ALKERMES INC Form 10-Q November 04, 2010

#### 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, 2010

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

For the transition period from

to

Commission file number 1-14131 ALKERMES, INC.

(Exact name of registrant as specified in its charter)

#### **PENNSYLVANIA**

23-2472830

(State or other jurisdiction of incorporation or organization)

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

852 Winter Street, Waltham, MA 02451 (781) 609-6000

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

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

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files): Yes b No o

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

Large accelerated filer b

Accelerated filer o

Non-accelerated filer o

Smaller reporting company o

(Do not check if a smaller reporting company)

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

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

As of November 1, 2010

Class
Common Stock, \$0.01 par value

95,233,058

Non-Voting Common Stock, \$0.01 par value 382,632

# ALKERMES, INC. AND SUBSIDIARIES QUARTERLY REPORT ON FORM 10-Q FOR THE QUARTERLY PERIOD ENDED SEPTEMBER 30, 2010 INDEX

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#### PART I. FINANCIAL INFORMATION

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

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

	September 30, 2010		March 31, 2010	
	(In thousands, except share and per sha			
A CODETO		amo	ounts)	
ASSETS CURRENT ASSETS:				
Cash and cash equivalents	\$	37,256	\$	79,324
Investments short-term	φ	193,222	Φ	202,053
Receivables		35,770		25,316
Inventory		18,257		20,653
Prepaid expenses and other current assets		14,696		10,936
Trepaid expenses and other current assets		14,070		10,730
Total current assets		299,201		338,282
PROPERTY, PLANT AND EQUIPMENT, NET		97,184		96,905
INVESTMENTS LONG-TERM		43,087		68,816
OTHER ASSETS		9,660		11,597
0111EN 1100E10		2,000		11,00,
TOTAL ASSETS	\$	449,132	\$	515,600
LIABILITIES AND SHAREHOLDERS EQUITY CURRENT LIABILITIES:				
Accounts payable and accrued expenses	\$	31,123	\$	37,881
Deferred revenue current		3,894		2,220
Non-Recourse RISPERDAL® CONSTA® Secured 7% Notes		·		
Current				51,043
Total current liabilities		35,017		91,144
DEFERRED REVENUE LONG-TERM		5 102		5 105
OTHER LONG-TERM LIABILITIES		5,123 6,901		5,105 6,735
OTHER LONG-TERM LIABILITIES		0,901		0,733
Total liabilities		47,041		102,984
COMMITMENTS AND CONTINGENCIES (Note 13)				
COMMITMENTS AND CONTINGENCIES (NOC 15)				
SHAREHOLDERS EQUITY: Common stock, par value, \$0.01 per share; 160,000,000 shares authorized; 105,248,764 and 104,815,328 shares issued; 95,206,971 and 94,870,063 shares outstanding at September 30,				
2010 and March 31, 2010, respectively		1,050		1,047
, , <u>,</u> ,		•		,

Non-voting common stock, par value, \$0.01 per share; 450,000		
shares authorized; 382,632 shares issued and outstanding at		
September 30, 2010 and March 31, 2010	4	4
Treasury stock, at cost (10,041,793 and 9,945,265 shares at		
September 30, 2010 and March 31, 2010, respectively)	(130,779)	(129,681)
Additional paid-in capital	921,024	910,326
Accumulated other comprehensive loss	(2,445)	(3,392)
Accumulated deficit	(386,763)	(365,688)
Total shareholders equity	402,091	412,616
TOTAL LIABILITIES AND SHAREHOLDERS EQUITY	\$ 449,132	\$ 515,600

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

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

	Three Months Ended September 30, 2010 2009		Six Months Ended September 30, 2010 2009		
	(In th	ousands, exce	pt per share am	ounts)	
REVENUES:					
Manufacturing revenues	\$33,163	\$ 32,835	\$ 60,054	\$ 61,639	
Royalty revenues	9,460	8,818	18,377	17,519	
Product sales, net	6,469	4,643	12,673	8,869	
Research and development revenue under collaborative					
arrangements	155	1,174	423	2,624	
Net collaborative profit		687		5,002	
Total revenues	49,247	48,157	91,527	95,653	
EXPENSES:					
Cost of goods manufactured and sold	13,911	15,092	26,576	27,758	
Research and development	23,932	20,664	46,909	46,250	
Selling, general and administrative	18,436	20,625	38,162	39,893	
Total expenses	56,279	56,381	111,647	113,901	
OPERATING LOSS	(7,032)	(8,224)	(20,120)	(18,248)	
OTHER EXPENSE, NET:					
Interest income	673	1,088	1,525	2,649	
Interest expense	(2,168)	(1,566)	(3,298)	(3,275)	
Other expense, net	(82)	(67)	(183)	(130)	
Total other expense, net	(1,577)	(545)	(1,956)	(756)	
LOSS BEFORE INCOME TAXES	(8,609)	(8,769)	(22,076)	(19,004)	
INCOME TAX BENEFIT	(943)	(60)	(1,001)	(130)	
NET LOSS	\$ (7,666)	\$ (8,709)	\$ (21,075)	\$ (18,874)	
LOSS PER COMMON SHARE:					
Basic and diluted	\$ (0.08)	\$ (0.09)	\$ (0.22)	\$ (0.20)	
WEIGHTED AVERAGE NUMBER OF COMMON SHARES OUTSTANDING:					
Basic and diluted	95,511	94,886	95,419	94,830	

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,	
	2010	2009
	(In thou	ısands)
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	\$ (21,075)	\$ (18,874)
Adjustments to reconcile net loss to cash flows from operating activities:		
Depreciation	4,062	15,482
Share-based compensation expense	9,404	7,438
Other non-cash charges	1,899	2,093
Changes in assets and liabilities:	(10.17.1)	(0.111)
Receivables	(10,454)	(9,111)
Inventory, prepaid expenses and other assets	1,791	10
Accounts payable and accrued expenses	(7,710)	(8,702)
Deferred revenue	1,692	(5,083)
Other long-term liabilities	(75)	(920)
Payment of non-recourse RISPERDAL CONSTA secured 7% notes principal	(6.611)	(1,000)
attributable to original issue discount	(6,611)	(1,009)
Cash flows used in operating activities	(27,077)	(18,676)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchase of property, plant and equipment	(6,719)	(3,885)
Sales of property, plant and equipment	206	169
Investment in Acceleron Pharmaceuticals, Inc.	(501)	
Purchases of investments	(240,371)	(295,318)
Sales and maturities of investments	276,437	298,134
Cash flows provided by (used in) investing activities	29,052	(900)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from the issuance of common stock for share-based compensation		
arrangements	1,354	183
Payment of non-recourse RISPERDAL CONSTA secured 7% notes principal	(45,397)	(11,824)
Purchase of common stock for treasury	(12,000)	(2,684)
Cash flows used in financing activities	(44,043)	(14,325)
Cash nows used in financing activities	(44,043)	(14,323)
NET DECREASE IN CASH AND CASH EQUIVALENTS	(42,068)	(33,901)
CASH AND CASH EQUIVALENTS Beginning of period	79,324	86,893
CASH AND CASH EQUIVALENTS End of period	\$ 37,256	\$ 52,992
SUPPLEMENTAL CASH FLOW DISCLOSURE:		

Cash paid for interest	\$	1,684	\$	2,784
Cash paid for taxes	\$	31	\$	53
Non-cash investing and financing activities:				
Purchased capital expenditures included in accounts payable and accrued expenses	\$	578	\$	1,967
The accompanying notes are an integral part of these unaudited condensed conso	lidated	financial s	tateme	ents.
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# ALKERMES, INC. AND SUBSIDIARIES NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED) 1. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

#### **Basis of Presentation**

Alkermes, Inc. (the Company or Alkermes) is a fully integrated biotechnology company committed to developing innovative medicines to improve patients—lives. The Company developed, manufactures and commercializes VIVITROL® for alcohol dependence and for the prevention of relapse to opioid dependence, following opioid detoxification. The Company also manufactures RISPERDAL® CONSTA® for schizophrenia and bipolar I disorder. The Company—s pipeline includes extended-release injectable and oral products for the treatment of prevalent, chronic diseases, such as central nervous system (CNS) disorders, reward disorders, addiction, diabetes and autoimmune disorders. The Company is headquartered in Waltham, Massachusetts and has a research facility in Massachusetts and a commercial manufacturing facility in Ohio.

The accompanying condensed consolidated financial statements of Alkermes for the three and six months ended September 30, 2010 and 2009 are unaudited and have been prepared on a basis substantially consistent with the audited financial statements for the year ended March 31, 2010. 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 (U.S.) (commonly referred to as GAAP). In the opinion of management, the condensed consolidated financial statements include all adjustments, which are of a normal recurring nature, that are necessary to present fairly the results of operations for the reported periods.

These financial statements should be read in conjunction with the Company s audited consolidated financial statements and notes thereto which are contained in the Company s Annual Report on Form 10-K for the year ended March 31, 2010, 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). Intercompany accounts and transactions have been eliminated.

Use of Estimates The preparation of the Company s condensed consolidated financial statements in conformity with GAAP necessarily requires management to make estimates and assumptions that affect the following: (1) reported amounts of assets and liabilities; (2) disclosure of contingent assets and liabilities at the date of the condensed consolidated financial statements; and (3) the reported amounts of revenues and expenses during the reporting period. Actual results could differ from these estimates.

