activity during the six months ended September 30, 2008 for the 2008 Restructuring is as follows:

	Facility		Other Contract					
(In thousands)	Closure	Severance	Losses	Total				
Balance, April 1, 2008	\$ 4,930	\$ 2,881	\$ 37	\$ 7,848				
Additions		78	70	148				
Payments	(490)	(2,952)	(107)	(3,549)				
Other adjustments	99			99				

Balance, September 30, 2008 (1)

\$ 4,539

\$

7 \$

\$ 4,546

(1) The

restructuring

liability at

September 30,

2008 consists of

\$0.8 million

classified as

current and

\$3.7 million

classified as

long-term in the

accompanying

condensed

consolidated

balance sheet.

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

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## ALKERMES, INC. AND SUBSIDIARIES

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

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 restructuring charges accrued in connection with the 2004 Restructuring to zero. As of September 30, 2008, the 2004 Restructuring was complete.

#### 9. SHARE-BASED COMPENSATION

Share-based compensation expense for the three and six months ended September 30, 2008 and 2007 is as follows:

	Three Moi Septem	Six Months Ended September 30,			
(In thousands)	2008	2007	2008	2007	
Cost of goods manufactured	\$ 428	\$ 334	\$ 857	\$ 960	
Research and development	1,282	1,785	2,870	3,636	
Selling, general and administrative	2,104	2,429	4,582	5,699	
Total	\$ 3,814	\$ 4,548	\$ 8,309	\$ 10,295	

At September 30, 2008 and March 31, 2008, \$0.5 million and \$0.3 million, respectively, of share-based compensation cost was capitalized and recorded as Inventory in the condensed consolidated balance sheets.

#### 10. EXTINGUISHMENT OF DEBT

During the six months ended September 30, 2008, the Company purchased, in three privately negotiated transactions, \$75.0 million in original 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 September 30, 2008. The Company recorded a loss on the extinguishment of the notes of \$2.0 million during the six months ended September 30, 2008, which was recorded as interest expense.

#### 11. INCOME TAXES

The Company records a deferred tax asset or liability based on the difference between the financial statement and tax bases of assets and liabilities, as measured by enacted tax rates assumed to be in effect when these differences reverse. At September 30, 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 income tax benefit in the amount of \$0.1 million and income tax provision of \$1.0 million for the three and six months ended September 30, 2008, respectively, and the income tax provision of \$0.2 million and \$2.6 million for the three and six months ended September 30, 2007, respectively, related to the U.S. alternative minimum tax (AMT). Included in the \$0.1 million benefit for the three months ended September 30, 2008 is \$0.1 million which represents the amount the Company estimates it will benefit from 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 charge was recorded in the three and six months ended September 30, 2008 and 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.

#### 12. COMMITMENTS AND CONTINGENCIES

From time to time, the Company may be subject to legal proceedings and claims in the ordinary course of business. The Company is not aware of any such proceedings or claims that it believes will have, individually or in the aggregate, a material adverse effect on its business, financial condition or results of operations.

In 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

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# ALKERMES, INC. AND SUBSIDIARIES

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

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.

#### 13. SEGMENT INFORMATION

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

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#### Item 2. Management s Discussion and Analysis of Financial Condition and Results of Operations

Alkermes, Inc. (as used in this section, together with our subsidiaries, us, we, our or the Company) is a biotechnology company committed to developing innovative medicines to improve patients—lives. We manufacture RISPERDAL® CONSTA® for schizophrenia and developed and manufacture VIVITROL® for alcohol dependence. Our pipeline includes extended-release injectable, pulmonary and oral products for the treatment of prevalent, chronic diseases, such as central nervous system disorders, addiction and diabetes. Headquartered in Cambridge, Massachusetts, we have research and manufacturing facilities in Massachusetts and Ohio.

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 in connection with certain collaborative arrangements and as we expand the development of our proprietary product candidates, including costs related to preclinical studies, clinical trials and facilities expansion. Our costs, including research and development costs for our product candidates and selling, marketing and promotion expenses for any future products to be marketed by us or our collaborators, if any, may exceed revenues in the future, which may result in losses from operations.

