

ALKERMES INC  
Form 10-Q  
February 08, 2007

**Table of Contents**

**UNITED STATES SECURITIES AND EXCHANGE COMMISSION  
Washington, D.C. 20549**

**Form 10-Q**

(Mark One)

- QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d)  
OF THE SECURITIES EXCHANGE ACT OF 1934  
For the quarterly period ended December 31, 2006**
- TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d)  
OF THE SECURITIES EXCHANGE ACT OF 1934  
For the transition period from        to**

**Commission file number 1-14131**

**ALKERMES, INC.**

*(Exact name of registrant as specified in its charter)*

**PENNSYLVANIA**

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

**88 Sidney Street, Cambridge, MA**

*(Address of principal executive offices)*

**23-2472830**

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

**02139-4234**

*(Zip Code)*

**Registrant's telephone number including area code:**

**(617) 494-0171**

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

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

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

Large accelerated filer  Accelerated filer  Non-accelerated filer

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

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

<b>Class</b>	<b>As of February 1, 2007</b>
Common Stock, \$.01 par value	100,578,967
Non-Voting Common Stock, \$.01 par value	382,632

---

**ALKERMES, INC. AND SUBSIDIARIES**

**INDEX**

**Page No.**

**PART I FINANCIAL INFORMATION**

<u>Item 1.</u>	<u>Condensed Consolidated Financial Statements:</u>	
	<u>Condensed Consolidated Balance Sheets December 31, 2006 and March 31, 2006</u>	3
	<u>Condensed Consolidated Statements of Operations For the Three and Nine Months Ended December 31, 2006 and 2005</u>	4
	<u>Condensed Consolidated Statements of Cash Flows For the Nine Months Ended December 31, 2006 and 2005</u>	5
	<u>Notes to Condensed Consolidated Financial Statements</u>	6
<u>Item 2.</u>	<u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	20
<u>Item 3.</u>	<u>Quantitative and Qualitative Disclosures about Market Risk</u>	34
<u>Item 4.</u>	<u>Controls and Procedures</u>	35

**PART II OTHER INFORMATION**

<u>Item 1.</u>	<u>Legal Proceedings</u>	37
<u>Item 1A.</u>	<u>Risk Factors</u>	37
<u>Item 2.</u>	<u>Unregistered Sales of Equity Securities and Use of Proceeds</u>	39
<u>Item 6.</u>	<u>Exhibits</u>	39
<b><u>Signatures</u></b>		40
<b><u>Exhibit Index</u></b>		41
	<u>EX-10.1 1998 Equity Incentive Plan</u>	
	<u>EX-10.2 1999 Stock Option Plan</u>	
	<u>EX-10.3 2002 Restricted Stock Award Plan</u>	
	<u>EX-31.1 Section 302 CEO Certification</u>	
	<u>EX-31.2 Section 302 CFO Certification</u>	
	<u>EX-32.1 Section 906 CEO &amp; CFO Certification</u>	

**Table of Contents****PART 1. FINANCIAL INFORMATION****Item 1. Condensed Consolidated Financial Statements:****ALKERMES, INC. AND SUBSIDIARIES****CONDENSED CONSOLIDATED BALANCE SHEETS  
(unaudited)**

	<b>December 31, 2006</b>	<b>March 31, 2006</b>
	<b>(In thousands, except share and per share amounts)</b>	
<b>ASSETS</b>		
<b>CURRENT ASSETS:</b>		
Cash and cash equivalents	\$ 83,224	\$ 33,578
Investments short-term	267,875	264,389
Receivables	62,381	39,802
Inventory, net	13,933	7,341
Prepaid expenses and other current assets	6,673	2,782
Total current assets	434,086	347,892
<b>PROPERTY, PLANT AND EQUIPMENT:</b>		
Land	301	301
Building and improvements	25,138	20,966
Furniture, fixtures and equipment	69,907	61,086
Equipment under capital lease	464	464
Leasehold improvements	34,664	45,842
Construction in progress	35,016	23,555
	165,490	152,214
Less: accumulated depreciation and amortization	(48,523)	(39,297)
Property, plant and equipment net	116,967	112,917
RESTRICTED INVESTMENTS long-term	5,144	5,145
OTHER ASSETS	7,179	11,209
<b>TOTAL ASSETS</b>	<b>\$ 563,376</b>	<b>\$ 477,163</b>

**LIABILITIES, REDEEMABLE CONVERTIBLE PREFERRED STOCK AND SHAREHOLDERS EQUITY  
CURRENT LIABILITIES:**

Edgar Filing: ALKERMES INC - Form 10-Q

Accounts payable and accrued expenses	\$ 25,085	\$ 36,141
Accrued interest	2,985	3,239
Accrued restructuring costs	311	852
Unearned milestone revenue current portion	39,037	83,338
Deferred revenue current portion	200	200
Convertible subordinated notes current portion	676	676
Long-term debt current portion	1,287	1,214
 Total current liabilities	 69,581	 125,660
 NON-RECOURSE RISPERDAL CONSTA SECURED 7% NOTES	 156,026	 153,653
CONVERTIBLE SUBORDINATED NOTES LONG-TERM PORTION		124,346
LONG-TERM DEBT	629	1,519
UNEARNED MILESTONE REVENUE LONG-TERM PORTION	119,259	16,198
DEFERRED REVENUE LONG-TERM PORTION	19,266	750
OTHER LONG-TERM LIABILITIES	6,378	6,821
 TOTAL LIABILITIES	 371,139	 428,947
 REDEEMABLE CONVERTIBLE PREFERRED STOCK, par value, \$0.01 per share; authorized and issued, none and 1,500 shares at December 31, 2006 and March 31, 2006, respectively (at liquidation preference),		15,000
 COMMITMENTS AND CONTINGENCIES:		
 SHAREHOLDERS EQUITY:		
Capital stock, par value, \$0.01 per share; authorized, 4,550,000 shares (includes 2,997,000 shares of preferred stock); issued, none		
Common stock, par value, \$0.01 per share; authorized, 160,000,000 shares; 101,386,949 and 91,744,680 shares issued, 100,560,298 and 91,744,680 shares outstanding at December 31, 2006 and March 31, 2006, respectively	1,014	917
Nonvoting common stock, par value, \$0.01 per share; authorized 450,000 shares; issued and outstanding, 382,632 shares at December 31, 2006 and March 31, 2006	4	4
Treasury stock, at cost (823,677 shares and none at December 31, 2006 and March 31, 2006, respectively)	(12,492)	
Additional paid-in capital	830,392	664,596
Deferred compensation		(374)
Accumulated other comprehensive income	365	1,064
Accumulated deficit	(627,046)	(632,991)
 TOTAL SHAREHOLDERS EQUITY	 192,237	 33,216
 TOTAL LIABILITIES, REDEEMABLE CONVERTIBLE PREFERRED STOCK AND SHAREHOLDERS EQUITY	 \$ 563,376	 \$ 477,163

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

**Table of Contents****ALKERMES, INC. AND SUBSIDIARIES****CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS****(unaudited)**

	<b>Three Months Ended December 31,</b>		<b>Nine Months Ended December 31,</b>	
	<b>2006</b>	<b>2005</b>	<b>2006</b>	<b>2005</b>
	<b>(In thousands, except per share amounts)</b>			
<b>REVENUES:</b>				
Manufacturing revenues	\$ 28,763	\$ 14,715	\$ 77,078	\$ 42,224
Royalty revenues	5,673	4,228	16,625	11,867
Research and development revenue under collaborative arrangements	19,532	9,951	51,620	33,935
Net collaborative profit	8,445	12,524	29,798	24,918
<b>Total revenues</b>	<b>62,413</b>	<b>41,418</b>	<b>175,121</b>	<b>112,944</b>
<b>EXPENSES:</b>				
Cost of goods manufactured	12,989	6,077	34,149	14,954
Research and development	29,908	22,501	85,588	63,493
Selling, general and administrative	16,365	9,332	48,572	27,393
<b>Total expenses</b>	<b>59,262</b>	<b>37,910</b>	<b>168,309</b>	<b>105,840</b>
<b>OPERATING INCOME</b>	<b>3,151</b>	<b>3,508</b>	<b>6,812</b>	<b>7,104</b>
<b>OTHER INCOME (EXPENSE):</b>				
Interest income	4,260	3,278	13,329	7,928
Interest expense	(4,141)	(5,177)	(13,648)	(15,497)
Derivative loss related to convertible subordinated notes		(315)		(1,084)
Other income (expense), net	89	113	212	971
<b>Total other income (expense)</b>	<b>208</b>	<b>(2,101)</b>	<b>(107)</b>	<b>(7,682)</b>
<b>INCOME (LOSS) BEFORE INCOME TAXES</b>	<b>3,359</b>	<b>1,407</b>	<b>6,705</b>	<b>(578)</b>
<b>INCOME TAXES</b>	<b>426</b>		<b>761</b>	
<b>NET INCOME (LOSS)</b>	<b>\$ 2,933</b>	<b>\$ 1,407</b>	<b>\$ 5,944</b>	<b>\$ (578)</b>
<b>EARNINGS (LOSS) PER COMMON SHARE:</b>				
<b>BASIC</b>	<b>\$ 0.03</b>	<b>\$ 0.02</b>	<b>\$ 0.06</b>	<b>\$ (0.01)</b>
<b>DILUTED</b>	<b>\$ 0.03</b>	<b>\$ 0.01</b>	<b>\$ 0.06</b>	<b>\$ (0.01)</b>
<b>WEIGHTED AVERAGE NUMBER OF COMMON SHARES OUTSTANDING:</b>				

Edgar Filing: ALKERMES INC - Form 10-Q

BASIC	100,896	91,505	98,690	90,826
DILUTED	104,746	96,720	103,156	90,826

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



**Table of Contents****ALKERMES, INC. AND SUBSIDIARIES****CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS****(unaudited)**

	<b>Nine Months Ended December 31,</b>	
	<b>2006</b>	<b>2005</b>
	<b>(In thousands)</b>	
<b>CASH FLOWS FROM OPERATING ACTIVITIES:</b>		
Net income (loss)	\$ 5,944	\$ (578)
Adjustments to reconcile net income (loss) to net cash provided by operating activities:		
Share-based compensation	22,218	
Depreciation and amortization	8,838	7,856
Other non-cash charges	2,738	4,410
Derivative loss related to convertible subordinated notes		1,084
Loss (gain) on sale of investments	510	(1,000)
Gain on sale of equipment	(93)	(54)
Changes in assets and liabilities:		
Receivables	(11,079)	(14,599)
Inventory, prepaid expenses and other current assets	(10,058)	(5,096)
Accounts payable, accrued expenses and accrued interest	(11,205)	9,444
Accrued restructuring costs	(393)	(780)
Unearned milestone revenue	58,760	128,526
Deferred revenue	18,516	
Other long-term liabilities	202	506
Net cash provided by operating activities	84,898	129,719
<b>CASH FLOWS FROM INVESTING ACTIVITIES:</b>		
Additions to property, plant and equipment	(24,728)	(20,809)
Proceeds from the sale of equipment	159	105
Purchases of short and long-term investments	(217,453)	(613,813)
Sales and maturities of short and long-term investments	214,193	478,933
Decrease in other assets	18	95
Net cash used in investing activities	(27,811)	(155,489)
<b>CASH FLOWS FROM FINANCING ACTIVITIES:</b>		
Proceeds from issuance of common stock	5,868	3,077
Payment of debt	(817)	(835)
Purchase of treasury stock	(12,492)	
Net cash (used in) provided by financing activities	(7,441)	2,242
<b>NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS</b>	<b>49,646</b>	<b>(23,528)</b>

Edgar Filing: ALKERMES INC - Form 10-Q

CASH AND CASH EQUIVALENTS	Beginning of period	33,578	47,485
CASH AND CASH EQUIVALENTS	End of period	\$ 83,224	\$ 23,957
SUPPLEMENTARY INFORMATION:			
Cash paid for interest		\$ 10,647	\$ 10,371
Cash paid for taxes		896	
Noncash activities:			
Conversion of 2.5% convertible subordinated notes into common stock		125,000	
Conversion of redeemable convertible preferred stock into common stock			15,000
Redemption of redeemable convertible preferred stock		15,000	

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

**Table of Contents**

**ALKERMES, INC. AND SUBSIDIARIES**

**NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

**1. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES**

***Basis of Presentation***

The accompanying condensed consolidated financial statements of Alkermes, Inc. (the Company or Alkermes ) for the three and nine months ended December 31, 2006 and 2005 are unaudited and have been prepared on a basis substantially consistent with the audited financial statements for the year ended March 31, 2006. In the opinion of management, the condensed consolidated financial statements include all adjustments that are necessary to present fairly the results of operations for the reported periods. The Company s condensed consolidated financial statements are prepared in conformity with accounting principles generally accepted in the United States of America (commonly referred to as GAAP ).

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/A for the year ended March 31, 2006, 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 unaudited condensed consolidated financial statements include the accounts of Alkermes, Inc. and its wholly-owned subsidiaries: Alkermes Controlled Therapeutics, Inc. ( ACT I ); Alkermes Acquisition Corp.; Alkermes Europe, Ltd.; Advanced Inhalation Research, Inc. ( AIR ); and RC Royalty Sub LLC ( Royalty Sub ). The assets of Royalty Sub are not available to satisfy obligations of Alkermes and its subsidiaries, other than the obligations of Royalty Sub including Royalty Sub s non-recourse RISPERDA® CONSTA® secured 7% notes (the Non-Recourse 7% Notes ). Alkermes Controlled Therapeutics Inc. II ( ACT II ) was dissolved on July 31, 2006. Intercompany accounts and transactions have been eliminated.

***Use of Estimates*** The preparation of the Company s unaudited 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 unaudited condensed consolidated financial statements; and (3) the reported amounts of revenues and expenses during the reporting period. Actual results could differ from these estimates.