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

#### New Accounting Pronouncements

In September 2009, the Emerging Issues Task Force (EITF) of the Financial Accounting Standards Board (FASB) issued accounting guidance related to revenue recognition that amends the previous guidance on arrangements with multiple deliverables. The new guidance provides accounting principles and application guidance on whether multiple deliverables exist, how the arrangement should be separated, and provides for separate revenue recognition based upon management s estimate of the selling price for an undelivered item when there is no other means to determine the fair value of that undelivered item. Accounting guidance previously required that the fair value of the undelivered item be the price of the item either sold in a separate transaction between unrelated third parties or the price charged for each item when the item is sold separately by the vendor. This was difficult to determine when the product was not individually sold because of its unique features. Under the previous guidance, if the fair value of all of the elements in the arrangement was not determinable, then revenue was deferred until all of the items were delivered or fair value was determined. This guidance is effective prospectively for revenue arrangements entered into or materially modified

in the Company s fiscal year beginning April 1, 2011, and the Company is currently evaluating the potential impact of this standard on its consolidated financial statements. Early adoption is permitted, however, adoption of this guidance as of a date other than April 1, 2011 will require the Company to apply this guidance retrospectively effective as of April 1, 2010, and will require disclosure of the effect of this guidance as applied to all previously reported interim periods in the fiscal year of adoption.

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

In January 2010, the FASB issued accounting guidance related to fair value measurements that requires additional disclosure related to transfers in and out of Levels 1 and 2 of the fair value hierarchy. The guidance also requires additional disclosure for activity within Level 3 of the fair value hierarchy. The guidance requires a reporting entity to disclose separately the amounts of significant transfers in and out of Level 1 and Level 2 and describe the reasons for the transfers. In addition, this guidance requires a reporting entity to present information separately about purchases, sales issuances and settlements in the reconciliation for fair value measurements using significant unobservable inputs, or Level 3. This accounting standard was effective for interim and annual reporting periods beginning after December 31, 2009, other than for disclosures about purchases, sales, issuances and settlements in the roll forward of activity in Level 3 fair value measurements. Those disclosures are effective for fiscal years beginning after December 31, 2010 and for interim periods within those fiscal years. The Company adopted all provisions of this pronouncement, except for those related to the disclosure of disaggregated Level 3 activity, on January 1, 2010, and as this guidance only amends required disclosures in the Company s condensed consolidated financial statements, it did not have an effect upon the Company s financial position or results of operations. The Company does not expect the adoption of the remaining provisions of this amendment to have a significant impact on its consolidated financial statements.

In April 2010, the FASB issued accounting guidance related to the milestone method of revenue recognition for research and development arrangements. Under this guidance, the Company may recognize revenue contingent upon the achievement of a milestone in its entirety, in the period in which the milestone is achieved, only if the milestone meets all the criteria within the guidance to be considered substantive. This guidance is effective on a prospective basis for research and development milestones achieved in the Company s fiscal year beginning April 1, 2011. Early adoption is permitted, however, adoption of this guidance as of a date other than April 1, 2011 will require the Company to apply this guidance retrospectively effective as of April 1, 2010, and will require disclosure of the effect of this guidance as applied to all previously reported interim periods in the fiscal year of adoption. The Company plans to implement this guidance prospectively and the effect of this guidance will be limited to future transactions. The Company does not expect adoption of this standard to have a material impact on its financial position or results of operations.

#### 2. COMPREHENSIVE LOSS

Comprehensive loss is as follows:

	Three Mor Septem			
(In thousands)	2010	2009	2010	2009
Net loss	\$ (7,666)	\$ (8,709)	\$ (21,075)	\$ (18,874)
Unrealized gains on available-for-sale securities: Holding gains (losses), net of tax	453	(228)	947	1,760
Unrealized gains (losses) on available-for-sale securities	453	(228)	947	1,760
Comprehensive loss	\$ (7,213)	\$ (8,937)	\$ (20,128)	\$ (17,114)

#### 3. LOSS PER SHARE

Basic loss per common share is calculated based upon net loss available to holders of common shares divided by the weighted average number of common shares outstanding. For the three and six months ended September 30, 2010 and 2009, as the Company was in a net loss position, the diluted loss per share does not assume conversion or exercise of stock options and awards as they would have an anti-dilutive effect on loss per share. Therefore, the weighted average number of basic and diluted voting shares of common stock outstanding for the three and six months ended September 30, 2010 and 2009 were as follows:

	Three Months Ended September 30,		Six Months Ended September 30,	
(In thousands)	2010	2009	2010	2009
Weighted average number of common shares outstanding	95,511	94,886	95,419	94,830
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# ALKERMES, INC. AND SUBSIDIARIES NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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

		Three Months Ended September 30,			
(In thousands)	2010	2009	Septem 2010	2009	
Stock options	13,898	17,821	13,736	17,920	
Restricted stock units	909	407	850	308	
Total	14,807	18,228	14,586	18,228	

#### 4. INVESTMENTS

Investments consist of the following:

			Gross Unrea	alized	
			Losses		
	Amortized		Less than One	Greater than	Estimated Fair
	Cost	Gains	Year (In thousa	One Year	Value
<b>September 30, 2010</b>			(=== 0== 0==		
Short-term investments:					
Available-for-sale securities:					
U.S. government and agency debt					
securities	\$ 164,185	\$ 402	\$ (1)	\$	\$ 164,586
International government agency debt					
securities	18,078	265			18,343
Corporate debt securities	9,029	78		(15)	9,092
	191,292	745	(1)	(15)	192,021
Management from da	1 201				1 201
Money market funds	1,201				1,201
Total short-term investments	192,493	745	(1)	(15)	193,222
Long-term investments:					
Available-for-sale securities:					
Corporate debt securities	25,238			(664)	24,574
Auction rate securities	5,000			(571)	4,429
International government agency debt	3,000			(5,1)	.,.25
securities	4,994		(1)		4,993
U.S. government and agency debt	,		,		,
securities	1,997		(1)		1,996
Strategic equity investments	644	594			1,238
	37,873	594	(2)	(1,235)	37,230

Held-to-maturity securities: Certificates of deposit U.S. government debt securities	5,440 417				5,440 417
	5,857				5,857
Total long-term investments	43,730	594	(2)	(1,235)	43,087
Total investments	\$ 236,223	\$ 1,339	\$ (3)	\$ (1,250)	\$ 236,309
March 31, 2010 Short-term investments: Available-for-sale securities: U.S. government and agency debt					
securities International government agency debt	\$ 160,876	\$ 204	\$	\$	\$ 161,080
securities Corporate debt securities Asset backed debt securities	23,441 15,225 983	136 14		(1) (2) (24)	23,576 15,237 959
	200,525	354		(27)	200,852
Money market funds	1,201				1,201
Total short-term investments	201,726	354		(27)	202,053
Long-term investments: Available-for-sale securities: Corporate debt securities	26,109			(942)	25,167
U.S. government and agency debt securities Auction rate securities International government agency debt	24,727 10,000		(39)	(1,454)	24,688 8,546
securities Strategic equity investments	3,225 644	691	(2)		3,223 1,335
	64,705	691	(41)	(2,396)	62,959
Held-to-maturity securities: Certificates of deposit U.S. government debt securities	5,440 417 5,857				5,440 417 5,857
Total long-term investments	70,562	691	(41)	(2,396)	68,816
Total investments	\$ 272,288	\$ 1,045	\$ (41)	\$ (2,423)	\$ 270,869

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

Proceeds from the sales and maturities of marketable securities, excluding strategic equity investments, which were primarily reinvested and resulted in realized gains and losses, were as follows:

	Six Months Ended			
	September		September	
	30	,		30,
(In thousands)	201	10		2009
Proceeds from the sales and maturities of marketable securities	\$ 276	,437	\$	298,134
Realized gains	\$	63	\$	186
Realized losses	\$	20	\$	1

The Company s available-for-sale and held-to-maturity securities at September 30, 2010 have contractual maturities in the following periods:

	Available-for-Sale		Held-to-Maturity	
	Amortized	Estimated	Amortized	Estimated Fair
(In thousands)	Cost	Fair Value	Cost	Value
Within 1 year	\$ 72,430	\$ 72,527	\$ 5,857	\$ 5,857
After 1 year through 5 years (1)	123,024	123,408		
After 5 years through 10 years (1)	28,067	27,649		
After 10 years	5,000	4,429		
Total	\$ 228,521	\$ 228,013	\$ 5,857	\$ 5,857

(1) Investments in available-for-sale securities within these categories, with an amortized cost of \$49.1 million and an estimated fair value of \$48.6 million, have issuer call dates prior to May 2011.

At September 30, 2010, the Company believes that the unrealized losses on its available-for-sale investments are temporary. The investments with unrealized losses consist of corporate debt securities and an auction rate security. In making the determination that the decline in fair value of these securities was temporary, the Company considered various factors, including but not limited to: the length of time each security was in an unrealized loss position; the extent to which fair value was less than cost; financial condition and near term prospects of the issuers; and the Company s intent not to sell these securities and the assessment that it is more likely than not that the Company would not be required to sell these securities before the recovery of their amortized cost basis.