## **Forward-Looking Statements**

Any statements herein or otherwise made in writing or orally by us with regard to our expectations as to financial results and other aspects of our business may constitute forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, including, but not limited to, statements concerning future operating results, the achievement of certain business and operating goals, manufacturing revenues, research and development spending, plans for clinical trials and regulatory approvals, spending relating to selling and marketing and clinical development activities, financial goals and projections of capital expenditures, recognition of revenues, and future financings. These statements relate to our future plans, objectives, expectations and intentions and may be identified by words like believe, expect, designed, may, will, should, seek, or anticipate, and similar expressions.

Although we believe that our expectations are based on reasonable assumptions within the bounds of our knowledge of our business and operations, the forward-looking statements contained in this document are neither promises nor guarantees, and our business is subject to significant risk and uncertainties and there can be no assurance that our actual results will not differ materially from our expectations. These forward looking statements include, but are not limited to, statements concerning: the achievement of certain business and operating milestones and future operating results and profitability; continued revenue growth from RISPERDAL CONSTA; the commercialization of VIVITROL in the U.S. by Cephalon and in Russia and countries in the Commonwealth of Independent States by Cilag GmbH International ( Cilag ), a subsidiary of Johnson & Johnson; recognition of milestone payments from our partners related to the future sales of VIVITROL; the successful continuation of development activities for our programs, including exenatide once weekly; the successful manufacture of our products and product candidates, including RISPERDAL CONSTA and VIVITROL at a commercial scale, and the successful manufacture of exenatide once weekly by Amylin Pharmaceuticals, Inc. ( Amylin ); and the building of a selling and marketing 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 selling and marketing 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

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economically; (viii) we may not be able to source raw materials for our production processes from third parties; (ix) we may not be able to successfully transfer manufacturing technology and related systems for exenatide once weekly to Amylin, and Amylin may not be able to successfully operate the manufacturing facility for exenatide once weekly; (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 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 U.S. Food and Drug Administration (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 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 and the submission for marketing approval, the FDA or other health authorities could refuse to accept such filings or could request additional preclinical or clinical studies be conducted, each of which could result in significant delays or the failure of such product to receive marketing approval; (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; (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 enter into select collaborations with pharmaceutical and biotechnology companies to develop significant new product candidates, based on existing drugs and incorporating our technologies. In addition, we develop our own proprietary therapeutics by applying our innovative formulation expertise and drug development capabilities to create new pharmaceutical products. Each of these approaches is discussed in more detail below.

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

RISPERDAL CONSTA is a long-acting formulation of risperidone, a product of Janssen. RISPERDAL CONSTA is the first and only long-acting, atypical antipsychotic to be approved by the FDA. 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 (U.K.) 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 27 million people with bipolar disorder.

In May 2008, we and Janssen agreed to begin development of a four-week formulation of RISPERDAL CONSTA, which could offer patients and physicians another dosing option.

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 twenty-four 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.

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 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.

#### **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 launched in June 2006. Cephalon is primarily responsible for marketing VIVITROL in the U.S. We are the exclusive manufacturer of VIVITROL.

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In April 2007, we submitted a Marketing Authorization Application (MAA) for VIVITROL for the treatment of alcohol dependence to regulatory authorities in the U.K. 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 U.K. health authorities that data from a single study would not be sufficient to register VIVITROL in the U.K. 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 will retain exclusive development and marketing rights to VIVITROL in all markets outside the U.S., 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 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 will form the basis of a sNDA to the FDA for VIVITROL for the treatment of opioid dependence, a chronic brain disease.

#### 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 BYETT® (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 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. Seventy-four 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 Alkermes 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. Amylin is in active discussions with the FDA regarding options to enable a New Drug Application, or NDA, submission by the end of the first half of 2009. If Amylin is required to initiate a new clinical study, the timing of the NDA submission would depend on the parameters of the new study, and the submission could be delayed beyond the previously stated filing timeline of by the end of the first half of 2009.