***New Accounting Pronouncements***

In September 2006, the Financial Accounting Standards Board ( FASB ) issued Statement of Financial Accounting Standards ( SFAS ) No. 157, *Fair Value Measurements* ( SFAS No. 157 ), which establishes a framework for measuring fair value in GAAP and expands disclosures about the use of fair value to measure assets and liabilities in interim and annual reporting periods subsequent to initial recognition. Prior to SFAS No. 157, which emphasizes that fair value is a market-based measurement and not an entity-specific measurement, there were different definitions of fair value and limited guidance for applying those definitions in GAAP. SFAS No. 157 is effective for the Company on a prospective basis for the reporting period beginning April 1, 2008. The Company is in the process of evaluating the impact of the adoption of SFAS No. 157 on its financial statements and related disclosures.

In June 2006, the FASB issued FASB Interpretation ( FIN ) No. 48, *Accounting for Uncertainty in Income Taxes* ( FIN No. 48 ) an interpretation of SFAS No. 109, *Accounting for Income Taxes* . FIN No. 48 clarifies the accounting for uncertainty in income taxes recognized in a company s financial statements and prescribes a recognition threshold and measurement process for financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. FIN No. 48 also provides guidance on derecognition, classification, interest and penalties, accounting in interim periods, disclosure and transition and

**Table of Contents**

**ALKERMES, INC. AND SUBSIDIARIES**

**NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)** will become effective for the Company on April 1, 2007. The Company is in the process of evaluating the impact of the adoption of FIN No. 48 on its financial statements and related disclosures.

**2. COLLABORATIVE ARRANGEMENTS**

***Lilly***

In December 2006, the Company and Eli Lilly and Company ( *Lilly* ) entered into a commercial manufacturing agreement for AIR<sup>®</sup> Inhaled Insulin ( *AIR Insulin* ). Under the agreement, the Company is the exclusive commercial manufacturer and supplier of AIR Insulin powder for the AIR Inhaled Insulin System ( *AIR Insulin System* ). The agreement provides for Lilly to fund all operating costs of the portion of the Company's commercial-scale production facility used to manufacture AIR insulin products, including the cost of AIR Insulin products manufactured at the Company's facility. In addition, Lilly funds the construction, development, validation and scale-up of a second manufacturing line at the facility to meet post-launch requirements for AIR Insulin production. The Company is responsible for overseeing the construction, development, validation and scale-up of the second manufacturing line.

Under the agreement, Lilly supplies all bulk active pharmaceutical product at no cost to the Company and is responsible for product packaging. Lilly will reimburse the Company for costs it previously incurred for the construction of the second manufacturing line, and Lilly will own all equipment purchased. The Company has the option to purchase this equipment from Lilly at any time at Lilly's then net book value or at a negotiated purchase price not to exceed Lilly's then net book value upon termination of the commercial manufacturing agreement.

In the event that the AIR Insulin product is commercialized, Lilly will purchase delivered product from the Company on a cost plus fee basis. In addition to the manufacturing fee, the Company earns royalties at a low double digit rate on net sales of the AIR Insulin product by Lilly.

Lilly has the right to terminate the commercial manufacturing agreement at any time following the fourth anniversary of the effective date of the agreement by providing ninety days prior written notice to the Company, subject to certain continuing rights and obligations. The Company has the right to terminate the commercial manufacturing agreement at any time within ninety days after the end of any calendar year that is four or more years after the launch of the first product, by providing ninety days prior written notice to Lilly, if the manufacture of the manufactured items purchased by Lilly in such calendar year requires less than seventy-five percent of the capacity of the manufacturing lines covered by the agreement. This termination right is subject to certain continuing rights and obligations. In addition, either party may terminate the agreement for any material breach by the other party which is not cured within ninety days of written notice of this material breach or within a longer period that is reasonably necessary to effect this cure.

The term of the commercial manufacturing agreement continues until expiration or termination of the development and license agreement that the Company entered into with Lilly in April 2001 for the development of inhaled formulations of insulin and other compounds.

***Cephalon***

In October 2006, the Company and Cephalon, Inc. ( Cephalon ) entered into a binding amendment to each of the existing license and collaboration agreement dated June 23, 2005 between the parties (the License Agreement ), and the supply agreement dated June 23, 2005 between the parties (the Supply Agreement ) (the amendments taken together, the Amendments ). Under the Amendments, the parties agreed to revise the provisions set forth in the License Agreement with respect to the first \$120.0 million of cumulative net losses of the collaboration incurred prior to December 31, 2007, for which the Company is responsible (the cumulative net loss cap ). Under the Amendments, Cephalon agreed to be responsible for its own VIVITROL<sup>®</sup> related costs during the period August 1, 2006 through December 31, 2006 and, consequently,

**Table of Contents**

**ALKERMES, INC. AND SUBSIDIARIES**

**NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)**  
during this period no such costs were charged by Cephalon to the collaboration and against the cumulative net loss cap.

The Company is manufacturing VIVITROL on one manufacturing line at the Company's manufacturing facility. Under the Amendments, the parties agreed that Cephalon will purchase from the Company two additional VIVITROL manufacturing lines (and related equipment) under construction, which will continue to be operated by the Company at its manufacturing facility. Through December 31, 2006, the Company billed Cephalon \$18.7 million for the sale of the two manufacturing lines, and the Company will bill Cephalon for future costs it incurs related to the construction of the two manufacturing lines. Cephalon has granted the Company an option, exercisable after two years, to repurchase the manufacturing lines at the then net book value of the assets.

Amounts received from Cephalon for the purchase of the physical assets associated with the additional VIVITROL manufacturing lines were recorded under the caption "Deferred revenue - long-term portion" in the consolidated balance sheets and will be recognized as revenue over the depreciable life of the assets in amounts equal to the related asset depreciation. Future purchases of physical assets by Cephalon will be accounted for the same way.

During the three months ended December 31, 2006, the Company received a \$4.6 million payment from Cephalon as reimbursement for certain costs incurred by the Company prior to October 2006 and charged to the collaboration, related to the construction of the additional VIVITROL manufacturing lines, consisting primarily of internal or temporary employee or full-time equivalent ( FTE )-related time. The payment was recorded under the caption "Unearned milestone revenue" in the consolidated balance sheets and will be recognized as milestone revenue - cost recovery under the caption "Net collaborative profit" in accordance with the Company's revenue recognition policy for VIVITROL. The Company and Cephalon have agreed to increase the cumulative net loss cap from \$120.0 million to \$124.6 million to account for this reimbursement.

Beginning October 2006, all FTE-related costs incurred by the Company that are reimbursable by Cephalon related to the construction and validation of the VIVITROL manufacturing lines are recorded as research and development revenue as incurred.

***Indevus***

In January 2007, the Company and Indevus Pharmaceuticals, Inc. ( Indevus ) announced that they had entered into a joint collaboration for the development of ALKS 27, an inhaled formulation of trospium chloride for the treatment of chronic obstructive pulmonary disease ( COPD ). The announcement of this collaboration followed the completion of extensive feasibility work, preclinical studies and a phase 1 study in healthy volunteers. Preliminary results from the phase 1 study showed that ALKS 27 was well tolerated over a wide dose range, with no dose-limiting effects observed.

ALKS 27 is an inhaled formulation of trospium chloride, a muscarinic receptor antagonist that relaxes smooth muscle tissue and has the potential to improve airflow in patients with COPD. Trospium chloride is the active ingredient in SANCTURA®, Indevus' currently marketed product for overactive bladder. The formulation under development for ALKS 27 is specifically designed for inhalation utilizing the Company's proprietary AIR pulmonary delivery system.

The Company and Indevus plan to initiate a phase 2a clinical study in the first half of 2007 designed to evaluate the clinical efficacy of ALKS 27, administered once-daily, in subjects with COPD. Pending results of the phase 2a study,

the companies plan to engage a partner for future development and commercialization of ALKS 27.



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

Under the joint collaboration, the Company and Indevus share equally all costs of development and commercial returns on a worldwide basis. The Company will perform all formulation work and manufacturing. Indevus will conduct the clinical development program.

***Rensselaer Polytechnic Institute***

In September 2006, the Company and Rensselaer Polytechnic Institute ( RPI ) entered into a license agreement granting the Company exclusive rights to a family of opioid receptor compounds discovered at RPI. These compounds represent an opportunity for the Company to develop therapeutics for a broad range of diseases and medical conditions, including addiction, pain and other central nervous system disorders. The Company will screen this library of compounds and plans to pursue preclinical work of an undisclosed, lead oral compound that has already been identified.

Under the terms of the agreement, RPI granted the Company an exclusive worldwide license to certain patents and patent applications relating to its compounds designed to modulate opioid receptors. The Company will be responsible for the continued research and development of any resulting product candidates. The Company paid RPI a nonrefundable upfront payment and will pay certain milestones relating to clinical development activities and royalties on products resulting from the agreement. All amounts paid to RPI under this license agreement have been expensed and are included in research and development expenses.

**3. COMPREHENSIVE INCOME (LOSS)**

Comprehensive income (loss) for the three and nine months ended December 31, 2006 and 2005 is as follows:

	<b>Three Months Ended December 31, 2006</b>		<b>Nine Months Ended December 31, 2006</b>	
	<b>2006</b>	<b>2005</b>	<b>2006</b>	<b>2005</b>
<b>(In thousands)</b>				
Net income (loss)	\$ 2,933	\$ 1,407	\$ 5,944	\$ (578)
Unrealized (loss) gain on available-for-sale investments	(1,152)	(52)	(699)	82
Comprehensive income (loss)	\$ 1,781	\$ 1,355	\$ 5,245	\$ (496)

**4. EARNINGS (LOSS) PER COMMON SHARE**

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

convertible debt. For periods during which the Company reports a net loss from operations, basic and diluted net loss per common share are equal since the impact of potential common shares would have an anti-dilutive effect.

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

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

	<b>Three Months Ended December 31,</b>		<b>Nine Months Ended December 31,</b>	
	<b>2006</b>	<b>2005</b>	<b>2006</b>	<b>2005</b>
<b>(In thousands)</b>				
Numerator:				
Net income (loss)	\$ 2,933	\$ 1,407	\$ 5,944	\$ (578)
Denominator:				
Weighted average number of common shares outstanding	100,896	91,505	98,690	90,826
Effect of dilutive securities:				
Stock options	2,723	4,180	3,633	
Restricted stock awards	291	86	244	
Redeemable convertible preferred stock	836	949	589	
Dilutive common share equivalents	3,850	5,215	4,466	
Shares used in calculating diluted earnings (loss) per common share	104,746	96,720	103,156	90,826

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

	<b>Three Months Ended December 31,</b>		<b>Nine Months Ended December 31,</b>	
	<b>2006</b>	<b>2005</b>	<b>2006</b>	<b>2005</b>
<b>(In thousands)</b>				
Numerator:				
Adjustment for interest	\$ 8	\$ 787	\$ 1,243	\$ 2,361
Adjustment for derivative loss		315		1,084
Total	\$ 8	\$ 1,102	\$ 1,243	\$ 3,445
Denominator:				
Stock options				19,196

Edgar Filing: ALKERMES INC - Form 10-Q

Restricted stock awards				83
Redeemable convertible preferred stock				2,835
2.5% convertible subordinated notes		9,025	2,461	9,025
3.75% convertible subordinated notes	10	10	10	10
Total	10	9,035	2,471	31,149

**Table of Contents****ALKERMES, INC. AND SUBSIDIARIES****NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)****5. INVENTORY, NET**

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

<b>(In thousands)</b>	<b>December 31, 2006</b>	<b>March 31, 2006</b>
Raw materials	\$ 5,741	\$ 4,211
Work in process	4,500	2,345
Finished goods	4,669	1,629
Inventory, gross	14,910	8,185
Allowances	(977)	(844)
Inventory, net	\$ 13,933	\$ 7,341

**6. CONVERTIBLE SUBORDINATED NOTES**

*2.5% Convertible Subordinated Notes* On June 15, 2006, the Company converted all of the outstanding \$125.0 million principal amount of the 2.5% convertible subordinated notes due 2023 (the 2.5% Subordinated Notes ) into 9,025,271 shares of the Company's common stock. The book value of the 2.5% Subordinated Notes at the time of the conversion was \$124.4 million. In connection with the conversion, the Company paid approximately \$0.6 million in cash to satisfy a three-year interest make-whole provision in the note indenture, which was recorded as additional interest expense at the date of the conversion. None of the 2.5% Subordinated Notes were outstanding as of December 31, 2006, and no gain or loss was recorded on the conversion of the 2.5% Subordinated Notes, which was executed in accordance with the underlying indenture.

**7. RESTRUCTURING**

In connection with the 2004 restructuring program, in which the Company and Genentech, Inc. announced the decision to discontinue commercialization of NUTROPIN DEPOT® (the 2004 Restructuring ), the Company recorded net restructuring charges of approximately \$11.5 million in the year ended March 31, 2005. As of December 31, 2006, the Company had paid in cash, written off, recovered and made restructuring charge adjustments that aggregate approximately \$10.2 million in facility closure costs and \$0.1 million in employee separation costs in connection with the 2004 Restructuring. The amounts remaining in the restructuring accrual as of December 31, 2006 are expected to be paid out through fiscal 2009 and relate primarily to estimates of lease costs, net of sublease income, associated with the exited facility.

The following table displays the restructuring activity during the nine months ended December 31, 2006:

<b>(In thousands)</b>	<b>Balance March 31, 2006</b>	<b>Write-Downs and Adjustments(1)</b>	<b>Payments</b>	<b>Balance December 31, 2006</b>
Facility closure and employee separation	\$ 2,368	\$ (792)	\$ (394)	\$ 1,182
Total	\$ 2,368	\$ (792)	\$ (394)	\$ 1,182

(1) Consists of \$0.3 million of non-cash write-downs and \$0.5 million of adjustments for sublease income due to the Company under a facility sublease agreement related to facility that the Company had closed in connection with the 2004 Restructuring. These adjustments are included in selling, general and administrative expense.