The Company s strategic equity investments include common stock in public companies with which the Company has or had a collaborative arrangement. In addition, in December 2009, the Company entered into a collaborative arrangement with, and made an investment in, Acceleron Pharma, Inc. ( Acceleron ). The Company s Chairman, President and Chief Executive Officer is one of nine members of Acceleron s board of directors. The Company s December 2009 investment in Acceleron consisted of an \$8.0 million purchase of shares of Series D-1 convertible, redeemable preferred stock. In July 2010, the Company invested an additional \$0.5 million in exchange for shares of Series E convertible, redeemable preferred stock and common stock warrants. The Company accounts for its investment in Acceleron under the cost method as Acceleron is a privately-held company over which the Company does not exercise significant influence. The Company will continue to monitor this investment to evaluate whether any decline in its value has occurred that would be other-than-temporary, based on the implied value from any recent rounds of financing completed by Acceleron, specific events at Acceleron, market prices of comparable public companies and general market conditions. The Company s investment balance of \$8.5 million and \$8.0 million at September 30, 2010 and March 31, 2010, respectively, is recorded within Other assets in the accompanying

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# ALKERMES, INC. AND SUBSIDIARIES NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued 5. FAIR VALUE MEASUREMENTS

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

	Se	eptember 30,			
(In thousands)		2010	Level 1	Level 2	Level 3
Cash equivalents and money market funds	\$	1,303	\$ 1,303	\$	\$
U.S. government and agency debt securities		166,582	166,582		
International government agency debt securities		23,336	23,336		
Corporate debt securities		33,666		31,912	1,754
Auction rate securities		4,429			4,429
Strategic equity investments		1,238	1,238		
Total	\$	230,554	\$ 192,459	\$31,912	\$ 6,183
	M	Iarch 31,			
		2010	Level 1	Level 2	Level 3
Cash equivalents and money market funds	\$	1,289	\$ 1,289	\$	\$
U.S. government and agency debt securities		185,768	185,768		
International government agency debt securities		26,799	26,799		
Corporate debt securities		40,404		38,668	1,736
Auction rate securities		8,546			8,546
Asset backed debt securities		959			959
Strategic equity investments		1,335	1,335		
Total	\$	265,100	\$215,191	\$ 38,668	\$ 11,241

There were no transfers or reclassifications of any securities between Level 1 and Level 2 during the six months ended September 30, 2010. The following table illustrates the rollforward of the fair value of the Company s investments whose fair value is determined using Level 3 inputs:

	Fair
(In thousands)	Value
Balance, March 31, 2010	\$ 11,241
Total unrealized gains included in comprehensive loss	925
Sales and redemptions, at par value	(5,983)
Balance, September 30, 2010	\$ 6,183

Substantially all of the Company s investments in corporate debt securities have been classified as Level 2 investments. These securities have been initially valued at the transaction price and subsequently valued, at the end of each reporting period, utilizing market observable data. The market observable data includes reportable trades, benchmark yields, credit spreads, broker/dealer quotes, bids, offers and other industry and economic events. The Company validates the prices developed using the market observable data by obtaining market values from other

pricing sources, analyzing pricing data in certain instances and confirming that the relevant markets are active.

The Company used a discounted cash flow model to determine the estimated fair value of its Level 3 investments. The Company s most significant Level 3 investment at September 30, 2010 consists of its investment in a student loan backed auction rate security, with an amortized cost of \$5.0 million, which was not trading at September 30, 2010. The assumptions used in the discounted cash flow model include estimates for interest rates, timing of cash flows, expected holding periods and risk adjusted discount rates, which include provisions for default and liquidity risk, which the Company believes to be the most critical assumptions utilized within the analysis. The valuation analysis considers, among other items, assumptions that market participants would use in their estimates of fair value, such as the collateral underlying the security, the creditworthiness of the issuer and any associated guarantees, the timing of expected future cash flows, the timing of, and the likelihood that the security will have a successful auction or when callability features may be exercised by the issuer. The securities were also compared, where possible, to other observable market data with similar characteristics to the securities held by the Company.

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

The carrying amounts reflected in the condensed consolidated balance sheets for cash and cash equivalents, accounts receivable, other current assets, accounts payable and accrued expenses approximate fair value due to their short-term nature. The Company s non-recourse RISPERDAL CONSTA secured 7% notes (the non-recourse 7% Notes ) were fully redeemed on July 1, 2010 and had a carrying value of \$51.0 million and a fair value of \$48.7 million at March 31, 2010. The estimated fair value of the non-recourse 7% Notes at March 31, 2010 was based on a discounted cash flow model.

#### 6. INVENTORY

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

	September				
		30,	Ma	arch 31,	
(In thousands)		2010			
Raw materials	\$	3,822	\$	4,130	
Work in process		6,306		7,788	
Finished goods (1)		7,505		8,501	
Consigned-out inventory (2)		624		234	
Total inventory	\$	18,257	\$	20,653	

- (1) At September 30, 2010 and March 31, 2010, the Company had \$0.8 million and \$0.7 million of finished goods inventory located at its third party warehouse and shipping service provider.
- (2) At September 30, 2010 and March 31, 2010, consigned-out inventory relates to VIVITROL inventory in the distribution channel for which the Company has not recognized revenue.

#### 7. PROPERTY, PLANT AND EQUIPMENT

Property, plant and equipment consist of the following:

	Se	eptember 30,	м	arch 31,
(In thousands)		2010	IVI	2010
Land	\$	301	\$	301
Building and improvements		36,766		36,759
Furniture, fixture and equipment		65,276		62,501
Leasehold improvements		44,488		42,660
Construction in progress		42,165		43,695
Subtotal		188,996		185,916
Less: accumulated depreciation		(91,812)		(89,011)
Total property, plant and equipment, net	\$	97,184	\$	96,905

#### 8. ACCOUNTS PAYABLE AND ACCRUED EXPENSES

Accounts payable and accrued expenses consist of the following:

March 31,

(In thousands)		-	otember 30, 2010	2010
Accounts payable Accrued compensation Accrued other		\$	7,903 10,880 12,340	\$ 8,197 15,276 14,408
Total accounts payable and accrued expenses		\$	31,123	\$ 37,881
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# ALKERMES, INC. AND SUBSIDIARIES NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued) 9. LONG-TERM DEBT

Long-term debt consists of the following:

	September		
	30, 2010	March 31, 2010	
Non-recourse 7% Notes Less: current portion	\$	\$ 51,043 (51,043)	
Long-term debt	\$	\$	

On July 1, 2010, in addition to the scheduled principal payment of \$6.4 million, the Company fully redeemed the balance of the non-recourse 7% Notes for \$39.2 million, representing 101.75% of the outstanding principal balance in accordance with the terms of the Indenture for the non-recourse 7% Notes. The non-recourse 7% Notes were previously scheduled to mature on January 1, 2012.

#### 10. SHARE-BASED COMPENSATION

Share-based compensation expense consists of the following:

	Three Months Ended September 30,		Six Months Ended September 30,	
(In thousands)	2010	2009	2010	2009
Cost of goods manufactured and sold	\$ 525	\$ 519	\$ 886	\$ 829
Research and development	1,637	919	3,152	1,726
Selling, general and administrative	2,786	2,770	5,366	4,883
Total share-based compensation expense	\$ 4,948	\$ 4,208	\$ 9,404	\$ 7,438

At September 30, 2010 and March 31, 2010, \$0.5 million, respectively, of share-based compensation cost was capitalized and recorded as Inventory in the condensed consolidated balance sheets.

#### 11. RESTRUCTURING

In connection with the 2008 restructuring program, in which the Company and Eli Lilly and Company announced the decision to discontinue the AIR® Insulin development program (the 2008 Restructuring ), the Company recorded net restructuring charges of approximately \$6.9 million in the year ended March 31, 2008. Activity related to the 2008 Restructuring in the six months ended September 30, 2010 was as follows:

(In thousands)	Balance
Accrued restructuring, March 31, 2010	\$ 3,596
Payments for facility closure costs	(451)
Other adjustments	340
	<b>4.2.40</b>
Accrued restructuring, September 30, 2010	\$ 3,485

At September 30, 2010 and March 31, 2010, the restructuring liability related to the 2008 Restructuring consists of \$0.7 million classified as current and \$2.8 million classified as long-term, respectively, in the accompanying condensed consolidated balance sheets. As of September 30, 2010, the Company had paid in cash, written off, recovered and made restructuring charge adjustments that totaled approximately \$0.4 million in facility closure costs, \$2.9 million in employee separation costs and \$0.2 million in other contract termination costs in connection with the

2008 Restructuring. The \$3.5 million remaining in the restructuring accrual at September 30, 2010 is expected to be paid out through fiscal 2016 and relates primarily to future lease costs associated with an exited facility.

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# ALKERMES, INC. AND SUBSIDIARIES NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued) 12. INCOME TAXES

The Company records a deferred tax asset or liability based on the difference between the financial statement and tax bases of assets and liabilities, as measured by enacted tax rates assumed to be in effect when these differences reverse. At September 30, 2010, the Company determined that it is more likely than not that the deferred tax assets may not be realized and a full valuation allowance continues to be recorded.

The Company recorded an income tax benefit of \$0.9 million and \$1.0 million for the three and six months ended September 30, 2010, respectively, primarily related to a \$0.8 million tax benefit for bonus depreciation pursuant to the *Small Business Jobs Act of 2010* ( Act ). Bonus depreciation increases the Company s 2010 alternative minimum tax ( AMT ) net operating loss ( NOL ) carryback and will allow the Company to recover AMT paid in the carryback period. The tax benefit was recorded as a discrete item during the three months ended September 30, 2010, the period in which the Act was enacted. The income tax benefit of less than \$0.1 million and \$0.1 million for the three and six months ended September 30, 2009, represented the amount the Company estimated it would benefit from the *Housing and Economic Recovery Act of 2008*.