#### 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 day s 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 17

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more drinks per day for women. We plan to initiate additional clinical studies to support ALKS 29 during calendar year 2008.

#### 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 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 active control (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 active control when cultured with human hepatocytes (liver cells), suggesting that they are not readily metabolized by the liver. Pharmacokinetic results showed that the oral bioavailability of ALKS 33 was significantly greater than that of the active control. We are on track to file our Investigational New Drug Application (IND) and begin a phase 1 study of ALKS 33 in healthy volunteers by the end of calendar 2008.

#### **Critical Accounting Policies**

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. 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. 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.

#### **Results of Operations**

Net income for the three months ended September 30, 2008 was \$1.7 million, or \$0.02 per common share basic and diluted, as compared to net income of \$7.7 million, or \$0.08 per common share basic and \$0.07 per common share diluted, for the three months ended September 30, 2007.

Net income for the six months ended September 30, 2008 was \$31.4 million, or \$0.33 per common share basic and \$0.32 per common share diluted, as compared to net income of \$16.4 million, or \$0.16 per common share basic and diluted, for the six months ended September 30, 2007.

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#### Revenues

		ree Months E September 30		Six Months Ended September 30,				
(In millions)	2008	2007	Change	2008	2007	Change		
Manufacturing revenue: RISPERDAL CONSTA VIVITROL	\$ 30.7 2.3	\$ 22.9 1.2	\$ 7.8 1.1	\$ 66.7 5.0	\$ 53.1 2.5	\$ 13.6 2.5		
Total manufacturing revenue	33.0	24.1	8.9	71.7	55.6	16.1		
Royalty revenue Research and development revenue under collaborative	8.4	7.4	1.0	17.0	14.3	2.7		
arrangements Net collaborative profit	5.3 0.6	21.2 5.9	(15.9) (5.3)	36.7 1.9	44.7 12.9	(8.0) (11.0)		
Total revenues	\$ 47.3	\$ 58.6	\$ (11.3)	\$ 127.3	\$ 127.5	\$ (0.2)		

The increase in RISPERDAL CONSTA manufacturing revenues for the three and six months ended September 30, 2008, as compared to the three and six months ended September 30, 2007, was primarily due to a 25% and 16% increase, respectively, in the units of RISPERDAL CONSTA shipped to Janssen. There was also a slight increase in the net sales price of RISPERDAL CONSTA in the three and six months ended September 30, 2008, as compared to the three and six months ended September 30, 2007, which was due in part to fluctuations in the exchange ratio of the U.S. dollar and 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.

Under our manufacturing and supply agreement with Janssen, we earn manufacturing revenues when product is shipped to Janssen, based on a percentage of Janssen s estimated unit net sales price. Revenues include a quarterly adjustment from Janssen s estimated unit net sales price to Janssen s actual unit net sales price for product shipped. In the three and six months ended September 30, 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 in the fiscal year ending March 31, 2009 and beyond.

VIVITROL manufacturing revenues for the three and six months ended September 30, 2008 consisted of \$1.7 million and \$2.8 million, respectively, of billings to Cephalon for failed batches and \$0 and \$1.4 million, respectively, for shipments of VIVITROL to Cephalon and \$0.4 million for shipments of VIVITROL to Janssen-Cilag to support commercialization of VIVITROL in Russia. In addition, VIVITROL manufacturing revenues for the three and six months ended September 30, 2008 included \$0.2 million and \$0.4 million, respectively, of milestone revenue related to manufacturing profit on VIVITROL under our arrangement with Cephalon, which equals a 10% markup on VIVITROL cost of goods manufactured and draws down from unearned milestone revenue from Cephalon.

VIVITROL manufacturing revenues for the three and six months ended September 30, 2007 consisted of billings to Cephalon for idle capacity costs and no product was shipped to them during these reporting periods. VIVITROL manufacturing revenues for the three and six months ended September 30, 2007 included \$0.1 million and \$0.2 million, respectively, of milestone revenue related to the manufacturing profit on VIVITROL under our arrangement with Cephalon, which equals a 10% markup on VIVITROL cost of goods manufactured and draws down from unearned milestone revenue from Cephalon.