**Table of Contents**

**ALKERMES, INC. AND SUBSIDIARIES**

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

**8. REDEEMABLE CONVERTIBLE PREFERRED STOCK**

In December 2002, the Company and Lilly expanded the collaboration for the development of inhaled formulations of insulin and hGH based on the Company's AIR pulmonary drug delivery technology. In connection with the expansion, Lilly purchased \$30.0 million of the Company's 2002 redeemable convertible preferred stock, \$0.01 par value per share (the Preferred Stock) in accordance with a stock purchase agreement dated December 13, 2002 (the Stock Purchase Agreement). The Preferred Stock had a liquidation preference of \$10,000 per share and no dividends were payable by the Company on these securities. Lilly had the right to return the Preferred Stock in exchange for a reduction in the royalty rate payable to the Company on future sales of the AIR Insulin product by Lilly, if approved. The Preferred Stock was convertible into the Company's common stock at market price under certain conditions at the Company's option, and automatically upon the filing of a new drug application (NDA) with the Food and Drug Administration (FDA) for an AIR Insulin product.

Under the expanded collaboration, the royalty rate payable to the Company on future sales of the AIR Insulin product by Lilly, if approved, was increased. The Company agreed to use the proceeds from the issuance of the Preferred Stock primarily to fund the AIR Insulin development program and to use a portion of the proceeds to fund the AIR hGH development program. The Company did not record research and development revenue on these programs while the proceeds from the Preferred Stock funded this development. The \$30.0 million of research and development expended by the Company was recognized as research and development expense as incurred. All of the proceeds from the sale of the Preferred Stock had been spent through fiscal year 2005.

The Preferred Stock was carried on the condensed consolidated balance sheets at its estimated redemption value in the amount of \$0 million and \$15.0 million as of December 31, 2006 and March 31, 2006, respectively. In October 2005, the Company converted 1,500 shares of the Preferred Stock with a carrying value of \$15.0 million into 823,677 shares of Company common stock. This conversion secured a proportionate increase in the royalty rate payable to the Company on future sales of the AIR Insulin product by Lilly, if approved. In December 2006, Lilly exercised its right to put the remaining 1,500 shares of the Company's outstanding Preferred Stock, with a carrying value of \$15.0 million, in exchange for a reduction in the royalty rate payable to the Company on future sales of the AIR Insulin product by Lilly, if approved. At that time, the remaining Preferred Stock was reclassified to shareholders equity in the condensed consolidated balance sheets under the caption Additional paid-in capital at its redemption value of \$15.0 million.

Because Lilly had a put right and the Preferred Stock could have been returned in circumstances outside of the Company's control, the Company accounted for the initial issuance of the Preferred Stock as an equity instrument in temporary equity at its initial issuance and redemption value. The Preferred Stock remained in temporary equity until such time as the put right was exercised, at which time it was reclassified to shareholders' equity. The Preferred Stock was carried on the condensed consolidated balance sheets at its redemption value, and the Company re-evaluated the redemption value on a quarterly basis. The redemption value represented the estimated present value of the reduction in royalties payable to the Company by Lilly on future sales of the AIR Insulin product by Lilly, if approved, in the event that Lilly exercised its right to put the Preferred Stock or the Company exercised its right to call the Preferred Stock. This value was based on an estimate of future revenues generated by our partner Lilly for certain products still in development and assumptions about the future market potential for insulin based products, taking into consideration progress on the Company's development programs, the likelihood of product approvals and other factors. Certain of

these assumptions were highly subjective and required the exercise of management judgment.

The Company considers its agreements with Lilly for the development of inhaled formulations of insulin and the Stock Purchase Agreement a single arrangement (the Arrangement ). As the Arrangement contains elements of funded research and development activities, the Company determined that the Arrangement should be accounted for as a financing arrangement under SFAS No. 68, *Research and Development Arrangements*.



**Table of Contents****ALKERMES, INC. AND SUBSIDIARIES****NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)****9. SHAREHOLDERS EQUITY**

In December 2006, Lilly exercised its right to put the remaining 1,500 shares of the Company's outstanding Preferred Stock, with a carrying value of \$15.0 million, in exchange for a reduction in the royalty rate payable to the Company on future sales of the AIR Insulin product by Lilly, if approved. At that time, the remaining Preferred Stock was reclassified to shareholders' equity in the condensed consolidated balance sheets under the caption "Additional paid-in capital" at its redemption value of \$15.0 million (see Note 8).

In June 2006, the Company converted all of its outstanding 2.5% Subordinated Notes into 9,025,271 shares of the Company's common stock (see Note 6).

In September 2005, the Company's Board of Directors authorized a share repurchase program up to \$15.0 million of common stock to be repurchased in the open market or through privately negotiated transactions. The repurchase program has no set expiration date and may be suspended or discontinued at any time. During the nine months ended December 31, 2006 and since September 2005, the Company had repurchased 823,677 shares at a cost of approximately \$12.5 million under the program.

**10. SHARE-BASED COMPENSATION**

Effective April 1, 2006, the Company adopted the provisions of SFAS No. 123(R), *Share-Based Payment* (SFAS No. 123(R)) which is a revision of SFAS No. 123 *Accounting for Stock-Based Compensation* and supersedes accounting principles board (APB) Opinion No. 25, *Accounting for Stock Issued to Employees* (APB No. 25). Under the provisions of SFAS No. 123(R), share-based compensation cost is measured at the grant date based on the fair value of the award and is recognized as an expense over the employee's requisite service period (generally the vesting period of the equity grant).

Prior to April 1, 2006, the Company accounted for share-based compensation to employees in accordance with APB No. 25 and related interpretations, and the Company also followed the disclosure requirements of SFAS No. 123.

The Company has elected to adopt the provisions of SFAS No. 123(R) using the modified prospective transition method, and recognizes share-based compensation cost on a straight-line basis over the requisite service periods of awards. Under the modified prospective transition method, share-based compensation expense is recognized for the portion of outstanding stock options and stock awards granted prior to the adoption of SFAS No. 123(R) for which service has not been rendered, and for any future grants of stock options and stock awards. The Company recognizes share-based compensation cost for awards that have graded vesting on a straight-line basis over the requisite service period of each separately vesting portion.

The following table presents share-based compensation expense for continuing operations included in the Company's unaudited condensed consolidated statements of operations:

<b>Three Months Ended</b>	<b>Nine Months Ended</b>
-------------------------------	------------------------------

	<b>December 31, 2006</b>	<b>December 31, 2006</b>
<b>(In thousands)</b>		
Cost of goods manufactured	\$ 931	\$ 2,094
Research and development	1,897	6,965
Selling, general and administrative	4,672	13,159
Total share-based compensation expense	\$ 7,500	\$ 22,218

As of December 31, 2006, \$0.4 million of share-based compensation cost was capitalized and recorded under the caption, Inventory, net in the unaudited condensed consolidated balance sheet.

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

The Company estimates the fair value of stock options on the grant date using the Black-Scholes option-pricing model. Assumptions used to estimate the fair value of stock options are the expected option term, expected volatility of the Company's common stock over the option's expected term, the risk-free interest rate over the option's expected term and the Company's expected annual dividend yield. The Company believes that the valuation technique and the approach utilized to develop the underlying assumptions are appropriate in calculating the fair values of the Company's stock options granted in the three and nine months ended December 31, 2006. Estimates of fair value may not represent actual future events or the value to be ultimately realized by persons who receive equity awards.

The Company used historical data as the basis for estimating option terms and forfeitures. Separate groups of employees that have similar historical stock option exercise and forfeiture behavior were considered separately for valuation purposes. The ranges of expected terms disclosed below reflect different expected behavior among certain groups of employees. Expected stock volatility factors were based on a weighted average of implied volatilities from traded options on the Company's common stock and historical stock price volatility of the Company's common stock, which was determined based on a review of the weighted average of historical weekly price changes of the Company's common stock. The risk-free interest rate for periods commensurate with the expected term of the share option was based on the United States ( U.S. ) treasury yield curve in effect at the time of grant. The dividend yield on the Company's common stock was estimated to be zero as the Company has not paid and does not expect to pay dividends. The exercise price of option grants equals the average of the high and low of the Company's common stock traded on the NASDAQ Global Market on the date of grant.

During the three and nine months ended December 31, 2006, the fair value of each stock option grant was estimated on the grant date with the following assumptions:

	<b>Three Months Ended December 31, 2006</b>	<b>Nine Months Ended December 31, 2006</b>
Expected option term	4 -5 years	4 - 5 years
Expected stock volatility	50%	50%
Risk-free interest rate	4.45% - 4.61%	4.45% - 5.07%
Expected annual dividend yield		

Upon adoption of SFAS No. 123(R), the Company recognized a benefit of approximately \$0.02 million as a cumulative effect of a change in accounting principle resulting from the requirement to estimate forfeitures on the Company's restricted stock awards at the date of grant under SFAS No. 123(R) rather than recognizing forfeitures as incurred under APB No. 25. An estimated forfeiture rate was applied to previously recorded compensation expense for the Company's unvested restricted stock awards to determine the cumulative effect of a change in accounting principle. The cumulative benefit, net of tax, was immaterial for separate presentation in the unaudited condensed consolidated statement of operations and was included in operating income in the quarter ended June 30, 2006.

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

The Company had previously adopted the provisions of SFAS No. 123, as amended by SFAS No. 148, *Accounting for Stock-Based Compensation Transition and Disclosure* through disclosure only. The following table illustrates the effects on net income (loss) and earnings (loss) per common share, basic and diluted, for the three and nine months ended December 31, 2005 as if the Company had applied the fair value recognition provisions of SFAS No. 123 to share-based employee awards.

	<b>Three Months Ended December 31, 2005</b>	<b>Nine Months Ended December 31, 2005</b>
<b>(In thousands, except per share amounts)</b>		
Net income (loss) as reported	\$ 1,407	\$ (578)
Add: employee share-based compensation expense as reported in the unaudited condensed consolidated statement of operations	47	162
Deduct: employee share-based compensation expense determined under the fair-value method for all options and awards	(5,540)	(16,651)
Net loss pro-forma	\$ (4,086)	\$ (17,067)
Reported earnings (loss) per common share:		
Basic	\$ 0.02	\$ (0.01)
Diluted	\$ 0.01	\$ (0.01)
Pro-forma loss per common share:		
Basic	\$ (0.04)	\$ (0.19)
Diluted	\$ (0.04)	\$ (0.19)

The fair value of each option grant was estimated on the grant date using the Black-Scholes option pricing model with the following assumptions:

	<b>Three Months Ended December 31, 2005</b>	<b>Nine Months Ended December 31, 2005</b>
Expected option term	5 years	5 years
Expected stock volatility	49%	50%
Risk-free interest rate	4.35%	4.08%
Expected annual dividend yield		

***Stock Options and Award Plans***

The Company's stock option plans (the Plans) provide for issuance of nonqualified and incentive stock options to employees, officers and directors of, and consultants to, the Company. Stock options generally expire ten years from the grant date and generally vest ratably over a four-year period, except for grants to the non-employee directors and part-time employee directors, which vest over six months. With the exception of one plan, under which the option exercise price may be below the fair market value, but not below par value, of the underlying stock at the time the option is granted, the exercise price of stock options granted under the Plans may not be less than 100% of the fair market value of the common stock on the measurement date of the option grant. The measurement date for accounting purposes is the date that all elements of the grant are fixed.

The Compensation Committee of the Board of Directors is responsible for administering the Company's equity plans other than the non-employee director stock plans. The Limited Compensation Sub-Committee has the authority to make individual grants of options to purchase shares of common stock under certain of the Company's stock option plans to employees of the Company who are not subject to the reporting requirements

**Table of Contents**

**ALKERMES, INC. AND SUBSIDIARIES**

**NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Continued)**  
of the Securities Exchange Act. The Limited Compensation Sub-Committee has generally approved new hire employee stock option grants of up to the limit of its authority. Until July 2006, such authority was limited to 5,000 shares per individual grant. In July 2006, this limit was raised by the Compensation Committee to 25,000 shares per individual grant and limited to employees who are not subject to the reporting requirements of the Securities Exchange Act and who are below the level of Vice President of the Company.

The Compensation Committee has established procedures for the grant of options to new employees. Within the limits of its authority, the Limited Compensation Sub-Committee grants options to new hires that commenced their employment with the Company the prior month on the first Wednesday following the first Monday of each month (or the first business day thereafter if such day is a holiday) (the New Hire Grant Date ). New hire grants that exceed the authority of the Limited Compensation Sub-Committee will be granted on the New Hire Grant Date by the Compensation Committee as a whole.

The Compensation Committee has also established procedures for regular grants of stock options to Company employees. The Compensation Committee considers the grant of stock options twice a year at meetings held in conjunction with meetings of the Company s Board of Directors regularly scheduled around May and November. The measurement date for the May option grants will not be less than forty-eight hours after the announcement of the Company s fiscal year-end results, and the measurement date for the November option grants will not be less than forty-eight hours after the announcement of the Company s second quarter fiscal year results.

The Board of Directors administers the stock option plans for non-employee directors.

Under the 1990 Omnibus Stock Option Plan, (the 1990 Plan ) limited stock appreciation rights ( LSARs ) may be granted to all or any portion of shares covered by stock options granted to directors and executive officers. LSARs may be granted with the grant of a nonqualified stock option or at any time during the term of such option but may only be granted at the time of the grant in the case of an incentive stock option. The grants of LSARs are not effective until six months after their date of grant. Upon the occurrence of certain triggering events, including a change of control, the options with respect to which LSARs have been granted shall become immediately exercisable and the persons who have received LSARs will automatically receive a cash payment in lieu of shares. As of December 31, 2006, there were no LSARs outstanding under the 1990 Plan. No LSARs were granted during the three and nine months ended December 31, 2006 and 2005.