#### 13. COMMITMENTS AND CONTINGENCIES

From time to time, the Company may be subject to legal proceedings and claims in the ordinary course of business. The Company does not believe that it is currently party to 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.

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

The following discussion should be read in conjunction with our condensed consolidated financial statements and related notes beginning on page 6 of this Quarterly Report on Form 10-Q, and the audited financial statements and notes thereto, and Management s Discussion and Analysis of Financial Condition and Results of Operations included in our Annual Report on Form 10-K, which has been filed with the Securities and Exchange Commission (SEC).

#### **Forward-Looking Statements**

This document contains and incorporates by reference forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. In some cases, these statements can be identified by the use of forward-looking terminology such as may, will, could, should, we expect, anticipate, continue or other similar words. These statements discuss future expectations; contain projections of results of operations or of financial condition, or state trends and known uncertainties or other forward looking information. Forward-looking statements in this Quarterly Report on Form 10-Q include, without limitation, statements regarding:

our expectations regarding our financial performance, including, but not limited to revenues, expenses, gross margins, liquidity, capital expenditures and income taxes;

our expectations regarding the commercialization of RISPERDAL CONSTA and VIVITROL including the sales and marketing efforts of our partners Ortho-McNeil-Janssen Pharmaceuticals, Inc. and Janssen Pharmaceutica International, a division of Cilag International AG ( Janssen ), and our ability to establish and maintain successful sales and marketing, reimbursement and distribution arrangements for VIVITROL;

our expectation and timeline for regulatory approval of the New Drug Application ( NDA ) submission for BYDUREON<sup>TM</sup> (exenatide for extended-release injectable suspension) and, if approved, the commercialization of BYDUREON by Amylin Pharmaceuticals, Inc. ( Amylin ), and Eli Lilly & Co. ( Lilly );

our expectations regarding our product candidates, including the development, regulatory review and commercial potential of such product candidates and the costs and expenses related thereto;

our expectations regarding the successful manufacture of our products and product candidates, including RISPERDAL CONSTA and VIVITROL, by us at a commercial scale, and our expectations regarding the successful manufacture of BYDUREON by our partner Amylin;

the continuation of our collaborations and other significant agreements and our ability to establish and maintain successful development collaborations;

the impact of new accounting pronouncements;

our expectations concerning the status, intended use and financial impact of our properties, including manufacturing facilities; and

our future capital requirements and capital expenditures and our ability to finance our operations and capital requirements.

You are cautioned that forward-looking statements are based on current expectations and are inherently uncertain. Actual performance and results of operations may differ materially from those projected or suggested in the forward-looking statements due to various risks and uncertainties, including:

manufacturing and royalty revenues from RISPERDAL CONSTA may not continue to grow, particularly because we rely on our partner, Janssen, to forecast and market and sell this product;

we may be unable to manufacture RISPERDAL CONSTA, VIVITROL and our product candidates in sufficient quantities and with sufficient yields to meet our and our partners requirements;

Amylin may not be able to successfully operate the manufacturing facility for BYDUREON;

we may be unable to develop the commercial capabilities, and/or infrastructure, necessary to successfully commercialize VIVITROL;

the United States (U.S.) Food and Drug Administration (FDA) and foreign regulatory agencies may not approve BYDUREON and, even if approved, such product may not be successfully commercialized;

we rely solely on our collaborative partners to determine and implement, and to inform us in a timely manner of any developments concerning, the regulatory and marketing strategies for RISPERDAL CONSTA and BYDUREON, including the four-week formulation of exenatide once weekly currently being developed by us, and

our collaborators could elect to terminate or delay programs at any time and disputes with collaborators or failure to negotiate acceptable collaborative arrangements for our technologies could occur;

RISPERDAL CONSTA, VIVITROL and BYDUREON, if and when approved, experience and will continue to experience competition, including from competing products marketed by our collaborative partners, such as INVEGA® SUSTENNA<sup>TM</sup> (paliperidone palmitate), and from marketing approvals for new products; third party payors may not cover or reimburse our products;

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the impact of recently enacted, and any future, health reform legislation may be greater than initially expected; 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; RISPERDAL CONSTA, VIVITROL, BYDUREON, if and when approved, and our product candidates in commercial use may have unintended side effects, adverse reactions or incidents of misuse and the FDA or other health authorities could require post approval studies or require removal of our products from the market; clinical trials may take more time or consume more resources than initially envisioned and the results of earlier clinical trials may not necessarily be predictive of the safety and efficacy results of larger clinical trials; U.S. and foreign regulatory agencies may refuse to accept applications for marketing authorization for our product candidates, may request additional preclinical or clinical studies be conducted or request a safety monitoring program, any of which could result in significant delays or the failure of such products to receive marketing approval or acceptance in the marketplace;

difficulties in obtaining and enforcing our patents and difficulties with the patent rights of others could occur; we may suffer potential costs resulting from product liability or other third party claims; we may incur losses in the future:

we may not be able to liquidate or otherwise recoup our investments in corporate debt securities and auction rate securities;

exchange rate valuations and fluctuations may negatively impact our revenues, results of operations and financial condition; and

the other risks and uncertainties described or discussed in Part 1, Item 1A, Risk Factors of our Annual Report on Form 10-K for the year ended March 31, 2010.

The forward-looking statements contained and incorporated herein represent our judgment as of the date of this Quarterly Report, and we caution readers not to place undue reliance on such statements. The information contained in this Quarterly Report is provided by us as of the date of this Quarterly Report, and, except as required by law, we do not undertake any obligation to update any forward-looking statements contained in this document as a result of new information, future events or otherwise.

Unless otherwise indicated, information contained in this Quarterly Report concerning the disorders targeted by our products and product candidates and the markets in which we operate is based on information from various sources (including industry publications, medical and clinical journals and studies, surveys and forecasts and our internal research), on assumptions that we have made, which we believe are reasonable, based on those data and other similar sources and on our knowledge of the markets for our products and development programs. Our internal research has not been verified by any independent source and we have not independently verified any third-party information. These projections, assumptions and estimates are necessarily subject to a high degree of uncertainty and risk due to a variety of factors, including those described in Part 1, Item 1A, Risk Factors of our Annual Report on Form 10-K for the year ended March 31, 2010. These and other factors could cause results to differ materially from those expressed in the estimates included in this prospectus.

#### Overview

Alkermes, Inc. (as used in this section, together with our subsidiaries, us , we , our or the Company ) is a fully integrated biotechnology company committed to developing innovative medicines to improve patients lives. We developed, manufacture and commercialize VIVITROL® (naltrexone for extended-release injectable suspension) for alcohol dependence and for the prevention of relapse to opioid dependence, following opioid detoxification. We also manufacture RISPERDAL® CONSTA® ((risperidone) long-acting injection) for schizophrenia and bipolar I disorder. Our robust pipeline includes extended-release injectable and oral products for the treatment of prevalent, chronic diseases, such as central nervous system ( CNS ) disorders, reward disorders, addiction, diabetes and autoimmune disorders. We are headquartered in Waltham, Massachusetts and have a research facility in Massachusetts and a commercial manufacturing facility in Ohio.

We leverage our formulation expertise and proprietary product platforms to develop, both with partners and on our own, innovative and competitively advantaged medications that can enhance patient outcomes in major therapeutic

areas. We enter into select collaborations with pharmaceutical and biotechnology companies to develop significant new product candidates, based on existing drugs and incorporating our proprietary product platforms. In addition, we apply our innovative formulation expertise and drug development capabilities to create our own new, proprietary pharmaceutical products.

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#### **Financial Highlights**

Net loss for the three months ended September 30, 2010 was \$7.7 million, or \$0.08 per common share, basic and diluted, as compared to a net loss of \$8.7 million, or \$0.09 per common share, basic and diluted, for the three months ended September 30, 2009. Net loss for the six months ended September 30, 2010 was \$21.1 million, or \$0.22 per common share, basic and diluted, as compared to a net loss of \$18.9 million, or \$0.20 per common share, basic and diluted, for the six months ended September 30, 2009. Revenues for the three and six months ended September 30, 2010 were driven by strong manufacturing and royalty revenues from RISPERDAL CONSTA. Worldwide sales of RISPERDAL CONSTA by Janssen were \$377.7 million and \$733.4 million for the three and six months ended September 30, 2010, respectively, an increase of 7.1% and 4.7% from the three and six months ended September 30, 2009, respectively.

On July 1, 2010, we redeemed the remaining non-recourse RISPERDAL CONSTA secured 7% notes (the non-recourse 7% Notes ) for \$45.6 million. As a result of this transaction, we recorded charges of \$1.4 million relating to the write-off of the unamortized portion of deferred financing costs and \$0.8 million primarily related to the premium paid on the redemption of the non-recourse 7% Notes. We expect to save \$3.2 million in interest and accretion expense through the previously scheduled maturity date of January 1, 2012 as a result of redeeming the non-recourse 7% Notes.

## **Products and Development Programs**

#### RISPERDAL CONSTA

RISPERDAL CONSTA is a long-acting formulation of risperidone, a product of Janssen, and is the first and only long-acting, atypical antipsychotic approved by the FDA for the treatment of schizophrenia and for the treatment of bipolar I disorder. The medication uses our proprietary Medisorb® injectable extended-release technology to deliver and maintain therapeutic medication levels in the body through just one injection every two weeks. RISPERDAL CONSTA is marketed by Janssen and is exclusively manufactured by us. RISPERDAL CONSTA was first approved for the treatment of schizophrenia by regulatory authorities in the United Kingdom and Germany in August 2002 and by the FDA in October 2003. The Pharmaceuticals and Medical Devices Agency in Japan approved RISPERDAL CONSTA for the treatment of schizophrenia in April 2009. RISPERDAL CONSTA is the first long-acting atypical antipsychotic to be available in Japan. RISPERDAL CONSTA is approved for the treatment of schizophrenia in approximately 85 countries and marketed in approximately 70 countries, and Janssen continues to launch the product around the world.