Royalty revenues for the three and six months ended September 30, 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 six months ended September 30, 2008 were based on RISPERDAL CONSTA sales of \$337.5 million and \$680.7 million, respectively. Royalty revenues for the three and six months ended September 30, 2007 were based on RISPERDAL CONSTA sales of \$293.6 million and \$572.3 million, respectively. The increase in sales of RISPERDAL CONSTA for the three and six months ended September 30, 2008, as compared to the three and six months ended September 30, 2007, was due in part to fluctuations in the exchange ratio of the U.S. dollar and 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.

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The decrease in research and development revenue under collaborative arrangements ( R&D Revenue ) for the three and six months ended September 30, 2008, as compared to the three and six months ended September 30, 2007, was primarily due to the termination of the AIR Insulin development program in March 2008 and the AIR parathyroid hormone ( AIR PTH ) development program in September 2007, and reductions in revenues under the exenatide once weekly development program. In June 2008, we entered into an agreement with Lilly in connection with their 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 \$12.0 million and \$25.9 million for the three and six months ended September 30, 2007, respectively. Revenues from the AIR PTH development program, which was terminated during the three months ended September 30, 2007, totaled \$1.8 million and \$4.9 million in the three and six months ended September 30, 2007, respectively. We did not record any revenues under the AIR PTH development program in the three and six months ended September 30, 2008.

Net collaborative profit for the three and six months ended September 30 consists of the following:

		nths Ended aber 30,	Six Months Ended September 30,			
(In millions)	2008	2007	2008	2007		
Milestone revenue cost recovery	\$	\$	\$	\$ 5.3		
Milestone revenue license	1.3	1.3	2.6	2.6		
Total milestone revenue cost recovery and license	1.3	1.3	2.6	7.9		
Net payments (to) from Cephalon	(0.7)	4.6	(0.7)	5.0		
Net collaborative profit	\$ 0.6	\$ 5.9	\$ 1.9	\$ 12.9		

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 profits or losses earned on VIVITROL within the collaboration are divided between us and Cephalon in approximately equal shares. The net profits earned or losses incurred on VIVITROL are dependent upon end-market sales and on the level of expenditures by both us and Cephalon in developing, manufacturing and commercializing VIVITROL, all of which is subject to change. Gross sales of VIVITROL by Cephalon were \$4.7 million and \$9.5 million for the three and six months ended September 30, 2008, respectively, and \$4.7 million and \$8.8 million for the three and six months ended September 30, 2007, respectively. Through September 30, 2008, the cumulative net losses on VIVITROL were \$190.7 million, of which \$75.9 million was incurred by us on behalf of the collaboration and \$114.8 million was incurred by Cephalon on behalf of the collaboration.

For the three and six months ended September 30, 2008, we recognized no milestone revenue cost recovery, as VIVITROL had reached the cumulative loss cap prior to the reporting periods. For the three and six months ended September 30, 2007, we recognized \$0 and \$5.3 million, respectively, of milestone revenue cost recovery, respectively, to offset net losses on VIVITROL that we funded under the cumulative loss cap.

For the three and six months ended September 30, 2008 and 2007, we recognized \$1.3 million and \$2.6 million, respectively, of milestone revenue related to the licenses provided to Cephalon to commercialize VIVITROL. The license revenue is recognized on a straight-line basis over 10 years.