The Company has also adopted restricted stock award plans (the Award Plans ) which provide for awards to certain eligible employees, officers and directors of, and consultants to, the Company of up to a maximum of 1,300,000 shares of common stock. Awards may vest based on cliff vesting or graded vesting and vest over various periods. As of December 31, 2006, the Company has reserved a total of 646,724 shares of common stock for issuance upon release of awards that have been or may be granted under the Award Plans.

The Company generally issues common stock from previously authorized but unissued shares to satisfy option exercises and restricted stock awards.

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

The following table sets forth the stock option and restricted stock award activity during the nine months ended December 31, 2006:

	Options Outstanding			Restricted Stock Awards Outstanding	
	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (In years)	Number of Shares	Weighted Average Grant Date Fair Value
Outstanding at March 31, 2006	18,733,823	\$ 16.09	6.71	91,000	\$ 8.15
Granted	2,427,930	16.97		297,500	18.99
Exercised	(547,830)	10.71			
Vesting of restricted stock				(99,425)	17.39
Cancelled	(547,615)	16.16		(2,000)	11.45
Outstanding at December 31, 2006	20,066,308	\$ 16.35	6.37	287,075	\$ 16.16
Exercisable at December 31, 2006	13,427,747	\$ 16.52	5.25		

Outstanding and exercisable stock options under the Plans as of December 31, 2006 are summarized below:

Range of Exercise Prices	Options Outstanding			Options Exercisable	
	Number Outstanding	Weighted Average Remaining Contractual Life (In years)	Weighted Average Exercise Price	Number Exercisable	Weighted Average Exercise Price
\$ 0.30 - \$ 7.69	2,540,554	5.17	\$ 6.57	2,483,505	\$ 6.54
7.72 - 12.16	2,723,869	5.80	10.71	2,126,926	10.58
12.19 - 14.57	3,250,774	8.21	13.75	1,261,950	13.58
14.76 - 16.24	2,746,812	7.85	15.03	1,322,388	14.99
16.28 - 18.60	3,672,372	6.39	17.61	2,167,102	17.12
18.61 - 28.30	2,886,077	6.39	21.28	1,820,026	21.31
28.40 - 96.88	2,245,850	3.88	31.24	2,245,850	31.24

Edgar Filing: ALKERMES INC - Form 10-Q

\$ 0.30 - \$ 96.88	20,066,308	6.37	\$ 16.35	13,427,747	\$ 16.51
--------------------	------------	------	----------	------------	----------

As of December 31, 2006, the Company has reserved a total of 22,219,052 shares of common stock for issuance upon exercise of stock options that have been or may be granted under the Plans.



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

The following table sets forth the activity for unvested stock options and restricted stock awards for the nine months ended December 31, 2006:

	<b>Unvested Stock Options</b>		<b>Unvested Restricted Stock Awards</b>	
		<b>Weighted Average</b>		<b>Weighted Average Grant Date Fair Value</b>
	<b>Number of Shares</b>	<b>Exercise Price</b>	<b>Number of Shares</b>	
Unvested at March 31, 2006	7,373,398	\$ 16.97	91,000	\$ 8.15
Granted	2,427,930	16.97	297,500	18.99
Vested	(2,721,046)	19.60	(99,425)	17.39
Cancelled	(441,721)	15.05	(2,000)	11.45
Unvested at December 31, 2006	6,638,561	\$ 16.02	287,075	\$ 16.16

The weighted average grant date fair value of stock options granted during the nine months ended December 31, 2006 and 2005 was \$8.16 and \$8.18, respectively. The aggregate intrinsic value of stock options exercised during the nine months ended December 31, 2006 and 2005 was \$3.9 million and \$3.6 million, respectively. As of December 31, 2006, the aggregate intrinsic value of stock options outstanding and exercisable was \$25.5 million and \$23.4 million, respectively. The intrinsic value of a stock option is the amount by which the market value of the underlying stock exceeds the exercise price of the stock option.

As of December 31, 2006, there was \$23.1 million and \$3.2 million of total unrecognized compensation cost related to unvested share-based compensation arrangements granted under the Company's Plans and Award Plans, respectively. This cost is expected to be recognized over a weighted average period of approximately 1.5 years and 1.5 years for the Company's Plans and Award Plans, respectively.

Cash received from option exercises under the Company's Plans during the nine months ended December 31, 2006 was \$5.9 million.

Due to the Company's full valuation allowance on its deferred tax assets and carryforwards, the Company did not record any tax benefits from option exercises under the share-based payment arrangements during the three and nine months ended December 31, 2006 and 2005.

**11. INCOME TAXES**

The Company records a deferred tax asset or liability based on the difference between the financial statement and tax bases of assets and liabilities, as measured by enacted tax rates assumed to be in effect when these differences reverse.

As of December 31, 2006, the Company determined that the deferred tax assets may not be realized and a full valuation allowance has been recorded.

The provision for income taxes in the amount of approximately \$0.4 million and \$0.8 million for the three and nine months ended December 31, 2006, respectively, related to the U.S. alternative minimum tax ( AMT ). Tax recognition of a portion of the nonrefundable payment received from Cephalon during fiscal 2006 was deferred to fiscal 2007 when it will be recognized in full. Utilization of tax loss carryforwards is limited in the calculation of AMT. As a result, a federal tax charge is reflected for fiscal 2007. The current AMT liability is available as a credit against future tax obligations upon the full utilization or expiration of the Company s net operating loss carryforward.

## **12. LEGAL MATTERS**

On August 16, 2006, a purported shareholder derivative lawsuit, captioned Maxine Phillips vs. Richard Pops et al. and docketed as CIV-06-2931, was filed ostensibly on the Company s behalf in Middlesex County

**Table of Contents**

**ALKERMES, INC. AND SUBSIDIARIES**

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

Superior Court, Massachusetts. The complaint in that lawsuit alleged, among other things, that, in connection with certain stock option grants made by the Company, certain of the Company's directors and officers committed violations of state law, including breaches of fiduciary duty. The complaint named the Company as a nominal defendant, but did not seek any monetary relief from the Company. The lawsuit sought recovery of damages allegedly caused to the Company as well as certain other relief. On September 13, 2006, the plaintiff voluntarily dismissed this action without prejudice.

On October 10, 2006, a purported shareholder derivative lawsuit, captioned Thomas Bennett, III vs. Richard Pops et al. and docketed as CIV-06-3606, was filed ostensibly on the Company's behalf in Middlesex County Superior Court, Massachusetts. The complaint in that lawsuit alleges, among other things, that, in connection with certain stock option grants made by the Company, certain of the Company's directors and officers committed violations of state law, including breaches of fiduciary duty. The complaint names Alkermes as a nominal defendant, but does not seek any monetary relief from the Company. The lawsuit seeks recovery of damages allegedly caused to the Company as well as certain other relief, including an order requiring the Company to take action to enhance its corporate governance and internal procedures. On January 31, 2007, the defendants served the plaintiff with a motion to dismiss the complaint.

The Company has received four letters, allegedly sent on behalf of owners of its securities, which claim, among other things, that certain of the Company's officers and directors breached their fiduciary duties to the Company by, among other allegations, allegedly violating the terms of the Company's stock option plans, allegedly violating generally accepted accounting principles in the United States of America by failing to recognize compensation expenses with respect to certain option grants during certain years, and allegedly publishing materially inaccurate financial statements relating to the Company. The letters demand, among other things, that the Company's board of directors (the Board) take action on the Company's behalf to recover from the current and former officers and directors identified in the letters the damages allegedly sustained by the Company as a result of their alleged conduct, among other amounts. The letters do not seek any monetary recovery from the Company itself. The Company's Board appointed a special independent committee of the Board to investigate, assess and evaluate the allegations contained in these and any other demand letters relating to the Company's stock option granting practices and to report its findings, conclusions and recommendations to the Board. The special independent committee was assisted by independent outside legal counsel. In November 2006, based on the results of its investigation, the special independent committee of the Board concluded that the assertions contained in the demand letters lacked merit, that nothing had come to its attention that would cause it to believe that there are any instances where management of the Company or the Compensation Committee of the Company had retroactively selected a date for the grant of stock options during the 1995 through 2006 period, and that it would not be in the best interests of the Company or its shareholders to commence litigation against the Company's current or former officers or directors as demanded in the letters. The findings and conclusions of the special independent committee of the Board have been presented to and adopted by our Board.

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

Alkermes, Inc. (as used in this section, together with our subsidiaries, us, we or our) is a biotechnology company that develops innovative medicines designed to yield better therapeutic outcomes and improve the lives of patients with serious disease. We currently have two commercial products: RISPERDAL® CONSTA® [(risperidone) long-acting injection], the first and only long-acting atypical antipsychotic medication approved for use in schizophrenia, and marketed worldwide by Janssen-Cilag (Janssen), a wholly owned division of Johnson & Johnson; and VIVITROL® (naltrexone for extended-release injectable suspension), the first and only once-monthly injectable medication approved for the treatment of alcohol dependence and marketed in the U.S. primarily by Cephalon, Inc. Our pipeline includes extended-release injectable, pulmonary, and oral products for the treatment of prevalent, chronic diseases such as central nervous system disorders, addiction and diabetes. Our headquarters are in Cambridge, Massachusetts, and we operate research and manufacturing facilities in Massachusetts and Ohio.

We have funded our operations primarily through public offerings and private placements of debt and equity securities, bank loans, term loans, equipment financing arrangements and payments received under research and development agreements and other agreements with collaborators. We expect to incur significant additional research and development and other costs in connection with collaborative arrangements as we expand the development of our proprietary product candidates, including costs related to preclinical studies, clinical trials and facilities expansion. Our costs, including research and development costs for our product candidates and sales, marketing and promotion expenses for any future products to be marketed by us or our collaborators, if any, may exceed revenues in the future, which may result in losses from operations.

**Forward-Looking Statements**

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

Although we believe that our expectations are based on reasonable assumptions within the bounds of our knowledge of our business and operations, the forward-looking statements contained in this document are neither promises nor guarantees; and our business is subject to significant risk and uncertainties and there can be no assurance that our actual results will not differ materially from our expectations. These forward looking statements include, but are not limited to, statements concerning: the achievement of certain business and operating milestones and future operating results and profitability; continued revenue growth from RISPERDAL CONSTA; the successful commercialization of VIVITROL; recognition of milestone payments from our partner Cephalon related to the future sales of VIVITROL; the successful continuation of development activities for our programs, including long-acting release (LAR) formulation of exenatide (exenatide LAR), AIRhaled Insulin (AIR Insulin) and AIR parathyroid hormone (AIR PTH); the successful manufacture of our products and product candidates, including RISPERDAL CONSTA and VIVITROL at a commercial scale, and the successful manufacture of exenatide LAR by Amylin Pharmaceuticals, Inc. (Amylin); the building of a selling and marketing infrastructure for VIVITROL by ourselves or our partner Cephalon; and the successful scale-up, establishment and expansion of manufacturing capacity. Factors which could cause actual results to differ materially from our expectations set forth in our forward-looking statements include, among others:

(i) manufacturing and royalty revenues for RISPERDAL CONSTA may not continue to grow, particularly because we rely on our partner, Janssen, to forecast and market this product; (ii) we may be unable to manufacture RISPERDAL CONSTA in sufficient quantities and with sufficient yields to meet Janssen's requirements or to add additional production capacity for RISPERDAL CONSTA, or unexpected events could interrupt manufacturing operations at our RISPERDAL CONSTA facility, which is the sole

**Table of Contents**

source of supply for that product; (iii) we may be unable to manufacture VIVITROL economically or in sufficient quantities and with sufficient yields to meet our own or our partner Cephalon's requirements or add additional production capacity for VIVITROL, or unexpected events could interrupt manufacturing operations at our VIVITROL facility, which is the sole source of supply for that product; (iv) we and our partner Cephalon may be unable to develop the selling and marketing capabilities, and/or infrastructure necessary to jointly support the commercialization of VIVITROL; (v) we and our partner Cephalon may be unable to commercialize VIVITROL successfully; (vi) VIVITROL may not produce significant revenues; (vii) due to the nature of our collaboration with Cephalon and because we have limited selling, marketing and distribution experience, we rely primarily on our partner Cephalon to successfully commercialize VIVITROL in the U.S.; (viii) third party payors may not cover or reimburse VIVITROL; (ix) we may be unable to scale-up and manufacture our product candidates, including exenatide LAR, AIR Insulin, AIR PTH, ALKS 27, ALKS 29 and extended-release naltrexone, commercially or economically; (x) we may not be able to source raw materials for our production processes from third parties; (xi) we may not be able to successfully transfer manufacturing technology for exenatide LAR to Amylin and Amylin may not be able to successfully operate the manufacturing facility for exenatide LAR; (xii) our product candidates, if approved for marketing, may not be launched successfully in one or all indications for which marketing is approved and, if launched, may not produce significant revenues; (xiii) we rely on our partners to determine the regulatory and marketing strategies for RISPERDAL CONSTA and our other partnered, non-proprietary programs; (xiv) RISPERDAL CONSTA, VIVITROL and our product candidates in commercial use may have unintended side effects, adverse reactions or incidents of misuse and the U.S. Food and Drug Administration ( FDA ) or other health authorities could require post approval studies or require removal of our products from the market; (xv) our collaborators could elect to terminate or delay programs at any time and disputes with collaborators or failure to negotiate acceptable new collaborative arrangements for our technologies could occur; (xvi) clinical trials may take more time or consume more resources than initially envisioned; (xvii) results of earlier clinical trials may not necessarily be predictive of the safety and efficacy results in larger clinical trials; (xviii) 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; (xix) after the completion of clinical trials for our product candidates and the submission for marketing approval, the FDA or other health authorities could refuse to accept such filings or could request additional preclinical or clinical studies be conducted, each of which could result in significant delays or the failure of such product to receive marketing approval; (xx) even if our product candidates appear promising at an early stage of development, product candidates could fail to receive necessary regulatory approvals, be difficult to manufacture on a large scale, be uneconomical, fail to achieve market acceptance, be precluded from commercialization by proprietary rights of third parties or experience substantial competition in the marketplace; (xxi) technological change in the biotechnology or pharmaceutical industries could render our products and/or product candidates obsolete or non-competitive; (xxii) difficulties or set-backs in obtaining and enforcing our patents and difficulties with the patent rights of others could occur; (xxiii) we may continue to incur losses in the future; (xxiv) the effect of our adoption of Statement of Financial Accounting Standard ( SFAS ) No. 123(R), *Share-Based Payment* on our results of operations depends on a number of factors, many of which are out of our control, including estimates of stock price volatility, option terms, interest rates, the number and type of stock options and stock awards granted during the reporting period, as well as other factors; (xxv) we face potential liabilities and diversion of management's attention as a result of an ongoing informal SEC inquiry into, and private litigation relating to, our past practices with respect to equity incentives; (xxvi) we may not recoup any of our \$100.0 million investment in Reliant Pharmaceuticals, LLC ( Reliant ); and (xxvii) we may need to raise substantial additional funding to continue research and development programs and clinical trials and other operations and could incur difficulties or setbacks in raising such funds.