Schizophrenia is a chronic, severe and disabling brain disorder. The disease is marked by positive symptoms (hallucinations and delusions) and negative symptoms (depression, blunted emotions and social withdrawal), as well as by disorganized thinking. An estimated 2.4 million Americans have schizophrenia, with men and women affected equally. Worldwide, it is estimated that one person in every 100 develops schizophrenia, one of the most serious types of mental illness. Studies have demonstrated that as many as 75% of patients with schizophrenia have difficulty taking their oral medication on a regular basis, which can lead to worsening of symptoms. Clinical data have shown that treatment with RISPERDAL CONSTA may lead to improvements in symptoms, sustained remission and decreases in hospitalization in patients with schizophrenia.

In May 2009, the FDA approved RISPERDAL CONSTA as both monotherapy and adjunctive therapy to lithium or valproate in the maintenance treatment of bipolar I disorder. RISPERDAL CONSTA is also approved for the maintenance treatment of bipolar I disorder in Canada, Australia and Saudi Arabia.

Bipolar disorder is a brain disorder that causes unusual shifts in a person s mood, energy and ability to function. It is often characterized by debilitating mood swings, from extreme highs (mania) to extreme lows (depression). Bipolar I disorder is characterized based on the occurrence of at least one manic episode, with or without the occurrence of a major depressive episode. Bipolar disorder is believed to affect approximately 5.7 million American adults, or about 2.6% of the U.S. population age 18 and older, in a given year. The median age of onset for bipolar disorders is 25 years. Clinical data have shown that RISPERDAL CONSTA significantly delayed the time to relapse compared to placebo treatment in patients with bipolar I disorder.

#### **VIVITROL**

We developed VIVITROL, an extended-release Medisorb formulation of naltrexone, as the first and only once-monthly, non-narcotic, non-addictive injectable medication for the treatment of alcohol dependence and for the prevention of relapse to opioid dependence following opioid detoxification.

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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. According to the National Institute on Alcohol Abuse and Alcoholism s 2001 2002 National Epidemiologic Survey on Alcohol and Related Conditions, it is estimated that more than 18 million Americans suffer from alcohol dependence. Adherence to medication is particularly challenging with this patient population. In clinical trials, when used in combination with psychosocial support, VIVITROL was shown to reduce the number of drinking days and heavy drinking days and to prolong abstinence in patients who abstained from alcohol the week prior to starting treatment. VIVITROL was approved by the FDA in April 2006 for the treatment of alcohol dependence and was launched in the U.S. in June 2006 with our then partner, Cephalon, Inc. (Cephalon). In December 2008, we assumed responsibility for the commercialization of VIVITROL in the U.S. from Cephalon. In December 2007, we exclusively licensed the right to commercialize VIVITROL for the treatment of alcohol dependence and opioid dependence in Russia and other countries in the Commonwealth of Independent States (CIS) to Cilag GmbH international (Cilag). In August 2008, the Russian regulatory authorities approved VIVITROL for the treatment of alcohol dependence. Cilag launched VIVITROL in Russia in March 2009. In March 2010, the FDA approved a Risk Evaluation and Mitigation Strategy (REMS), for VIVITROL that consists of a Medication Guide and other customary REMS assessment requirements.

Opioid dependence is a chronic brain disease characterized by cognitive, behavioral and physiological symptoms in which an individual continues to use opioids despite significant harm to oneself and others. In addition to the use of heroin, an illegal opioid drug, opioid dependence includes the non-medical use of opioid analgesics, including prescription pain relievers, and represents a growing public health problem in the U.S. According to the 2009 U.S. National Survey on Drug Use and Health, an estimated 1.6 million people aged 18 or older were dependent on pain relievers or heroin. In October 2010, the FDA approved VIVITROL for the prevention of relapse to opioid dependence, following opioid detoxification. The FDA approval of VIVITROL for the prevention of relapse to opioid dependence, following opioid detoxification was based on data from a six-month phase 3 study in which patients treated with VIVITROL in combination with psychosocial support sustained complete abstinence (opioid-free urine screens and negative self-report of opioid use) during the study period at a rate significantly greater than those patients treated with placebo in combination with psychosocial support.

#### **BYDUREON**

We are collaborating with Amylin on the development of a once weekly formulation of exenatide, called BYDUREON, for the treatment of type 2 diabetes. BYDUREON is an injectable formulation of Amylin s BYETT® (exenatide) and is being developed with the goal of providing patients with an effective and more patient-friendly treatment option. BYETTA is an injection administered twice daily. Diabetes is a disease in which the body does not produce or properly use insulin. Diabetes can result in serious health complications, including cardiovascular, kidney and nerve disease. Diabetes is believed to affect more than 24 million people in the U.S. and an estimated 285 million adults worldwide. Approximately 90 95% of those affected have type 2 diabetes.

According to the Centers for Disease Control and Prevention s National Health and Nutrition Examination Survey, approximately 60% of people with diabetes do not achieve their target blood sugar levels with their current treatment regimen. In addition, 85% of type 2 diabetes patients are overweight and 55% are considered obese. BYETTA was approved by the FDA in April 2005 as adjunctive therapy to improve blood sugar control in patients with type 2 diabetes who have not achieved adequate control on metformin and/or a sulfonylurea, which are commonly used oral diabetes medications. In December 2006, the FDA approved BYETTA as an add-on therapy for people with type 2 diabetes unable to achieve adequate glucose control on thiazolidinediones, a class of diabetes medications. In October 2009, the FDA approved BYETTA as a stand-alone medication (monotherapy) along with diet and exercise to improve glycemic control in adults with type 2 diabetes. Amylin has an agreement with Lilly for the development and commercialization of exenatide, including BYDUREON.

In March 2010, Amylin received a complete response letter in reference to the NDA for BYDUREON submitted in May 2009. The complete response letter did not include requests for new pre-clinical or clinical trials. Requests raised in the letter primarily related to the finalization of the product labeling with accompanying REMS and clarification of existing manufacturing processes. In April 2010, Amylin announced that it had submitted a response to the FDA s complete response letter. In May 2010, the FDA accepted the response and issued a PDUFA action date of

October 22, 2010 for the NDA.

In April 2010, Lilly announced that the EMA had accepted the Marketing Authorization Application filing for BYDUREON for the treatment of type 2 diabetes.

In October 2010, Amylin, Lilly and we announced that the FDA issued a complete response letter regarding the NDA for BYDUREON. In the complete response letter, the FDA requested a thorough QT (tQT) study and the submission of the results of the DURATION-5 study to evaluate the efficacy, and the labeling of the safety and effectiveness, of the commercial formulation of BYDUREON.

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#### ALKS 33

ALKS 33, one of our proprietary candidates, is an oral opioid modulator that we are developing for the potential treatment of addiction and other CNS disorders. In November 2009, we initiated a phase 2 clinical study to assess the safety and efficacy of multiple doses of ALKS 33 in patients with alcohol dependence and to further define the clinical profile of ALKS 33.

In April 2010, we announced plans for the development of ALKS 33 for the treatment of binge-eating disorder and as a combination therapy with buprenorphine, an existing medication for the treatment of opioid addiction, for the treatment of addiction and mood disorders. Binge-eating disorder is characterized by recurrent binge eating episodes during which a person feels a loss of control over his or her eating. Unlike bulimia, binge eating episodes are not followed by purging, excessive exercise or fasting. As a result, people with binge-eating disorder often are overweight or obese. It is estimated that approximately 1% to 2% of Americans suffer from binge-eating disorder. We expect to receive data from a phase 2 study of ALKS 33 in binge eating disorder in the first half of calendar 2011.

In October 2010, we announced positive topline results from a randomized, double-blind, multi-dose, placebo-controlled phase 1 clinical study that assessed the safety, tolerability and pharmacodynamic effects of the combination of ALKS 33 and buprenorphine when administered alone and in combination to 12 opioid-experienced users. Data from the study showed that the combination therapy was generally well tolerated and sublingual administration of ALKS 33 effectively blocked the agonist effects of buprenorphine. Based on these positive results, we expect to initiate a phase 2a study of the combination therapy for the treatment of cocaine addiction in the first half of calendar year 2011. The phase 2a study is expected to be funded through a grant from the National Institute on Drug Abuse (NIDA). NIDA has granted us up to \$2.4 million to accelerate the clinical development of the ALKS 33 and buprenorphine combination therapy. Currently, there are no medications approved for the treatment of cocaine addiction.

#### **ALKS 37**

We are developing ALKS 37, an orally active, peripherally-restricted opioid antagonist for the treatment of opioid-induced constipation (OIC). According to IMS Health, over 243 million prescriptions were written for opioids in 2009 in the U.S. Many studies indicate that a high percentage of patients receiving opioids are likely to experience side effects affecting gastrointestinal motility. There are currently no available oral treatments for this condition, which has severe quality of life implications. ALKS 37 is a component of ALKS 36, which is discussed below.

In April 2010, we commenced a multicenter, randomized, double-blind, placebo-controlled, multidose study designed to evaluate the efficacy, safety and tolerability of ALKS 37 in approximately 60 patients with OIC. We expect to report preliminary results from the phase 2 study of ALKS 37 in the first quarter of calendar 2011.