During the three and six months ended September 30, 2008, we made net payments of \$0.7 million to Cephalon under the product loss sharing terms of the arrangement. During the three and six months ended September 30, 2007, we received net payments of \$4.6 and \$5.0 million, respectively, from Cephalon under the product loss sharing terms

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#### **Expenses**

		Th	ree M	onths E	nded	Six Months Ended						
			Septe	mber 30	0,	September 30,						
(In millions)	2008		2007		Change		2008		2007		Change	
Costs of goods manufactured:												
RISPERDAL CONSTA	\$	8.1	\$	8.1	\$		\$	18.9	\$	17.2	\$	1.7
VIVITROL		4.0		1.1		2.9		7.5		2.2		5.3
Total cost of goods												
manufactured		12.1		9.2		2.9		26.4		19.4		7.0
Research and development		19.7		28.3		(8.6)		42.0		60.9		(18.9)
Selling, general and administrative		11.7		14.5		(2.8)		23.6		29.9		(6.3)
Total expenses	\$	43.5	\$	52.0	\$	(8.5)	\$	92.0	\$	110.2	\$	(18.2)

RISPERDAL CONSTA cost of goods manufactured for the three months ended September 30, 2008 and 2007 was comparable in amount due to a 25% increase in the number of units shipped to Janssen offset by a decrease in the unit cost of RISPERDAL CONSTA shipped. The increase in RISPERDAL CONSTA cost of goods manufactured for the six months ended September 30, 2008, as compared to the six months ended September 30, 2007, was due to a 16% 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 manufactured for the three months ended September 30, 2008 consisted of \$2.6 million related to the restart of the VIVITROL manufacturing line following a shutdown of the line, \$1.1 million of cost for failed batches and \$0.3 million for shipments of VIVITROL to Janssen-Cilag to support the commercialization of VIVITROL in Russia. Cost of goods manufactured for VIVITROL for the three months ended September 30, 2007 consisted of idle capacity costs, which consisted of current period manufacturing costs related to underutilized VIVITROL manufacturing capacity.

VIVITROL cost of goods manufactured for the six months ended September 30, 2008 consisted of \$2.6 million related to the restart of the VIVITROL manufacturing line following a shutdown of the line, \$3.3 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. Cost of goods manufactured for VIVITROL for the six months ended September 30, 2007 consisted entirely of idle capacity costs, which consisted of current period manufacturing costs related to underutilized VIVITROL manufacturing capacity.

The decrease in research and development expenses for the three and six months ended September 30, 2008, as compared to the three and six months ended September 30, 2007, was primarily due to the termination of the AIR Insulin development program and the closure of our AIR commercial manufacturing facility in March 2008 (the 2008 Restructuring). As a result, our personnel-related costs, including share-based compensation expense, and our facility related costs, including occupancy and depreciation, decreased compared to the three and six months ended September 30, 2007. In addition, the use of raw materials and third party packaging of the clinical drug product used during the development of the AIR Insulin development program decreased in the three and six months ended September 30, 2008, as compared to the three and six months ended September 30, 2007. Also, no expenses were incurred in fiscal 2009 on the AIR PTH development program, which was terminated during the three months ended September 30, 2007.

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.

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The decrease in selling, general and administrative expenses for the three and six months ended September 30, 2008, as compared to the three and six months ended September 30, 2007, was primarily due to a decrease in professional fees, consisting of legal and consulting fees, decreased personnel related costs, including share-based compensation expense, and decreased taxes.

#### Other (Expense) Income

(In millions)	Three Months Ended September 30,							Six Months Ended September 30,					
	2008		2007		Change		2008		2007		Change		
Interest income	\$	2.7	\$	4.2	\$	(1.5)	\$	6.3	\$	8.7	\$	(2.4)	
Interest expense		(4.2)		(4.1)		(0.1)		(8.5)		(8.2)		(0.3)	
Other (expense) income		(0.7)		1.2		(1.9)		(0.8)		1.2		(2.0)	
Total other (expense) income	\$	(2.2)	\$	1.3	\$	(3.5)	\$	(3.0)	\$	1.7	\$	(4.7)	

The decrease in interest income for the three and six months ended September 30, 2008, as compared to the three and six months ended September 30, 2007, was due to lower interest rates earned during the comparable periods, partially offset by higher average balances of cash and investments. As our investments in corporate debt securities mature or are called by the issuers, we have reinvested the proceeds primarily in U.S. treasuries and agency securities. As such, we expect our interest earnings to decrease as compared to prior periods. Interest expense for the three and six months ended September 30, 2008 and 2007 was comparable in amount due to reduced interest expense as a result of the purchase of approximately 44% our non-recourse RISPERDAL CONSTA secured 7% notes (the 7% Notes), offset by debt extinguishment charges related to the purchases of our 7% Notes. During the six months ended September 30, 2008, we purchased, in three privately negotiated transactions, \$75.0 million in original principal amount of our outstanding 7% Notes. We recorded a loss on the extinguishment of the 7% Notes of \$2.0 million during the six months ended September 30, 2008, which was recorded as interest expense.