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



**Table of Contents**

**Collaborative Arrangements**

***Lilly***

In December 2006, we and Eli Lilly and Company ( *Lilly* ) entered into a commercial manufacturing agreement for AIR Insulin. Under the agreement, we are the exclusive commercial manufacturer and supplier of AIR Insulin powder for the AIR Inhaled Insulin System ( *AIR Insulin System* ). The agreement provides for Lilly to fund all operating costs of the portion of our commercial-scale production facility used to manufacture AIR Insulin products, including the cost of AIR Insulin products manufactured at the facility. In addition, Lilly funds the construction, development, validation and scale-up of a second manufacturing line at the facility to meet post-launch requirements for AIR Insulin production. We are responsible for overseeing the construction, development, validation and scale-up of the second manufacturing line.

Under the agreement, Lilly supplies all bulk active pharmaceutical product to us at no cost and is responsible for product packaging. Lilly will reimburse us for costs we previously incurred for the construction of the second manufacturing line, and Lilly will own all equipment purchased. We have the option to purchase this equipment from Lilly at any time at Lilly's then net book value or at a negotiated purchase price not to exceed Lilly's then net book value upon termination of the commercial manufacturing agreement.

In the event that the AIR Insulin product is commercialized, Lilly will purchase delivered product from us at cost plus a fee. In addition to the manufacturing fee, we earn royalties at a low double digit rate on net sales of the AIR Insulin product by Lilly.

Lilly has the right to terminate the commercial manufacturing agreement at any time following the fourth anniversary of the effective date of the agreement by providing ninety days prior written notice to us, subject to certain continuing rights and obligations. We have the right to terminate the commercial manufacturing agreement at any time within ninety days after the end of any calendar year that is four or more years after the launch of the first product, by providing ninety days prior written notice to Lilly, if the manufacture of the manufactured items purchased by Lilly in such calendar year requires less than seventy-five percent of the capacity of the manufacturing lines covered by the agreement. This termination right is subject to certain continuing rights and obligations. In addition, either party may terminate the agreement for any material breach by the other party which is not cured within ninety days of written notice of this material breach or within a longer period that is reasonably necessary to effect this cure.

The term of the commercial manufacturing agreement continues until expiration or termination of the development and license agreement that we entered into with Lilly in April 2001 for the development of inhaled formulations of insulin and other compounds.

***Cephalon***

In October 2006, we and Cephalon entered into a binding amendment to each of the existing license and collaboration agreement dated June 23, 2005 between the parties (the *License Agreement* ) and the supply agreement dated June 23, 2005 between the parties (the *Supply Agreement* ) (the amendments taken together, the *Amendments* ). Under the Amendments, the parties agreed to revise the provisions set forth in the License Agreement with respect to the first \$120.0 million of cumulative net losses of the collaboration incurred prior to December 31, 2007, for which we are responsible (the *cumulative net loss cap* ). Under the Amendments, Cephalon agreed to be responsible for its own VIVITROL related costs during the period August 1, 2006 through December 31, 2006 and, consequently, during this period no such costs were charged by Cephalon to the collaboration and against the cumulative net loss cap.



We are manufacturing VIVITROL on one manufacturing line at our manufacturing facility. Under the Amendments, the parties agreed that Cephalon will purchase from us our two additional VIVITROL manufacturing lines (and related equipment) under construction, which will continue to be operated by us at our manufacturing facility. Through December 31, 2006, we billed Cephalon \$18.7 million for the sale of the two manufacturing lines, and we will bill Cephalon for future costs we incur related to the construction of the two manufacturing lines. Cephalon has granted us an option, exercisable after two years, to repurchase the manufacturing lines at the then net book value of the assets.

## **Table of Contents**

Amounts we received from Cephalon for the purchase of the physical assets associated with the additional VIVITROL manufacturing lines were recorded under the caption *Deferred revenue – long-term portion* in the consolidated balance sheets and will be recognized as revenue over the depreciable life of the assets in amounts equal to the related asset depreciation. Future purchases of physical assets by Cephalon will be accounted for the same way.

During the three months ended December 31, 2006, we received a \$4.6 million payment from Cephalon as reimbursement for certain costs we incurred prior to October 2006 and charged to the collaboration, related to the construction of the additional VIVITROL manufacturing lines, consisting primarily of internal or temporary employee or full-time equivalent ( FTE )-related time. The payment was recorded under the caption *Unearned milestone revenue* in the consolidated balance sheets and will be recognized as milestone revenue – cost recovery under the caption *Net collaborative profit* in accordance with our revenue recognition policy for VIVITROL. We and Cephalon have agreed to increase the cumulative net loss cap from \$120.0 million to \$124.6 million to account for this reimbursement.

Beginning October 2006, all FTE-related costs we incur that are reimbursable by Cephalon related to the construction and validation of the additional VIVITROL manufacturing lines are recorded as research and development revenue as incurred.

### ***Indevus***

In January 2007, we and Indevus Pharmaceuticals, Inc. ( *Indevus* ) announced that we had entered into a joint collaboration for the development of ALKS 27, an inhaled formulation of trospium chloride for the treatment of chronic obstructive pulmonary disease ( *COPD* ). The announcement of this collaboration followed the completion of extensive feasibility work, preclinical studies and a phase 1 study in healthy volunteers. Preliminary results from the phase 1 study showed that ALKS 27 was well tolerated over a wide dose range, with no dose-limiting effects observed.

ALKS 27 is an inhaled formulation of trospium chloride, a muscarinic receptor antagonist that relaxes smooth muscle tissue and has the potential to improve airflow in patients with COPD. Trospium chloride is the active ingredient in SANCTURA®, Indevus' currently marketed product for overactive bladder. The formulation under development for ALKS 27 is specifically designed for inhalation utilizing our proprietary AIR pulmonary delivery system.

We and Indevus plan to initiate a phase 2a clinical study in the first half of 2007 designed to evaluate the clinical efficacy of ALKS 27, administered once-daily, in subjects with COPD. Pending results of the phase 2a study, the companies plan to engage a partner for future development and commercialization of ALKS 27.

Under the joint collaboration, we and Indevus share equally all costs of development and commercial returns on a worldwide basis. We will perform all formulation work and manufacturing. Indevus will conduct the clinical development program.

### ***Rensselaer Polytechnic Institute***

In September 2006, we and Rensselaer Polytechnic Institute ( *RPI* ) entered into a license agreement granting us exclusive rights to a family of opioid receptor compounds discovered at RPI. These compounds represent an opportunity for us to develop important therapeutics for a broad range of diseases and medical conditions, including addiction, pain and other central nervous system ( *CNS* ) disorders. We will screen this library of compounds and plan to pursue preclinical work of an undisclosed, lead oral compound that has already been identified.

Under the terms of the agreement, RPI granted us an exclusive worldwide license to certain patents and patent applications relating to its compounds designed to modulate opioid receptors. We will be responsible for the continued research and development of any resulting product candidates. We paid RPI a nonrefundable upfront payment and will pay certain milestones relating to clinical development activities and royalties on products resulting from the agreement. All amounts paid to RPI under this license agreement have been expensed and are included in research and development expenses.

**Table of Contents**

**Product Developments**

***RISPERDAL CONSTA***

In December 2006 we announced that the Japanese organization of our partner Janssen submitted a new drug application ( NDA ) to the Pharmaceuticals and Medical Devices Agency ( PMDA ) for marketing approval of RISPERDAL CONSTA in Japan.

In October 2006, the results of an observational study conducted among a population of United States veterans were presented at the American Psychiatric Association 's 58(th) Institute of Psychiatric Services. In this study, patients with schizophrenia or schizoaffective disorder taking RISPERDAL CONSTA were observed to have fewer psychiatric-related hospitalizations, and additionally fewer psychiatric-related inpatient days per month, improved antipsychotic medication compliance, and lower total monthly medical costs, as compared to their experience prior to initiating treatment with RISPERDAL CONSTA.

In this study, healthcare claims data were analyzed from 106 eligible patients with schizophrenia or schizoaffective disorder in the Ohio Veterans Affairs ( VA ) Healthcare System. Patients ranged in age from 30-85 years old and were mostly male. Eligible patients must have had at least four doses of RISPERDAL CONSTA during the analysis period. The primary analysis was based on a comparison of the patients ' own psychiatric-related hospitalizations and psychiatric-related healthcare resource utilization pre- and post- initiation of treatment with the therapy. The period of time reviewed for each patient prior to RISPERDAL CONSTA treatment was equal to the available period of follow up after treatment initiation. In this manner, each patient served as his or her own control.

***VIVITROL***

In June 2006, VIVITROL became commercially available in the United States.

***AIR Insulin***

In December 2006, we and Lilly entered into a commercial manufacturing agreement for AIR Insulin. Under the agreement, we are the exclusive commercial manufacturer and supplier of AIR Insulin powder for the AIR Insulin System. The agreement provides for Lilly to fund all operating costs of the portion of our commercial-scale production facility used to manufacture AIR Insulin products, including the cost of AIR Insulin products manufactured at the facility. In addition, Lilly funds the construction, development, validation and scale-up of a second manufacturing line at the facility to meet post-launch requirements for AIR Insulin production. We are responsible for overseeing the construction, process development, validation and scale-up of the second manufacturing line.

In June 2006, we and Lilly reported new study results of the companies ' investigational AIR Insulin System, including the first published analysis of the effect of COPD on inhaled insulin absorption and action; the importance to patients of simple, patient-directed training of an inhaled insulin system; and dosing flexibility with the AIR Insulin System. These study findings were presented at the American Diabetes Association 's 66th Annual Scientific Sessions in Washington, D.C. This Phase 1 study is the first published analysis of the effect of COPD on inhaled insulin absorption and action and was designed to evaluate the impact that compromised lung function has on inhaled insulin dose delivery. As expected in a patient population with compromised lung function, the absorption and action of AIR Insulin was reduced by a consistent amount in the presence of COPD. The results also demonstrated that AIR Insulin was able to deliver similar results on different days in patients with or without COPD and was generally well-tolerated.

In June 2006, we and Lilly announced the completion of patient enrollment in a pivotal safety study required for registration of the AIR Insulin System. The goal of the study was to more fully define the safety and efficacy of the AIR Insulin System in patients with type one diabetes. This study was part of a comprehensive Phase 3 clinical program that began in July 2005, and which includes pivotal efficacy studies and additional long-term safety studies in both type one and type two patients with diabetes.

**Table of Contents**

***Exenatide LAR***

In June 2006, we, Amylin and Lilly announced detailed results from a safety and efficacy study of the long-acting release ( LAR ) formulation of BYETTA (exenatide) injection. Data from the study demonstrated that 86 percent of patients using the higher of two doses of the once-weekly formulation of exenatide were able to achieve recommended levels of glucose control, as measured by hemoglobin A1C ( A1C ), with an average improvement of approximately two percent compared to placebo. These study findings were presented at the Annual Meeting of the European Association for the Study of Diabetes (EASD) in Copenhagen. The study was conducted in 45 patients with type two diabetes unable to achieve adequate glucose control with metformin or a diet and exercise regimen. The patients received a once-weekly subcutaneous injection of exenatide LAR (either 0.8 mg or 2.0 mg) or placebo. After 15 weeks of treatment there was a 12-week safety monitoring period during which no study medication was administered. Dose-dependent improvements in A1C and weight loss were observed at 15 weeks.

***ALKS 29***

ALKS 29 is a new product candidate for the treatment of alcohol dependence. In October 2006, we announced the expansion of our addiction drug franchise to include a program to develop oral products for the treatment of addiction. As part of this initiative, we have commenced enrollment in a clinical trial for an undisclosed oral compound, ALKS 29. The Phase 1/2 multi-center, randomized, double-blind, placebo-controlled clinical study is designed to assess the efficacy and safety of ALKS 29 in alcohol dependent patients. We intend to enroll 150 patients in the eight-week study. Patients will be segmented into several dose groups and will receive daily oral administrations of ALKS 29.

***ALKS 27***

In January 2007, we and Indevus announced that we had entered into a joint collaboration for the development of ALKS 27 for the treatment of COPD. The announcement of this collaboration followed the completion of extensive feasibility work, preclinical studies and a phase 1 study in healthy volunteers. Preliminary results from the phase 1 study showed that ALKS 27 was well tolerated over a wide dose range, with no dose-limiting effects observed.