#### **ALKS 36**

In October 2009, we announced our intention to develop ALKS 36, which is expected to consist of a co-formulation of an opioid analgesic and ALKS 37, for the treatment of pain without the side effects of constipation. Research indicates that a high percentage of patients receiving opioids are likely to experience side effects affecting gastrointestinal motility. A pain medication that does not inhibit gastrointestinal motility, such as ALKS 36, could provide an advantage over current therapies. The preliminary results from the phase 2 study of ALKS 37, which are expected in the first quarter of calendar 2011, will inform further development of ALKS 36.

#### **ALKS 9070**

ALKS 9070 is a once-monthly, injectable, sustained-release version of aripiprazole for the treatment of schizophrenia. ALKS 9070 is our first candidate to leverage our proprietary LinkeRx<sup>TM</sup> product platform. Aripiprazole is commercially available under the name ABILIFY® for the treatment of a number of CNS disorders. We recently initiated a phase 1 clinical study of ALKS 9070, and we expect to report topline data from this study in the first half of calendar 2011.

#### **ALKS 6931**

ALKS 6931 is a long-acting form of a TNF receptor-FC fusion protein for the treatment of rheumatoid arthritis and related autoimmune diseases. ALKS 6931 is our first candidate being developed using the Medifusion<sup>TM</sup> technology licensed from Acceleron Pharma, Inc. ALKS 6931 is structurally similar to etanercept, commercially available under the name ENBREL®. We continue to conduct preclinical studies of ALKS 6931 and intend to wait to file an IND until

such preclinical work is complete and we are convinced that we have the most optimized clinical candidate.

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## **ALKS 7921**

ALKS 7921, the second candidate from the LinkeRx platform, is a once-monthly, injectable, extended-release version of olanzapine for the treatment of schizophrenia. Olanzapine is commercially available under the trade name ZYPREXA® (olanzapine). We are engineering ALKS 7921 to seek to prevent early, inadvertent release of free olanzapine into systemic circulation and, in so doing, to provide another valuable option for patients and physicians to manage schizophrenia.

# **Results of Operations Manufacturing Revenues**

Three Months Ended September								
		30,		Six Mont	hs Ended Sep	tember 30,		
(In millions)	2010	2009	Change	2010	2009	Change		
Manufacturing revenues:								
RISPERDAL CONSTA	\$ 32.6	\$ 31.9	\$ 0.7	\$ 59.0	\$ 59.8	\$ (0.8)		
Polymer	0.6	0.4	0.2	1.1	1.4	(0.3)		
VIVITROL		0.5	(0.5)		0.4	(0.4)		
Manufacturing revenues	\$ 33.2	\$ 32.8	\$ 0.4	\$ 60.1	\$ 61.6	\$ (1.5)		

The increase in RISPERDAL CONSTA manufacturing revenues for the three months ended September 30, 2010, as compared to the three months ended September 30, 2009, was primarily due to a 9% increase in the number of units shipped to Janssen, partially offset by a decrease in the unit net sales price of 2%. The decrease in RISPERDAL CONSTA manufacturing revenues for the six months ended September 30, 2010, as compared to the six months ended September 30, 2009, was primarily due to a 2% decrease in the unit net sales price, partially offset by an increase in the number of units shipped to Janssen of 5%. The decrease in the net unit sales price for both the three and six month period is primarily due to increased sales deductions recorded by Janssen on RISPERDAL CONSTA sales as a result of healthcare reform in the U.S., as further described in Product Sales, net, below; and the strengthening of the U.S. dollar in relation to the foreign currencies 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, 2010 and 2009, our RISPERDAL CONSTA manufacturing revenues were based on an average of 7.5% of Janssen s unit net sales price. We anticipate that we will continue to 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, 2011 and beyond.

The increase in polymer manufacturing revenues for the three months ended September 30, 2010, as compared to the three months ended September 30, 2009, was primarily due to a 30% increase in the amount of polymer shipped to Amylin. The decrease in polymer manufacturing revenues for the six months ended September 30, 2010, as compared to the six months ended September 30, 2009, was primarily due to a 13% decrease in the amount of polymer shipped to Amylin. We record manufacturing revenues under our arrangement with Amylin for polymer sales at an agreed upon price when product is shipped to them. The polymer is used in the formulation of BYDUREON.

## **Royalty Revenues**

	Three Mo	onths Ended S	eptember			
		30,		Six Montl	hs Ended Sep	tember 30,
(In millions)	2010	2009	Change	2010	2009	Change
Royalty revenues	\$ 9.5	\$ 8.8	\$ 0.7	\$ 18.4	\$ 17.5	\$ 0.9

Substantially all of our royalty revenues for the three and six months ended September 30, 2010 and 2009 were related to sales of RISPERDAL CONSTA. Under our license agreements with Janssen, we record royalty revenues equal to 2.5% of Janssen s net sales of RISPERDAL CONSTA in the period that the product is sold by Janssen. RISPERDAL CONSTA royalty revenues for the three and six months ended September 30, 2010 were based on RISPERDAL CONSTA sales of \$377.7 million and \$733.4 million, respectively. RISPERDAL CONSTA royalty revenues for the three and six months ended September 30, 2009 were based on RISPERDAL CONSTA sales of \$352.6 million and \$700.3 million, respectively. 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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#### Product Sales, net

Our product sales consist of sales of VIVITROL in the U.S. to wholesalers, specialty distributors and specialty pharmacies. The following table presents the adjustments deducted from VIVITROL product sales, gross to arrive at VIVITROL product sales, net during the three and six months ended September 30, 2010 and 2009:

		Three Mont Septemb		Six Months Ended September 30,					
		% of		% of		% of		% of	
	2010	Sales	2009	Sales	2010	Sales	2009	Sales	
Product sales,									
gross	\$ 10.8	100.0 %	\$ 5.2	100.0%	\$ 18.2	100.0%	\$ 10.5	100.0%	
Adjustments to									
product sales,									
gross:									
Reserve for									
inventory in the									
distribution									
channel (1)	(2.1)	(19.4)%	0.1	1.9%	(1.7)	(9.3)%	(0.1)	(1.0)%	
Chargebacks	(0.5)	(4.6)%	(0.2)	(3.9)%	(0.9)	(5.0)%	(0.3)	(2.7)%	
Medicaid rebates	(0.3)	(2.8)%	(0.1)	(1.9)%	(0.8)	(4.4)%	(0.3)	(2.7)%	
Wholesaler fees	(0.3)	(2.8)%	(0.2)	(3.8)%	(0.6)	(3.3)%	(0.4)	(3.9)%	
Other	(1.1)	(10.2)%	(0.2)	(3.8)%	(1.5)	(8.2)%	(0.5)	(4.9)%	
Total adjustments	(4.3)	(39.8)%	(0.6)	(11.5)%	(5.5)	(30.2)%	(1.6)	(15.2)%	
Product sales, net	\$ 6.5	60.2%	\$ 4.6	88.5%	\$ 12.7	69.8%	\$ 8.9	84.8%	

(1) Our reserve for inventory in the distribution channel is an estimate that reflects the deferral of the recognition of revenue on shipments of VIVITROL to our customers until the product has left the distribution channel, as we do not yet have the history to reasonably estimate returns related to these shipments. We estimate the product shipments out of the distribution channel based on data provided by external sources, including information on inventory levels provided by our customers as well as prescription information.

The increase in product sales, gross for the three and six months ended September 30, 2010, as compared to the three and six months ended September 30, 2009, was primarily due to an 81% and 50% increase in the number of units sold into the distribution channel, respectively, and a 15% increase in price. The adjustments to product sales, gross to arrive at product sales, net, increased during the three and six months ended September 30, 2010, as compared to the three and six months ended September 30, 2009, primarily as a result of the increase in product shipped into the distribution channel during these periods.

Our product sales may fluctuate from period to period as a result of factors such as end user demand, which can create uneven purchasing patterns by our customers. Our product sales may also fluctuate as the result of changes or adjustments to our reserves or changes in government or customer rebates. For example, in March 2010, U.S. healthcare reform legislation was enacted which contains several provisions that impact our business. Although many provisions of the new legislation did not take effect immediately, several provisions became effective in the first quarter of calendar 2010, including the following:

an increase in the minimum statutory Medicaid rebate to states participating in the Medicaid program from 15.1% to 23.1%;

an extension of the Medicaid rebate to drugs dispensed to Medicaid beneficiaries enrolled with managed care organizations; and

an expansion of the 340(B)/Public Health Services ( PHS ) drug pricing program, which provides drugs at reduced rates, to include additional hospitals, clinics, and healthcare centers in an outpatient setting.

In addition, beginning in calendar 2011, we may incur our share of a new fee assessed on all branded prescription drug manufacturers and importers. This fee will be calculated based upon VIVITROL s percentage share of total branded prescription drug sales to U.S. government programs (such as Medicare, Medicaid and Veterans Administration and PHS discount programs) made during the previous year. The aggregated industry-wide fee is expected to total \$28 billion through 2019, ranging from \$2.5 billion to \$4.1 billion annually. Presently, uncertainty exists as many of the specific determinations necessary to implement this new legislation have yet to be decided and communicated to industry participants. For example, determinations as to how the annual fee on branded prescription drugs will be calculated and allocated remain to be clarified, though, as noted above, this provision will not be effective until calendar 2011.