Other (expense) for the three and six months ended September 30, 2008 consists primarily of the accretion of discounts related to restructurings and asset retirement obligations and an other-than-temporary impairment on the common stock of certain publicly held companies. Other income for the three and six months ended September 30, 2007 consisted primarily of income recognized on the changes in the fair value of warrants of certain publicly held companies, partially offset by the accretion of discounts related to restructurings and asset retirement obligations and an other-than-temporary impairment on the common stock of certain publicly held companies.

#### Income Taxes

	Thr	ee Months E	nded	Six Months Ended						
	;	September 30	),	September 30,						
(In millions)	2008	2007	Change	2008	2007	Change				
Income tax (benefit) provision	\$ (0.1)	\$ 0.2	\$ (0.3)	\$ 1.0	\$ 2.6	\$ (1.6)				

The income tax benefit for the three months ended September 30, 2008 and the income tax provision for the six months ended September 30, 2008 and the three and six months ended September 30, 2007 all related to the U.S. alternative minimum tax (AMT). Included in the \$0.1 million benefit for the three months ended September 30, 2008 is \$0.1 million which represents the amount that we estimated we will benefit from 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. Utilization of tax loss carryforwards is limited in the calculation of AMT. The current AMT liability is available as a credit against future tax obligations upon the full utilization or expiration of our net operating loss carryforward.

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

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

Our financial condition is summarized as follows:

	S	eptember 30,	Aarch 31,
(In millions)		2008	2008
Cash and cash equivalents	\$	68.5	\$ 101.2
Investments short-term		263.9	240.1
Investments long-term		93.4	119.1
Total cash, cash equivalents and investments	\$	425.8	\$ 460.4
Working capital	\$	354.1	\$ 371.1
Outstanding borrowings current and long-term	\$	91.9	\$ 160.4

We invest in short-term and long-term investments consisting 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 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 and conservation of capital and, second, to obtain investment income. We performed an analysis of our investment portfolio at September 30, 2008 for impairment and determined that we had a temporary impairment of \$3.5 million, attributed primarily to our investments in corporate debt securities, including asset backed debt securities, student loan backed auction rate securities, and 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, and other-than-temporary impairments are realized and recorded in our condensed consolidated statements of income.

At September 30, 2008, we have classified \$88.7 million of our available-for-sale investments in securities with temporary losses of \$3.5 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 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 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;

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 September 30, 2008 and March 31, 2008.

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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 September 30, 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 investments in auction rate securities of approximately \$0.7 million to accumulated other comprehensive income at September 30, 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 September 30, 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 deteriorate significantly.

Our investments in asset backed debt securities have a cost of \$8.2 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 September 30, 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 double A by Standard and Poor s ( S&P ), and MBIA was downgraded from triple A to A2 by Moody s and double A by S&P. Both downgrades were due to Ambac s and MBIA s inability to maintain triple A capital levels. In August 2008, S&P affirmed its double A ratings of Ambac and MBIA with negative outlook. In September 2008, Moody s placed Ambac and MBIA on review for possible downgrade. In November 2008, Moody s announced that it had downgraded Ambac s rating to Baa1 with a developing outlook.