ALKS 27 is an inhaled formulation of trospium chloride, a muscarinic receptor antagonist that relaxes smooth muscle tissue and has the potential to improve airflow in patients with COPD. Trospium chloride is the active ingredient in SANCTURA®, Indevus' currently marketed product for overactive bladder. The formulation under development for ALKS 27 is specifically designed for inhalation utilizing our proprietary AIR pulmonary delivery system.

We and Indevus plan to initiate a phase 2a clinical study in the first half of 2007 designed to evaluate the clinical efficacy of ALKS 27, administered once-daily, in subjects with COPD. Pending results of the phase 2a study, the companies plan to engage a partner for future development and commercialization of ALKS 27.

***Extended-release naltrexone***

In December 2006, we announced positive results from a Phase 2 exploratory study of injectable extended-release naltrexone in opioid-using adults not physically dependent on opioids, which showed that the two highest doses tested demonstrated opioid blockade for 28 days. The clinical data from this study will be used to support the further development of extended-release naltrexone for the treatment of opioid dependence, a serious chronic brain disease. This pilot study was conducted at the Johns Hopkins University School of Medicine and the National Institute on Drug Abuse ( NIDA ), two leading institutions in the treatment of addiction.

**Critical Accounting Policies**

As fully described in the Management's Discussion and Analysis of Financial Condition and Results of Operations section of our Annual Report on Form 10-K/A for the year ended March 31, 2006, we consider

**Table of Contents**

our critical accounting policies to be as follows. We refer the reader to our Annual Report on Form 10-K/A for more information on these policies.

Revenue recognition;

Cost of goods manufactured;

Research and development expenses;

Restructuring charges;

Warrant valuation;

Accrued expenses;

Derivatives embedded in certain debt securities; and

Income taxes.

We have added the following to our critical accounting policies discussed in our Annual Report on Form 10-K/A for the year ended March 31, 2006.

*Share-based Compensation.* Effective April 1, 2006, we account for share-based compensation in accordance with SFAS No. 123(R). Under SFAS No. 123(R), share-based compensation reflects the fair value of share-based awards measured at the grant date, is recognized as an expense over the employee's requisite service period (generally the vesting period of the equity grant) and is adjusted each period for anticipated forfeitures. We estimate the fair value of stock options on the grant date using the Black-Scholes option-pricing model. Assumptions used to estimate the fair value of stock options are the expected option term, expected volatility of our Company's common stock over the option's expected term, the risk-free interest rate over the option's expected term and our Company's expected annual dividend yield. Certain of these assumptions are highly subjective and require the exercise of management judgment. Our management must also apply judgment in developing an estimate of awards that may be forfeited.

We elected to adopt the provisions of SFAS No. 123(R) using the modified prospective transition method, and we recognize share-based compensation cost on a straight-line basis over the requisite service periods of awards. Under the modified prospective transition method, share-based compensation expense is recognized for the portion of outstanding stock options and stock awards granted prior to the adoption of SFAS No. 123(R) for which service has not been rendered, and for any future grants of stock options and stock awards. We recognize share-based compensation cost for awards that have graded vesting on a straight-line basis over the requisite service period of each separately vesting portion.

*Measurement of Redeemable Convertible Preferred Stock.* Our redeemable convertible preferred stock, \$0.01 par value per share (the Preferred Stock), was carried on the condensed consolidated balance sheets at its estimated redemption value while it was outstanding. We re-evaluated the redemption value of the Preferred Stock on a quarterly basis, and any increases or decreases in the redemption value of this redeemable security, of which there were none, would have been recorded as charges or credits to shareholders' equity in the same manner as dividends on nonredeemable stock, and would have been effected by charges or credits against retained earnings or, in the absence of retained earnings, by charges or credits against additional paid-in capital. Any increases or decreases in the redemption value of the Preferred Stock, of which there were none, would have decreased or increased income applicable to common shareholders in the calculation of earnings per common share and would not have had an



impact on reported net income or cash flows. The Preferred Stock was not a traded security, therefore, market quotations were not available, and the estimate of redemption value was based upon an estimation process used by management. The process of estimating the redemption value of a security with features such as those contained within the Preferred Stock was complex and involved multiple assumptions about matters such as future revenues generated by our partner Lilly for certain products still in development and assumptions about the future market potential for insulin based products, taking into consideration progress on our development programs, the likelihood of product approvals and other factors. Certain of these assumptions were highly subjective and required the exercise of management judgment.

**Table of Contents**

**Results of Operations**

Net income in accordance with accounting principles generally accepted in the United States of America (commonly referred to as GAAP ) for the three months ended December 31, 2006 was \$2.9 million, or \$0.03 per common share basic and diluted, as compared to net income of \$1.4 million, or \$0.02 per common share basic and \$0.01 per common share diluted, for the three months ended December 31, 2005.

Net income in accordance with GAAP for the nine months ended December 31, 2006 was \$5.9 million, or \$0.06 per common share basic and diluted, as compared to a net loss of \$0.6 million, or a net loss of \$0.01 per common share basic and diluted, for the nine months ended December 31, 2005.

Total revenues were \$62.4 million and \$175.1 million for the three and nine months ended December 31, 2006, respectively, as compared to \$41.4 million and \$112.9 million for the three and nine months ended December 31, 2005, respectively.

Total manufacturing revenues were \$28.8 million and \$77.1 million for the three and nine months ended December 31, 2006, respectively, as compared to \$14.7 million and \$42.2 million for the three and nine months ended December 31, 2005, respectively. The increase in manufacturing revenues for the three and nine months ended December 31, 2006, as compared to the same periods in 2005, was due to increased shipments of RISPERDAL CONSTA to Janssen and shipments of VIVITROL to our partner Cephalon.

RISPERDAL CONSTA manufacturing revenue was \$23.6 million and \$63.6 million for the three and nine months ended December 31, 2006, respectively, as compared to \$14.7 million and \$42.2 million for the three and nine months ended December 31, 2005, respectively. The increase in RISPERDAL CONSTA revenues in the three and nine months ended December 31, 2006, as compared to the same periods in 2005, was due to increased shipments of the product to Janssen to satisfy demand. Under our manufacturing and supply agreement with Janssen, we earn manufacturing revenues upon shipment of product by us to Janssen based on a percentage of Janssen's net sales price. This percentage is based on the anticipated volume of units shipped to Janssen in any given calendar year, with a minimum manufacturing fee of 7.5%. We anticipate that we will earn manufacturing revenues at 7.5% of Janssen's net sales price for RISPERDAL CONSTA in the fiscal year ending March 31, 2007 and beyond. We earned manufacturing revenues at an average of 7.5% of Janssen's net sales price in the fiscal year ended March 31, 2006.

VIVITROL manufacturing revenue was \$5.2 million and \$13.5 million for the three and nine months ended December 31, 2006, respectively. We began shipping VIVITROL to our partner Cephalon for the first time during the quarter ended June 30, 2006 and therefore we did not record any manufacturing revenue related to VIVITROL for any periods in fiscal 2006. Under our agreements with Cephalon, we bill Cephalon at cost for finished commercial product shipped to them. VIVITROL manufacturing revenue for the three and nine months ended December 31, 2006 included \$0.5 million and \$1.2 million, respectively, of milestone revenue related to manufacturing profit on VIVITROL. This equates to a 10% profit margin on sales of VIVITROL to Cephalon. We recognized this revenue for the first time during the quarter ended June 30, 2006 as we began shipping VIVITROL to Cephalon.

Total royalty revenues were \$5.7 million and \$16.6 million for the three and nine months ended December 31, 2006, respectively, based on RISPERDAL CONSTA sales of approximately \$226 million and \$664 million, respectively, as compared to \$4.2 million and \$11.9 million for the three and nine months ended December 31, 2005, respectively, based on RISPERDAL CONSTA sales of approximately \$169 million and \$474 million, respectively. The increase in royalty revenues for the three and nine months ended December 31, 2006, as compared to the same periods in 2005, was due to an increase in global sales of RISPERDAL CONSTA by Janssen. Under our license agreements with Janssen, we record royalty revenues equal to 2.5% of Janssen's net sales of RISPERDAL CONSTA in the quarter

when the product is sold by Janssen, based upon net sales reports furnished by Janssen.

Research and development revenue under collaborative arrangements was \$19.5 million and \$51.6 million for the three and nine months ended December 31, 2006, respectively, as compared to \$10.0 million and \$33.9 million for the three and nine months ended December 31, 2005, respectively. The increase in research

**Table of Contents**

and development revenue for the three and nine months ended December 31, 2006, as compared to the same periods in 2005, was primarily due to increases in revenues related to work performed on the AIR Insulin and exenatide LAR programs and revenues related to work performed on the construction and validation of additional VIVITROL manufacturing lines at our Ohio manufacturing facility under the Amendments with Cephalon. Research and development revenue for the three and nine months ended December 31, 2006 included revenue of \$2.1 million for FTE-related costs we incurred that were reimbursable by Cephalon under the Amendments for the construction and validation of the additional VIVITROL manufacturing lines. Research and development revenue for the nine months ended December 31, 2005 included \$9.0 million for a milestone payment we received from Lilly in September 2005 in conjunction with the initiation of the Phase 3 clinical program for AIR Insulin.

Net collaborative profit was \$8.4 million and \$29.8 million for the three and nine months ended December 31, 2006, respectively. For the three and nine months ended December 31, 2006, we recognized \$7.3 million and \$50.8 million of milestone revenue cost recovery, respectively, to offset net losses incurred on VIVITROL by both us and Cephalon. This consisted of \$7.2 million and \$25.7 million of expenses that we incurred on behalf of the collaboration during the three and nine months ended December 31, 2006, respectively, \$0 million and \$24.8 million of net losses incurred by Cephalon on behalf of the collaboration during the three and nine months ended December 31, 2006, respectively, and \$0.1 million and \$0.3 million of expenses that we incurred outside the collaboration during the three and nine months ended December 31, 2006, respectively, for which we were solely responsible. In addition, following FDA approval of VIVITROL, we recognized \$1.2 million and \$3.8 million for the three and nine months ended December 31, 2006, respectively, of milestone revenue related to the licenses provided to Cephalon to commercialize VIVITROL. During the three and nine months ended December 31, 2006, we made payments of \$0 million and \$24.8 million, respectively, to Cephalon to reimburse their net losses on VIVITROL. In the aggregate, net collaborative profit of \$8.4 million and \$29.8 million for the three and nine months ended December 31, 2006, respectively, consisted of approximately \$8.4 million and \$54.6 million of milestone revenue, respectively, partially offset by the \$0 million and \$24.8 million, respectively, of payments we made to Cephalon to reimburse their net losses on VIVITROL.

Net collaborative profit was \$12.5 million and \$24.9 million for the three and nine months ended December 31, 2005, respectively. For the three and nine months ended December 31, 2005, we recognized \$17.9 million and \$31.5 million of milestone revenue cost recovery, respectively, to offset net losses incurred on VIVITROL by both us and Cephalon. This consisted of \$6.1 million and \$12.6 million of expenses that we incurred on behalf of the collaboration during the three and nine months ended December 31, 2005, respectively, \$5.4 million and \$6.6 million of net losses incurred by Cephalon on behalf of the collaboration during the three and nine months ended December 31, 2005, respectively, and \$6.4 million and \$12.3 million of expenses that we incurred with respect to our efforts to obtain FDA approval of VIVITROL during the three and nine months ended December 31, 2005, respectively, for which we were solely responsible. We did not recognize any milestone revenue related to the licenses provided to Cephalon to commercialize VIVITROL during the three and nine months ended December 31, 2005. During the three and nine months ended December 31, 2005, we made payments of \$5.4 million and \$6.6 million to Cephalon, respectively, to reimburse their net losses on VIVITROL. In the aggregate, net collaborative profit of \$12.5 million and \$24.9 million for the three and nine months ended December 31, 2005, respectively, consisted of \$17.9 million and \$31.5 million of milestone revenue, respectively, partially offset by the \$5.4 million and \$6.6 million, respectively, of payments we made to Cephalon to reimburse their net losses on VIVITROL.

**Table of Contents**

Following is a summary of net collaborative profit for the three and nine months ended December 31, 2006 and 2005:

(In thousands)	Three Months Ended December 31,		Nine Months Ended December 31,	
	2006	2005	2006	2005
Milestone revenue cost recovery:				
Alkermes expenses incurred on behalf of the collaboration	\$ 7,199	\$ 6,078	\$ 25,672	\$ 12,634
Cephalon net losses incurred on behalf of the collaboration		5,362	24,816	6,556
Alkermes expenses for which Alkermes was solely responsible	51	6,446	348	12,284
Total milestone revenue cost recovery	7,250	17,886	50,836	31,474
Milestone revenue licenses	1,195		3,778	
Total milestone revenue cost recovery and licenses	8,445	17,886	54,614	31,474
Payments made to Cephalon to reimburse their net losses		(5,362)	(24,816)	(6,556)
Net collaborative profit	\$ 8,445	\$ 12,524	\$ 29,798	\$ 24,918

In April 2006, we received a nonrefundable milestone payment of \$110.0 million from Cephalon following approval of VIVITROL by the FDA. The payment was deemed to be arrangement consideration in accordance with Emerging Issues Task Force 00-21, *Revenue Arrangements with Multiple Deliverables* ( EITF 00-21 ). The payment was recorded in our unaudited condensed consolidated balance sheets under the caption Unearned milestone revenue long-term portion. The classification between the current and long-term portions of unearned milestone revenue was based on our estimate of whether the related milestone revenue was expected to be recognized during or beyond the 12-month period following December 31, 2006, respectively.

We are responsible for the first \$124.6 million of cumulative net losses incurred on VIVITROL through December 31, 2007. Through December 31, 2006, the cumulative net losses incurred by us and Cephalon on VIVITROL, against this cumulative net loss cap, were \$91.5 million, of which \$45.5 million was incurred by us on behalf of the collaboration and \$46.0 million was incurred by Cephalon on behalf of the collaboration.