We expect that during the remainder of fiscal year 2011 and into the future, our net sales as a percentage of gross sales will be negatively affected as a result of certain aspects of the recently enacted healthcare legislation, specifically, the increase in the minimum Medicaid rebates, the expansion of those entities entitled to receive Medicaid rebates based on use of our product and the expansion of those entities entitled to purchase our products at a discounted basis under the 340(B)/PHS drug pricing program. It is possible that the effect of this legislation could further adversely impact our future revenues. We are still assessing the full extent of this legislation s future impact on our business.

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## Research and Development Revenue Under Collaborative Arrangements

	7	Three Mo	onths	Ended S	eptem	ıber						
	30,					Six Months Ended September 30,						
(In millions)	2	010	2	009	Cl	hange	2	010	2	009	Ch	nange
Research and development												
revenue												
under collaborative												
arrangements	\$	0.2	\$	1.2	\$	(1.0)	\$	0.4	\$	2.6	\$	(2.2)

The decrease in research and development ( R&D ) revenue under collaborative arrangements for the three and six months ended September 30, 2010, as compared to the three and six months ended September 30, 2009, was primarily due to the decision made by our collaborative partner, Johnson & Johnson Pharmaceutical Research and Development, L.L.C. ( J&JPRD ) in August 2009 not to pursue further development of a four week formulation of RISPERDAL CONSTA. The four week RISPERDAL CONSTA program contributed \$0.9 million and \$1.9 million of revenue during the three and six months ended September 30, 2009, respectively.

## **Net Collaborative Profit**

Net collaborative profit for the three and six months ended September 30, 2009 of \$0.7 million and \$5.0 million, respectively, consisted of revenue earned as a result of the \$11.0 million payment we received from Cephalon to fund their share of estimated VIVITROL losses during the one-year period following the termination of the VIVITROL collaboration in December 2008. We recorded the \$11.0 million as deferred revenue and recognized it as revenue through the application of a proportional performance model based on VIVITROL losses. The \$11.0 million payment was fully recognized as revenue during the six months ended September 30, 2009.

## **Cost of Goods Manufactured and Sold**

	,	Three M	onths	<b>Ended S</b>	eptem	ber					
30, Six Months Ended September									tembe	r 30,	
(In millions)	2	2010	2	2009	Ch	ange	2010	2	2009	Ch	ange
Cost of goods manufactured and sold:											
RISPERDAL CONSTA	\$	11.3	\$	12.1	\$	0.8	\$ 21.8	\$	21.8	\$	
VIVITROL		2.4		2.6		0.2	4.0		4.6		0.6
Polymer		0.2		0.4		0.2	0.8		1.4		0.6
Cost of goods manufactured											
and sold	\$	13.9	\$	15.1	\$	1.2	\$ 26.6	\$	27.8	\$	1.2

The decrease in cost of goods manufactured for RISPERDAL CONSTA in the three months ended September 30, 2010, as compared to the three months ended September 30, 2009, was primarily due to a 14% decrease in the unit cost of RISPERDAL CONSTA, partially offset by a 9% increase in the number of units shipped to Janssen. Cost of goods manufactured for RISPERDAL CONSTA for the six months ended September 30, 2010 was unchanged as compared to the six months ended September 30, 2009, due to a 5% decrease in the unit cost of RISPERDAL CONSTA, offset by an increase in the number of units shipped to Janssen of 5%. The decrease in the unit cost of RISPERDAL CONSTA in the three and six months ended September 30, 2010, as compared to the three and six months ended September 30, 2009, was partially due to a decrease in costs incurred for scrap of \$0.8 million and \$1.1 million, respectively.

The decrease in cost of goods manufactured and sold for VIVITROL in the three and six months ended September 30, 2010, as compared to the three and six months ended September 30, 2009, was primarily due to an \$0.8 million and \$1.8 million reduction in costs incurred for failed batches and costs related to the restart of the

manufacturing line, respectively, partially offset by a 31% increase in the number of units sold out of the distribution channel. Included in cost of goods sold for VIVITROL during the three and six months ended September 30, 2010 were idle capacity charges of \$0.9 million and \$1.4 million, respectively, which was the result of managing VIVITROL inventory levels and reducing manufacturing output.

The decrease in the cost of goods manufactured for polymer in the three months ended September 30, 2010, as compared to the three months ended September 30, 2009, was due to a \$0.2 million reduction in costs incurred for scrap, partially offset by a 30% increase in the amount of polymer shipped to Amylin. The decrease in the cost of goods manufactured for polymer in the six months ended September 30, 2010, as compared to the six months ended September 30, 2009, was due to a \$0.4 million reduction in costs incurred for scrap and a 13% decrease in the amount of polymer shipped to Amylin.

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## **Research and Development Expense**

	Three M	onths Ended S	eptember				
	30, Six Months Ended Septembe						
(In millions)	2010	2009	Change	2010	2009	Change	
Research and development	\$ 23.9	\$ 20.7	\$ (3.2)	\$ 46.9	\$ 46.3	\$ (0.6)	

The increase in R&D expenses in the three months ended September 30, 2010, as compared to the three months ended September 30, 2009, was primarily due to a \$5.8 million increase in internal clinical and preclinical study, laboratory and license and collaboration expenses due to an increase in the number of ongoing studies and clinical trials and a \$2.4 million increase in professional services, primarily for activities related to the approval of VIVITROL for opioid dependence. These increased expenses were partially offset by a decrease in relocation and occupancy related expenses of \$5.2 million as a result of the relocation of our corporate headquarters from Cambridge, Massachusetts, to Waltham, Massachusetts which was substantially completed during the fourth quarter of fiscal 2010.

The increase in R&D expenses in the six months ended September 30, 2010, as compared to the six months ended September 30, 2009, was primarily due to a \$11.1 million increase in internal clinical and preclinical study, laboratory and license and collaboration expenses due to an increase in the number of ongoing studies and clinical trials and a \$3.3 million increase in professional services, primarily for activities related to the approval of VIVITROL for opioid dependence. These increased expenses were partially offset by a decrease in relocation and occupancy related expenses of \$15.3 million as a result of the relocation of our corporate headquarters.

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 may be reimbursed to us by our partners. We account for our research and development expenses on a departmental and functional basis in accordance with our budget and management practices.

# Selling, General and Administrative Expense

	Three Mo	Three Months Ended September								
		30,	Six Months Ended September 30,							
(In millions)	2010	2009	Change	2010	2009	Change				
Selling, general and										
administrative	\$ 18.4	\$ 20.6	\$ 2.2	\$ 38.2	\$ 39.9	\$ 1.7				

The decrease in selling, general and administrative (SG&A) expense for the three and six months ended September 30, 2010, as compared to the three and six months ended September 30, 2009, was primarily due to a reduction in professional services of \$2.1 million and \$3.3 million, respectively, partially offset by an increase in marketing expenses of \$1.2 million and \$0.8 million, respectively. The decrease in professional services is primarily due to start-up costs related to the commercialization of VIVITROL in fiscal year 2010 that were not incurred during fiscal year 2011. The increase in marketing expenses is primarily due to costs incurred leading up to the launch of VIVITROL for opioid dependence.

## Other Expense, Net

	Three Mo	onths Ended S	eptember			
		30,		Six Mont	hs Ended Sep	tember 30,
(In millions)	2010	2009	Change	2010	2009	Change
Interest income	\$ 0.7	\$ 1.1	\$ (0.4)	\$ 1.5	\$ 2.6	\$ (1.1)

Interest expense Other expense, net	(2.2) (0.1)	(1.6) (0.1)	(0.6)	(3.3) (0.2)	(3.3) (0.1)	(0.1)
Total other expense, net	\$ (1.6)	\$ (0.6)	\$ (1.0)	\$ (2.0)	\$ (0.8)	\$ (1.2)

The decrease in interest income for the three and six months ended September 30, 2010, as compared to the three and six months ended September 30, 2009, was due to a lower average balance of cash and investments. Interest expense increased in the three months ended September 30, 2010, as compared to the three months ended September 30, 2009, due to the early redemption of the non-recourse 7% Notes on July 1, 2010. As a result of this transaction, we recorded charges of \$1.4 million relating to the write-off of the unamortized portion of deferred financing costs and \$0.8 million primarily related to the premium paid on the redemption of the non-recourse 7% Notes. The amount of interest expense in the six months ended September 30, 2010 was unchanged as compared to the six months ended September 30, 2010 consisted of \$2.2 million of charges associated with the redemption of the non-recourse 7% Notes, as previously discussed, and

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\$1.2 million of interest and accretion expense, as compared to \$3.3 million of interest and accretion expense in the six months ended September 30, 2009. We expect to save \$3.2 million in interest and accretion expense through the previously scheduled maturity date of January 1, 2012 as a result of redeeming the non-recourse 7% Notes on July 1, 2010.

# **Income Tax Benefit**

	Three Mo	onths Ended S	eptember			
		30,		Six Month	ns Ended Sep	tember 30,
(In millions)	2010	2009	Change	2010	2009	Change
Income tax benefit	\$ (0.9)	\$ (0.1)	\$ 0.8	\$ (1.0)	\$ (0.1)	\$ 0.9

We recorded an income tax benefit of \$0.9 million and \$1.0 million for the three and six months ended September 30, 2010, respectively, primarily related to a \$0.8 million tax benefit for bonus depreciation pursuant to the *Small Business Jobs Act of 2010* ( Act ). Bonus depreciation increases our 2010 alternative minimum tax ( AMT ) net operating loss ( NOL ) carryback and will allow us to recover AMT paid in the carryback period. The tax benefit was recorded as a discrete item during the three months ended September 30, 2010, the period in which the Act was enacted. The income tax benefit of less than \$0.1 million and \$0.1 million for the three and six months ended September 30, 2009 represented the amount we estimated we would benefit from the *Housing and Economic Recovery Act of 2008*.