We may not be able to liquidate our investment in the 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 September 30, 2008. Our valuation analyses consider, among other items, assumptions that market participants would use in their estimates of fair value such as the collateral

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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 September 30, 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 September 30, 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 deteriorate significantly or the credit ratings of the issuers are 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 in connection with collaborative arrangements and as we expand the development of our proprietary product candidates, including costs related to preclinical studies, clinical trials and facilities expansion. Our costs, including research and development costs for our product candidates and sales, marketing and promotional expenses for any future products to be marketed by us or our collaborators, if any, may exceed revenues in the future, which may result in losses from operations. We believe that our current cash and cash equivalents and short-term investments, combined with our unused equipment lease line, anticipated interest income and anticipated revenues will generate sufficient cash flows to meet our anticipated liquidity and capital requirements through at least September 30, 2009.

## **Operating Activities**

Cash provided by operating activities was \$39.2 million and \$9.6 million in the six months ended September 30, 2008 and 2007, respectively. Cash flows from operating activities in the six months ended September 30, 2008 increased over the six months ended September 30, 2007 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 changes in other working capital accounts.

## **Investing Activities**

Cash provided by investing activities was \$5.7 million and cash used in investing activities was \$12.2 million in the six months ended September 30, 2008 and 2007, respectively. During the six months ended September 30, 2008, we had net sales of investments of \$1.5 million and purchased \$3.6 million in property, plant and equipment, which was offset by \$7.7 million in cash we received on the sale of certain equipment to a collaborative partner. During the six months ended September 30, 2007, we had net sales of investments of \$2.4 million and purchased \$14.6 million in property, plant and equipment.

# Financing Activities

Cash used in financing activities was \$7.6 million and cash provided by financing activities was \$8.6 million for the six months ended September 30, 2008 and 2007, respectively. In the six months ended September 30, 2008, we used \$71.8 million to repurchase a portion of our outstanding 7% Notes and \$13.1 million to repurchase our common stock under our publicly announced stock repurchase program. These cash payments were partially offset by \$7.2 million of cash provided from the issuance of common stock in connection with the exercise of employee stock options. In the six months ended September 30, 2007, we received cash of \$9.1 million from the issuance of common stock in connection with the exercise of employee stock options, offset by debt payments of \$0.7 million.

## **Borrowings**

At September 30, 2008, our borrowings consisted primarily of our 7% Notes, which had a carrying value of \$91.9 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

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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 six months ended September 30, 2008. As a result of the purchases, \$95.0 principal amount of the 7% Notes remains outstanding, and we will save approximately \$11.2 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, competing technological and market developments, the establishment of additional collaborative arrangements, the cost of manufacturing facilities and of commercialization activities and arrangements and the cost of product in-licensing and any possible acquisitions and, for any future proprietary products, the sales, marketing and promotion expenses associated with marketing such products. We may 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.

We have an arrangement with General Electric Capital Corporation (GE) for an equipment lease line that provides us with the ability to finance up to \$18.3 million of new equipment purchases. The equipment financing would be secured by the purchased equipment and will be subject to a financial covenant, and this lease line expires in December 2008. At September 30, 2008, there were no amounts outstanding under this lease line.

Capital expenditures are expected in the range from \$4.0 million to \$5.0 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 10 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 September 30, 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.

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#### 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 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) are recorded at fair value; and (iii) are 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 \$1.3 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 our investments by approximately \$0.1 million and \$0.2 million at September 30, 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 the year 2012, this change would have the effect of reducing the fair value of these securities by approximately \$0.6 million at September 30, 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 \$0.1 million at September 30, 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 September 30, 2008, the fair value of our 7% Notes approximated the carrying value. The interest rate on these notes, and our capital lease obligations, are fixed and therefore not subject to interest rate risk.

## 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. Some of these sales are made in foreign countries and are denominated in foreign currencies. The manufacturing and royalty payment on these foreign sales is calculated initially in the foreign currency in which the sale is made and is then converted into U.S. dollars to determine the amount that Janssen pays us for 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.

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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 six months ended September 30, 2008, an average 10% strengthening of the U.S. dollar relative to the currencies in which RISPERDAL CONSTA is sold, our manufacturing and royalty revenues would have been reduced by approximately \$4.7 million and \$1.1 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 procedures (as defined in Rule 13a-15(e) under the Securities Exchange Act of 1934, as amended, or the Securities Exchange Act) at September 30, 2008. Based upon that evaluation, our principal executive officer and principal financial officer concluded that, at September 30, 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.