Pursuant to the Amendments discussed under Collaborative Arrangements *Cephalon* above, Cephalon was responsible for its own VIVITROL-related costs during the period August 1, 2006 through December 31, 2006, and for this period no such costs were charged by Cephalon to the collaboration and against the cumulative net loss cap. Accordingly, we did not reimburse Cephalon for any of their VIVITROL-related costs during this period.

Our estimates of the fair value of deliverables under our agreements with Cephalon are reviewed periodically and adjusted, as appropriate. Our methodologies for estimating the fair values are discussed under our Critical Accounting Policies in the Management's Discussion and Analysis of Financial Condition and Results of Operations section of our Annual Report on Form 10-K/A for the year ended March 31, 2006. We have adjusted the estimate of the deliverable shared profits and losses on the products from the previous estimate of \$144.0 million to \$144.4 million. This adjustment reflect the latest estimate of future product net losses. The estimate of the deliverable manufacturing of the products is \$77.8 million. We have adjusted the estimate of the deliverable development and licenses for the products

from the previous estimate of \$48.0 million to \$52.4 million. The estimate of this deliverable is based on the residual method of deriving fair value under the aforementioned accounting policies.

**Table of Contents**

Cost of goods manufactured was \$13.0 million and \$34.1 million for the three and nine months ended December 31, 2006, respectively, as compared to \$6.1 million and \$15.0 million for the three and nine months ended December 31, 2005, respectively. The increase in cost of goods manufactured for the three and nine months ended December 31, 2006, as compared to the same periods in 2005, was due to increased shipments of RISPERDAL CONSTA to Janssen, shipments of VIVITROL to Cephalon and to share-based compensation expense resulting from the adoption of SFAS No. 123(R) beginning April 1, 2006. Cost of goods manufactured for the three and nine months ended December 31, 2006 included share-based compensation expense in the amount of \$0.9 million and \$2.1 million, respectively.

Cost of goods manufactured for RISPERDAL CONSTA was \$8.2 million and \$21.8 million for the three and nine months ended December 31, 2006, respectively, as compared to \$6.1 million and \$15.0 million for the three and nine months ended December 31, 2005, respectively. The increase in cost of goods manufactured for RISPERDAL CONSTA during the three and nine months ended December 31, 2006, as compared to the same periods in 2005, was due to increased shipments of the product to satisfy demand.

Cost of goods manufactured for VIVITROL was \$4.8 million and \$12.3 million for the three and nine months ended December 31, 2006, respectively. We began shipping VIVITROL to our partner Cephalon for the first time during the quarter ended June 30, 2006 and therefore we did not record any manufacturing revenue related to VIVITROL for any periods in fiscal 2006. Cost of goods manufactured for the three and nine months ended December 31, 2006 included \$1.5 million of unabsorbed manufacturing costs related to VIVITROL. These costs consisted of current period manufacturing costs allocated to cost of goods manufactured which were related to underutilized VIVITROL manufacturing capacity.

Research and development expenses were \$29.9 million and \$85.6 million for the three and nine months ended December 31, 2006, respectively, as compared to \$22.5 million and \$63.5 million for the three and nine months ended December 31, 2005, respectively. The increase for the three and nine months ended December 31, 2006, as compared to the same periods in 2005, was primarily due to increased personnel-related costs, raw materials used during work performed on our product candidates, increased cost for third party packaging of clinical drug product and to share-based compensation expense in the amount of \$1.9 million and \$7.0 million, respectively, resulting from the adoption of SFAS No. 123(R) beginning April 1, 2006.

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 drug delivery technologies in general. Expenses incurred to purchase specific services from third parties to support our collaborative research and development activities are tracked by project and are reimbursed to us by our partners. We generally bill our partners under collaborative arrangements using a single full-time equivalent or hourly rate. This rate has been established by us based on our annual budget of employee compensation, employee benefits and the billable non-project-specific costs mentioned above and is generally increased annually based on increases in the consumer price index. Each collaborative partner is billed using a full-time equivalent or hourly rate for the hours worked by our employees on a particular project, plus any direct external research costs, if any. We account for our research and development expenses on a departmental and functional basis in accordance with our budget and management practices.

Selling, general and administrative expenses were \$16.4 million and \$48.6 million for the three and nine months ended December 31, 2006, respectively, as compared to \$9.3 million and \$27.4 million for the three and nine months ended December 31, 2005, respectively. The increase for the three and nine months ended December 31, 2006, as compared to the same period in 2005, was primarily due to share-based compensation expense in the amount of \$4.7 million and \$13.1 million, respectively, resulting from the adoption of SFAS No. 123(R) beginning April 1,

2006, and to increases in selling and marketing costs related to VIVITROL.

Interest income was \$4.3 million and \$13.3 million for the three and nine months ended December 31, 2006, respectively, as compared to \$3.3 million and \$7.9 million for the three and nine months ended December 31, 2005, respectively. The increase for the three and nine months ended December 31, 2006, as compared to the same periods in 2005, was primarily due to higher interest rates earned during the periods



## **Table of Contents**

and higher average cash and investment balances held due to the non-refundable payments we received from Cephalon in the amounts of \$160.0 million and \$110.0 million in June 2005 and April 2006, respectively.

Interest expense was \$4.1 million and \$13.6 million for the three and nine months ended December 31, 2006, respectively, as compared to \$5.2 million and \$15.5 million for the three and nine months ended December 31, 2005, respectively. The decrease for the three and nine months ended December 31, 2006, as compared to the same periods in 2005, was primarily due to the conversion of our 2.5% convertible subordinated notes due 2023 (the 2.5% Subordinated Notes ) in June 2006. Interest expense for the nine months ended December 31, 2006 includes a one-time interest charge of \$0.6 million for a payment we made in June 2006 in connection with the conversion of our 2.5% Subordinated Notes to satisfy the three-year interest make-whole provision in the note indenture. We incur approximately \$4.0 million of interest expense each quarter on the non-recourse RISPERDAL CONSTA secured 7% notes (the Non-Recourse 7% Notes ) through the period until principal repayment starts on April 1, 2009.

Derivative loss related to convertible subordinated notes for the three and nine months ended December 31, 2006 was \$0, as compared to a loss of \$0.3 million and \$1.1 million for the three and nine months ended December 31, 2005, respectively. As discussed in our Annual Report on Form 10-K/A for the year ended March 31, 2006, we are no longer required to account for the make-whole provision included in our 2.5% Subordinated Notes as a separate financial instrument. In addition, in June 2006 the 2.5% Subordinated Notes were converted to common stock and the related make-whole features were settled. Derivative loss represented changes in the fair value of the three-year interest make-whole provision included in our 2.5% Subordinated Notes prior to their conversion.

Other income (expense), net was net income of \$0.1 million and \$0.2 million for the three and nine months ended December 31, 2006, respectively, as compared to net income of \$0.1 million and \$1.0 million for the three and nine months ended December 31, 2005, respectively. Other income (expense), net primarily consists of income or expense recognized on changes in the fair value of warrants of public companies held by us in connection with collaboration and licensing arrangements, which were recorded under the caption Other assets on the unaudited condensed consolidated balance sheets. The recorded value of such warrants can fluctuate significantly based on fluctuations in the market value of the underlying securities of the issuer of the warrants.

Income taxes were \$0.4 million and \$0.8 million for the three and nine months ended December 31, 2006, respectively. We did not record a provision for income taxes for the three and nine months ended December 31, 2005. The provision for income taxes for the three and nine months ended December 31, 2006 related to the U.S. alternative minimum tax. Utilization of tax loss carryforwards is limited in the calculation of AMT. As a result, a federal tax charge is reflected for fiscal 2007. The current AMT liability is available as a credit against future tax obligations upon the full utilization or expiration of our net operating loss carryforward.

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

## **Financial Condition**

Cash and cash equivalents were \$83.2 million and \$33.6 million as of December 31, 2006 and March 31, 2006, respectively. Investments short-term were \$267.9 million and \$264.4 million as of December 31, 2006 and March 31, 2006, respectively. During the nine months ended December 31, 2006, combined cash and cash equivalents and short-term investments increased by \$53.1 million to \$351.1 million, primarily due to the receipt of a \$110.0 million non-refundable milestone payment from Cephalon on April 27, 2006 following FDA approval of VIVITROL, partially offset by cash used to fund our operations, to acquire fixed assets, to service our debt and to purchase our common stock under our stock repurchase program.

We invest in cash equivalents, U.S. government obligations, high-grade corporate notes and commercial paper, with the exception of our \$100.0 million investment in Reliant, and warrants we received in connection with our collaborations and licensing activities. Our investment objectives, other than our investment in Reliant and our warrants, are, first, to assure liquidity and conservation of capital and, second, to obtain investment income. We held approximately \$5.1 million of U.S. government obligations classified as restricted long-term

**Table of Contents**

investments as of December 31, 2006 and March 31 2006, which are pledged as collateral under certain letters of credit and lease agreements.

All of our investments in debt securities were classified as available-for-sale and were recorded at fair value. Fair value was determined based on quoted market prices.

Receivables were \$62.4 million and \$39.8 million as of December 31, 2006, and March 31, 2006, respectively. The increase of \$22.6 million during the nine month period was primarily due to increased development revenues related to the AIR Insulin, AIR PTH and exenatide LAR programs and to the timing of payments received from our partners with respect to these programs, amounts due from Lilly for the reimbursement of costs we previously incurred for the construction of the second manufacturing line at our commercial-scale production facility for inhaled medications, and amounts due from Cephalon for VIVITROL product deliveries and reimbursement for costs we incurred on the construction of the two VIVITROL manufacturing lines.

Inventory, net was \$13.9 million and \$7.3 million as of December 31, 2006, and March 31, 2006, respectively. This consisted of RISPERDAL CONSTA inventory of \$7.1 million and \$4.8 million as of December 31, 2006 and March 31, 2006, respectively, and VIVITROL inventory of \$6.8 million and \$2.5 million as of December 31, 2006 and March 31, 2006, respectively. The increase in inventory, net of \$6.6 million during the nine months ended December 31, 2006, was primarily due to increases in VIVITROL raw materials and work in process inventories, increases in RISPERDAL CONSTA finished goods inventory related to the timing of shipments to Janssen, and to the capitalization of share-based compensation cost to inventory in the amount of \$0.4 million resulting from the adoption of SFAS No. 123(R).

Convertible subordinated notes long-term portion was \$0 and \$124.3 million as of December 31, 2006 and March 31, 2006, respectively. In June 2006, we converted all of our outstanding 2.5% Subordinated Notes into 9,025,271 shares of the Company's common stock.

Unearned milestone revenue current and long-term portions, combined, were \$158.3 million and \$99.5 million as of December 31, 2006 and March 31, 2006, respectively. The increase during the nine months ended December 31, 2006 was due to the receipt of a \$110.0 million non-refundable milestone payment from Cephalon in April 2006 following FDA approval of VIVITROL and the receipt of \$4.6 million from Cephalon, pursuant to the Amendments, as reimbursement for certain costs that we incurred prior to October 2006 and charged to the collaboration, reduced by approximately \$54.6 million and \$1.2 million of milestone revenue we recognized under the captions Net collaborative profit and Manufacturing revenues, respectively, in the unaudited condensed consolidated statement of operations during the nine month period ended December 31, 2006.

Deferred revenue current and long-term portions, combined, were \$19.5 million and \$1.0 million as of December 31, 2006, and March 31, 2006, respectively. In the three months ended December 31, 2006 we recorded \$18.7 million of deferred revenue long-term portion related to the purchase by Cephalon of the two VIVITROL manufacturing lines currently under construction.

Redeemable convertible preferred stock was \$0 and \$15.0 million as of December 31, 2006 and March 31, 2006, respectively. In December 2006, Lilly exercised its right to put the remaining 1,500 shares of our outstanding Preferred Stock, with a carrying value of \$15.0 million, in exchange for a reduction in the royalty rate payable to us on future sales of the AIR Insulin product by Lilly, if approved. At that time, the remaining Preferred Stock was reclassified to shareholders' equity in the condensed consolidated balance sheets under the caption Additional paid-in capital at its redemption value of \$15.0 million. See Note 8 to the unaudited condensed consolidated financial statements for additional information on our Preferred Stock.

Treasury stock, at cost was \$12.5 million and \$0 as of December 31, 2006, and March 31, 2006, respectively. In September 2005, our Company's Board of Directors authorized a share repurchase program up to \$15.0 million of common stock to be repurchased in the open market or through privately negotiated transactions. The repurchase program has no set expiration date and may be suspended or discontinued at any time. During the nine months ended December 31, 2006 and since September 2005, we had repurchased 823,677 shares at a cost of approximately \$12.5 million under the program.

**Table of Contents**

**Liquidity and Capital Resources**

We have funded our operations primarily through public offerings and private placements of debt and equity securities, bank loans, term loans, equipment financing arrangements and payments received under research and development agreements and other agreements with collaborators. We expect to incur significant additional research and development and other costs in connection with collaborative arrangements and as we expand the development of our proprietary product candidates, including costs related to preclinical studies, clinical trials and facilities expansion. Our costs, including research and development costs for our product candidates and sales, marketing and promotion expenses for any future products to be marketed by us or our collaborators, if any, may exceed revenues in the future, which may result in losses from operations.

We believe that our current cash and cash equivalents and short-term investments, combined with our unused equipment lease line, anticipated interest income and anticipated revenues will generate sufficient cash flows to meet our anticipated liquidity and capital requirements through at least December 31, 2007.

We may continue to pursue opportunities to obtain additional financing in the future. Such financing may be sought through various sources, including debt and equity offerings, corporate collaborations, bank borrowings, arrangements relating to assets or other financing methods or structures. The source, timing and availability of any financings will depend on market conditions, interest rates and other factors. Our future capital requirements will also depend on many factors, including continued scientific progress in our research and development programs (including our proprietary product candidates), the magnitude of these programs, progress with preclinical testing and clinical trials, the time and costs involved in obtaining regulatory approvals, the costs involved in filing, prosecuting and enforcing patent claims, competing technological and market developments, the establishment of additional collaborative arrangements, the cost of manufacturing facilities and of commercialization activities and arrangements and the cost of product in-licensing and any possible acquisitions and, for any future proprietary products, the sales, marketing and promotion expenses associated with marketing such products.