# **Liquidity and Capital Resources**

Our financial condition is summarized as follows:

	September		
	30,	Ma	rch 31,
(In millions)	2010	2	2010
Cash and cash equivalents	\$ 37.3	\$	79.3
Investments short-term	193.2		202.1
Investments long-term	43.1		68.8
Total cash, cash equivalents and investments	\$ 273.6	\$	350.2
Working capital Outstanding borrowings current and long-term	\$ 264.2 \$	\$ \$	247.1 51.0

Our cash flows for the six months ended September 30, 2010 and 2009 were as follows:

	Six Months Ended September 30,						
(In millions)	2010		2009				
Cash and cash equivalents, beginning of period	\$ 79.3	\$	86.9				
Cash (used in) operating activities	(27.1)		(18.7)				
Cash provided by (used in) investing activities	29.1		(0.9)				
Cash (used in) financing activities	(44.0)		(14.3)				
Cash and cash equivalents, end of period	\$ 37.3	\$	53.0				

Our primary source of liquidity is cash provided by our operating activities. The increase in cash used in operating activities during the six months ended September 30, 2010, as compared to the six months ended September 30, 2009, is primarily due to the redemption of our non-recourse 7% Notes on July 1, 2010 and an increase in amounts paid to

our suppliers of \$2.4 million. On July 1, 2010, in addition to a scheduled principal payment of \$6.4 million, we redeemed the balance of our non-recourse 7% Notes in full in exchange for \$39.2 million, representing 101.75% of the outstanding principal balance in accordance with the terms of the Indenture for the non-recourse 7% Notes. We allocated \$6.6 million of the principal payments made during the six months ended September 30, 2010 to operating activities to account for the original issue discount on the non-recourse 7% Notes, and the remaining \$45.4 million of principal payments was allocated to financing activities in the condensed consolidated statement of cash flows.

The increase in cash flows provided by investing activities during the six months ended September 30, 2010, as compared to the six months ended September 30, 2009, is primarily due to the net conversion of \$36.1 million of our investments to cash during the six months ended September 30, 2010, as compared to \$2.8 million during the six months ended September 30, 2009.

The increase in cash flows used in financing activities during the six months ended September 30, 2010, as compared to the six months ended September 30, 2009, is primarily due to the redemption of our non-recourse 7% Notes on July 1, 2010,

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partially offset by the purchase of \$2.7 million of treasury stock during the six months ended September 30, 2009. During the six months ended September 30, 2010, we did not make any purchases of treasury stock.

Our investments at September 30, 2010 consist of the following:

		Amortized Cost		<b>Gross Unrealized</b>			Estimated Fair	
(in millions)				Gains		Losses	Value	
Investments	short-term	\$	192.4	\$	0.8	\$	\$	193.2
Investments	long-term available-for-sale		37.9		0.5	(1.2)		37.2
Investments	long-term held-to-maturity		5.9					5.9
Total		\$	236.2	\$	1.3	\$ (1.2)	\$	236.3

Our investment objectives are, first, to preserve liquidity and conserve capital and, second, to generate investment income. We mitigate credit risk in our cash reserves by maintaining a well diversified portfolio that limits the amount of investment exposure as to institution, maturity and investment type. However, the value of these securities may be adversely affected by the instability of the global financial markets which could, in turn, adversely impact our financial position and our overall liquidity. Our available-for-sale investments consist primarily of short and long-term U.S. government and agency debt securities, debt securities issued by foreign agencies and backed by foreign governments and corporate debt securities. Our held-to-maturity investments consist of investments that are restricted and held as collateral under certain letters of credit related to certain of our lease agreements.

We classify available-for-sale investments in an unrealized loss position, which do not mature within 12 months, as long-term investments. We have the intent and ability to hold these investments until recovery, which may be at maturity, and it is more likely than not that we would not be required to sell these securities before recovery of their amortized cost. At September 30, 2010, we performed an analysis of our investments with unrealized losses for impairment and determined that they are temporarily impaired.

At September 30, 2010 and March 31, 2010, 3% and 4%, respectively, of our investments are valued using unobservable, or Level 3, inputs to determine fair value as they are not actively trading and fair values could not be derived from quoted market prices. These investments consist primarily of a student loan backed auction rate security. During the six months ended September 30, 2010, \$6.0 million of our Level 3 investments were redeemed at par by the issuers.

#### **Borrowings**

We did not have any outstanding borrowings at September 30, 2010. On July 1, 2010, in addition to a scheduled principal payment of \$6.4 million, we redeemed the balance of our non-recourse 7% Notes in full in exchange for \$39.2 million, representing 101.75% of the outstanding principal balance in accordance with the terms of the Indenture for the non-recourse 7% Notes. We expect to save \$3.2 million in interest and accretion expense through the previously scheduled maturity date of January 1, 2012 as a result of redeeming these notes on July 1, 2010.

# **Contractual Obligations**

Refer to Part II, Item 7 of our Annual Report on Form 10-K for the year ended March 31, 2010 in the Contractual Obligations section for a discussion of our contractual obligations. Our contractual obligations as of September 30, 2010 were not materially changed from the date of that report with the exception of the non-recourse 7% Notes which, as noted in the Borrowings section above, were redeemed in full on July 1, 2010.

## **Off-Balance Sheet Arrangements**

At September 30, 2010, 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.

## **Critical Accounting Estimates**

The discussion and analysis of our financial condition and results of operations is based on our financial statements, which have been prepared in accordance with accounting principles generally accepted in the United

States of America (GAAP). The preparation of these financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of our financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results may differ from these estimates under different

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assumptions or conditions. Refer to Part II, Item 7 of our Annual Report on Form 10-K for the year ended March 31, 2010 in the Critical Accounting Estimates section for a discussion of our critical accounting estimates.

# **New Accounting Standards**

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

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

Our market risks, and the ways we manage them, are summarized in Part II, Item 7A, Quantitative and Qualitative Disclosures About Market Risk of our Annual Report on Form 10-K for the year ended March 31, 2010. We regularly review our marketable securities holdings and shift our investment holdings to those that best meet our investment objectives, which are, first, to preserve liquidity and conserve capital and, second, to generate investment income. Apart from such adjustments to our investment portfolio, there have been no material changes to our market risks in the first six months of fiscal year 2011, and we do not anticipate any near-term changes in the nature of our market risk exposures or in our management s objectives and strategies with respect to managing such exposures.

We are exposed to foreign currency exchange risk related to manufacturing and royalty revenues that we receive on RISPERDAL CONSTA as summarized in Part II, Item 7A, Quantitative and Qualitative Disclosures About Market Risk of our Annual Report on Form 10-K for the year ended March 31, 2010. There has been no material change in our assessment of our sensitivity to foreign currency exchange rate risk during the first six months of fiscal year 2011.

## **Item 4. Controls and Procedures**

a) Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, evaluated 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, (the Exchange Act )) at September 30, 2010. Based on that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective as of September 30, 2010 to provide reasonable assurance that the information required to be disclosed by us in the reports that we file under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC s rules and forms and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief 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**

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

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

On November 21, 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. On June 16, 2008, the board of directors authorized the expansion of this program to \$215.0 million. We did not purchase any shares under this program during the quarter ended September 30, 2010. As of September 30, 2010, we have purchased a total of 8,866,342 shares under this program at a cost of \$114.0 million.

During the three months ended September 30, 2010, we acquired, by means of net share settlements, 80 shares of Alkermes common stock at an average price of \$12.62 per share related to the vesting of employee stock awards to satisfy employee withholding tax obligations.

## **Item 5. Other Information**

The Company s policy governing transactions in its securities by its directors, officers and employees permits its officers, directors and employees to enter into trading plans in accordance with Rule 10b5-1 under the Exchange Act. During the quarter ended September 30, 2010, Mr. Robert A. Breyer and Mr. Michael A. Wall, each a director of the Company, and Dr. Elliot W. Ehrich and Mr. Gordon G. Pugh, each an executive officer of the Company, entered into trading plans in accordance with Rule 10b5-1, and the Company s policy governing transactions in its securities by its directors, officers and employees. The Company undertakes no obligation to update or revise the information provided herein, including for revision or termination of an established trading plan.

## Item 6. 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).
- The following materials from Alkermes, Inc. s Quarterly Report on Form 10-Q for the quarter ended September 30, 2010, formatted in XBRL (Extensible Business Reporting Language): (i) the Condensed Consolidated Balance Sheets, (ii) the Condensed Consolidated Statements of Operations, (iii) the Condensed Consolidated Statements of Cash Flows, and (iv) the Notes to the Condensed Consolidated Financial Statements, tagged as blocks of text (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/ Richard F. Pops Chairman, President and Chief Executive Officer (Principal Executive Officer)

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

Date: November 4, 2010

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## **EXHIBIT INDEX**

# **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).
- The following materials from Alkermes, Inc. s Quarterly Report on Form 10-Q for the quarter ended September 30, 2010, formatted in XBRL (Extensible Business Reporting Language): (i) the Condensed Consolidated Balance Sheets, (ii) the Condensed Consolidated Statements of Operations, (iii) the Condensed Consolidated Statements of Cash Flows, and (iv) the Notes to the Condensed Consolidated Financial Statements, tagged as blocks of text (furnished herewith).

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