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## 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 current credit and financial market conditions may exacerbate certain risks affecting our business.

Sales of our products are dependent, in large part, on reimbursement from government health administration authorities, private health insurers, distribution partners and other organizations. As a result of the current credit and financial market conditions, these organizations may be unable to satisfy their reimbursement obligations or may delay payment. In addition, federal and state health authorities may reduce Medicare and Medicaid reimbursements, and private insurers may increase their scrutiny of claims. A reduction in the availability or extent of reimbursement could negatively affect our product sales and revenue. Customers may also reduce spending during times of economic uncertainty.

In addition, we rely on third parties for several important aspects of our business. For example, we depend upon collaborators for both manufacturing and royalty revenue and the clinical development of collaboration products, we use third-party contract research organizations for many of our clinical trials, and we rely upon several single source providers of raw materials for the manufacture of our products. Due to the recent tightening of global credit and the disruption in the financial markets, there may be a disruption or delay in the performance of our third-party contractors, suppliers or collaborators. If such third parties are unable to satisfy their commitments to us, our business would be adversely affected.

Our investment portfolio may become impaired by further deterioration of the capital markets.

As a result of current adverse financial market conditions, investments in some financial instruments, such as auction rate securities and asset backed debt securities, may pose risks arising from liquidity and credit concerns. We have limited holdings of these investments in our portfolio; however, the current disruptions in the credit and financial markets have negatively affected investments in many industries, including those in which we invest. The current global economic crisis has had, and may continue to have, a negative impact on the market values of the investments in our investment portfolio. We cannot predict future market conditions or market liquidity and there can be no assurance that the markets for these securities will not deteriorate further or that the institutions that these investments are with will be able to meet their debt obligations at the time we may need to liquidate such investments or until such time as the investments mature. Although we currently have no plans to access the equity or debt markets to meet capital or liquidity needs, constriction and volatility in these markets may restrict future flexibility to do so if unforeseen capital or liquidity needs were to arise.

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

A summary of our stock repurchase activity for the six months ended September 30, 2008 is as follows:

				Γ	roximate Dollar alue of
			Total	S	hares
			<b>Number of Shares</b>	that	May Yet
	Total				
	Number	Average Price	Purchased as		urchased der the
	of Shares	Paid per	Part of a Publicly Announced	Pr	ogram
Period	Purchased(a)	Share	Program(a)	(in r	millions)
April 1 through April 30		\$		\$	81.6
May 1 through May 31					81.6
June 1 through June 30	1,038,455	12.11	1,038,455		109.1

July 1 through July 31 August 1 through August 31 September 1 through September 30	38,700	12.	89	38,700	\$ 109.1 109.1 108.6
Total	1,077,155	\$ 12	2.14	1,077,155	
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(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 six months ended September 30, 2008, we acquired, by means of net share settlements, 583 and 35,532 shares of Alkermes common stock, at an average price of \$13.01 and \$12.70 per share, respectively, related to the vesting of employee stock awards to satisfy withholding tax obligations. In addition, during the three and six months ended September 30, 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 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 September 30, 2008, Mr. James M. Frates, an executive officer of the Company, 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.

- 31.1 Rule 13a-14(a)/15d-14(a) Certification (furnished herewith).
- 31.2 Rule 13a-14(a)/15d-14(a) Certification (furnished herewith).
- 32.1 Certification pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (furnished herewith).

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#### **SIGNATURES**

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

ALKERMES, INC. (Registrant)

By: /s/ David A. Broecker
David A. Broecker
President and Chief Executive Officer
(Principal Executive Officer)

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

Date: November 7, 2008

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# **EXHIBIT INDEX**

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Exhibit No	
31.1	Rule 13a-14(a)/15d-14(a) Certification (furnished herewith).
31.2	Rule 13a-14(a)/15d-14(a) Certification (furnished herewith).
32.1	Certification pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (furnished herewith).