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

Capital expenditures were \$24.7 million for the nine months ended December 31, 2006. Our capital expenditures were primarily related to the purchase of equipment to make improvements to and expand our manufacturing facility in Ohio. Our capital expenditures for equipment, facilities and building improvements have been financed to date primarily with proceeds from bank loans and the sales of debt and equity securities. Under the provisions of our existing loans, General Electric Capital Corporation ( GE ) and Johnson & Johnson Finance Corporation have security interests in certain of our capital assets. Under our commercial manufacturing agreement with Lilly for AIR Insulin, in the quarter ended March 31, 2007, we expect to receive \$11.5 million from Lilly as payment for the purchase of certain assets related to the construction of a second manufacturing line at our commercial-scale production facility for inhaled medications.

Our 3.75% convertible subordinated notes due 2007 (the 3.75% Subordinated Notes ) mature on February 15, 2007. We expect to repay the \$0.7 million principal amount of the 3.75% Subordinated Notes on the maturity date. See Note 7 to the Consolidated Financial Statements in our Annual Report on Form 10-K/A for the fiscal year ended March 31, 2006 for information on the 3.75% Subordinated Notes.

Pursuant to the Amendments discussed under Collaborative Arrangements *Cephalon* above, Cephalon was responsible for its own VIVITROL-related costs during the period August 1, 2006 through December 31, 2006, and for this period no such costs were charged by Cephalon to the collaboration and against the cumulative net loss cap. Accordingly, we did not reimburse Cephalon for any of its VIVITROL-related costs during this period. Also under the Amendments, the parties agreed that Cephalon would purchase from us our

## **Table of Contents**

two VIVITROL manufacturing lines under construction (and related equipment). Through December 31, 2006, we had billed Cephalon \$18.7 million for the sale of the two manufacturing lines. We will bill Cephalon for future costs incurred related to the construction and validation of the two manufacturing lines.

In December 2002, we and Lilly expanded our collaboration for the development of inhaled formulations of insulin and hGH based on our AIR pulmonary drug delivery technology. In connection with the expansion, Lilly purchased \$30.0 million of our Preferred Stock. In October 2005, we converted 1,500 shares of the Preferred Stock with a carrying value of \$15.0 million into 823,677 shares of our Company's common stock. This conversion secured a proportionate increase in the royalty rate payable to us on future sales of the AIR Insulin product by Lilly, if approved. In December 2006, Lilly exercised its right to put the remaining 1,500 shares of our outstanding Preferred Stock, with a carrying value of \$15.0 million, in exchange for a reduction in the royalty rate payable to us on future sales of the AIR Insulin product by Lilly, if approved. See Note 2 Collaborative Arrangements *Lilly* to the unaudited condensed consolidated financial statements for information on royalties payable to us on sales of the AIR Insulin product by Lilly.

The Preferred Stock was carried on the condensed consolidated balance sheets at its estimated redemption value in the amount of \$0 million and \$15.0 million as of December 31, 2006 and March 31, 2006, respectively. Following Lilly's exercise of its put right, the Preferred Stock was reclassified to shareholders' equity in the condensed consolidated balance sheets under the caption Additional paid-in capital at its redemption value of \$15.0 million.

While the Preferred Stock was outstanding, we re-evaluated its redemption value on a quarterly basis. Any increases or decreases in the redemption value of the Preferred Stock, of which there were none, would have been recorded as charges or credits to shareholders' equity in the same manner as dividends on nonredeemable stock, and would have been effected by charges or credits against retained earnings or, in the absence of retained earnings, by charges or credits against additional paid-in capital. Any increases or decreases in the redemption value of the Preferred Stock, of which there were none, would have decreased or increased income applicable to common shareholders in the calculation of earnings per common share and would not have had an impact on reported net income or cash flows.

## **Contractual Obligations**

The contractual cash obligations disclosed in our Annual Report on Form 10-K/A for the year ended March 31, 2006 have not changed materially except for the elimination of our obligations related to the 2.5% Subordinated Notes, which we converted into common stock on June 15, 2006 (see Note 6 to the unaudited condensed consolidated financial statements).

## **Off-Balance Sheet Arrangements**

As of December 31, 2006, we were not a party to any off-balance sheet financing arrangements, other than operating leases.

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

We hold financial instruments in our investment portfolio that are sensitive to market risks. Our investment portfolio, excluding our investment in Reliant, and warrants we receive in connection with our collaborations and licensing activities, is used to preserve capital until it is required to fund operations. Our short-term and restricted long-term investments consist of U.S. government obligations, high-grade corporate notes and commercial paper. These debt securities are: (i) classified as available-for-sale; (ii) are recorded at fair value; and (iii) are subject to interest rate risk, and could decline in value if interest rates increase. Due to the conservative nature of our short-term and long-term investments and our investment policy, we do not believe that we have a material exposure to interest rate risk.

Although our investments, excluding our investment in Reliant, are subject to credit risk, our investment policies specify credit quality standards for our investments and limit the amount of credit exposure from any single issue, issuer or type of investment.



## **Table of Contents**

We also hold certain marketable equity securities, including warrants to purchase the securities of publicly traded companies we collaborate with, that are classified as available-for-sale and recorded at fair value under the caption

Other assets in the condensed consolidated balance sheets. These marketable equity securities are sensitive to changes in interest rates. Interest rate changes would result in a change in the fair value of these financial instruments due to the difference between the market interest rate and the rate at the date of purchase of the financial instrument. A 10% increase or decrease in market interest rates would not have a material impact on the condensed consolidated financial statements.

The process of estimating the fair value of a security with features such as those contained within our Preferred Stock is complex and involves multiple assumptions regarding factors such as future revenues generated by our partner for certain products still in development, judgments which may be made by the parties to the security, and assumptions about the future market potential for insulin based products. Certain of these assumptions are highly subjective and require the exercise of management judgment.

As of December 31, 2006, the fair value of our Non-Recourse 7% Notes and our 3.75% convertible subordinated notes (the 3.75% Subordinated Notes ) approximate the carrying values. The interest rates on these notes, and our capital lease obligations, are fixed and therefore not subject to interest rate risk. A 10% increase or decrease in market interest rates would not have a material impact on the condensed consolidated financial statements.

As of December 31, 2006, we have a term loan in the amount of \$1.7 million that bears a floating interest rate equal to the one-month London Interbank Offered Rate ( LIBOR ) plus 5.45%. A 10% increase or decrease in market interest rates would not have a material impact on the condensed consolidated financial statements.

### **Foreign Currency Exchange Rate Risk**

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

The impact on our royalty revenues from foreign currency exchange rate risk is based on a number of factors, including the exchange rate (and the change in the exchange rate from the prior period) between a foreign currency and the U.S. dollar, and the amount of sales by our collaborative partner that are denominated in foreign currencies. We do not currently hedge our foreign currency exchange rate risk.

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

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

As of December 31, 2006, our management, with the participation of our Chief Executive Officer and Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures pursuant to Rule 13a-15(b) promulgated under the Securities Exchange Act of 1934, as amended (the Exchange Act ). In designing and evaluating our disclosure controls and procedures, our management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives, and our management

necessarily applied its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Due to the identification of a material weakness in internal control over financial reporting related to the Company's accounting for stock-based compensation that resulted in the restatement of previously issued financial statements, as described in our Annual Report on Form 10-K/A for the fiscal year ended March 31, 2006, our Chief Executive Officer and Chief Financial Officer concluded that, as of December 31, 2006, our disclosure controls and procedures were not effective in

**Table of Contents**

ensuring that material information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission's rules and forms, including ensuring that such material 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.

The Public Company Accounting Oversight Board's Auditing Standard No. 2 defines a material weakness as a significant deficiency, or a combination of significant deficiencies, that results in there being a more than remote likelihood that a material misstatement of the annual or interim financial statements will not be prevented or detected. Management previously identified a material weakness in internal control over financial reporting related to the accounting for stock-based compensation, as reported in Item 9A of our Form 10-K/A for the fiscal year ended March 31, 2006. Specifically, we did not design and implement controls necessary to provide reasonable assurance that the measurement date for stock option grants was appropriately determined. As a result, the measurement date used for certain option grants was not appropriate resulting in those grants not being accounted for in accordance with GAAP. This material weakness resulted in the restatement of previously issued financial statements as described in our Annual Report on Form 10-K/A for the fiscal year ended March 31, 2006. This deficiency was determined to be a material weakness due to the actual misstatements identified, the potential for additional material misstatements to have occurred as a result of the deficiency and the lack of other mitigating controls.

To address the material weakness described above, we implemented the following new stock option granting controls and procedures during the quarter ended September 30, 2006 related to the granting of new hire and annual stock option grants, restricted stock awards and annual director stock option grants. We are continuing our efforts to improve and strengthen our internal controls over financial reporting to ensure that all of our internal controls over financial reporting are adequate and effective.

Stock option grants and restricted stock awards are now made on preset dates. New hire grants are made monthly on the first Wednesday following the first Monday of every month. Annual stock option grants are made on preset dates in November and May to correspond to our Board of Directors meetings; provided, that the date of measurement for the May grants will not be less than 48 hours after the release of earnings for our fiscal year, and the date of measurement for the November grants will not be less than 48 hours after the announcement of the Company's second quarter fiscal year results. A final list of proposed stock option grants and restricted stock awards will be delivered to the Compensation Committee prior to the Committee meeting. At the Compensation Committee meeting, whether in person or by telephone, the Committee will approve the final stock option grants and/or restricted stock awards. While the Board disfavors the use of written consents in the grant of stock options and restricted stock awards other than for new hire grants made by the Limited Compensation Sub-Committee, the Compensation Committee may, when it deems appropriate, take such action by written consent. Except for new hire grants, all written consents granting stock options or restricted stock awards will be effective upon the date of the last signature; all signatures on written consents shall be dated. New hire grants shall be effective on the later of the first Wednesday following the first Monday of every month or the date of the last signature on the written consent. The human resource representative attending the Compensation Committee meeting shall mark as final contemporaneously with its approval by the Compensation Committee the list of stock option grants and restricted stock awards and will promptly send such list to the legal and finance departments for recordkeeping. Finance promptly distributes stock option grant or restricted stock award certificates to grant recipients notifying them of the grant.

***(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, other than those described above relating to our accounting for stock-based compensation.



**Table of Contents**

**PART II. OTHER INFORMATION**

**Item 1. *Legal Proceedings***

On August 16, 2006, a purported shareholder derivative lawsuit, captioned Maxine Phillips vs. Richard Pops et al. and docketed as CIV-06-2931, was filed ostensibly on our behalf in Middlesex County Superior Court, Massachusetts. The complaint in that lawsuit alleged, among other things, that, in connection with certain stock option grants made by us, certain of our directors and officers committed violations of state law, including breaches of fiduciary duty. The complaint named us as a nominal defendant, but did not seek monetary relief from us. The lawsuit sought recovery of damages allegedly caused to us as well as certain other relief. On September 13, 2006, the plaintiff voluntarily dismissed this action without prejudice.

On October 10, 2006, a purported shareholder derivative lawsuit, captioned Thomas Bennett, III vs. Richard Pops et al. and docketed as CIV-06-3606, was filed ostensibly on our behalf in Middlesex County Superior Court, Massachusetts. The complaint in that lawsuit alleges, among other things, that, in connection with certain stock option grants made by us, certain of our directors and officers committed violations of state law, including breaches of fiduciary duty. The complaint names us as a nominal defendant, but does not seek monetary relief from us. The lawsuit seeks recovery of damages allegedly caused to us as well as certain other relief, including an order requiring us to take action to enhance our corporate governance and internal procedures. On January 31, 2007, the defendants served the plaintiff with a motion to dismiss the complaint.

We have received four letters, allegedly sent on behalf of owners of our securities, which claim, among other things, that certain of our officers and directors breached their fiduciary duties to us by, among other allegations, allegedly violating the terms of our stock option plans, allegedly violating generally accepted accounting principles in the United States of America by failing to recognize compensation expenses with respect to certain option grants during certain years, and allegedly publishing materially inaccurate financial statements relating to us. The letters demand, among other things, that our board of directors ( the Board ) take action on our behalf to recover from the current and former officers and directors identified in the letters the damages allegedly sustained by us as a result of their alleged conduct, among other amounts. The letters do not seek any monetary recovery from us. Our Board appointed a special independent committee of the Board to investigate, assess and evaluate the allegations contained in these and any other demand letters relating to our stock option granting practices and to report its findings, conclusions and recommendations to the Board. The special independent committee was assisted by independent outside legal counsel. In November 2006, based on the results of its investigation, the special independent committee of the Board concluded that the assertions contained in the demand letters lacked merit, that nothing had come to its attention that would cause it to believe that there are any instances where management of the Company or the Compensation Committee of the Company had retroactively selected a date for the grant of stock options during the 1995 through 2006 period, and that it would not be in our best interests or the best interests of our shareholders to commence litigation against our current or former officers or directors as demanded in the letters. The findings and conclusions of the special independent committee of the Board have been presented to and adopted by our Board.

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

The following Risk Factor should be read in conjunction with the Risk Factors disclosed in our Annual Report on Form 10-K/A for the year ended March 31, 2006.

*We face risks related to an ongoing informal SEC inquiry into, and private litigation relating to, our past practices with respect to equity incentives.*

In May 2006, we were mentioned in a third-party report suggesting that we were at moderate risk for options backdating (the Report ) with respect to our annual grants of options to all employees of the Company dated October 28, 1999 and November 20, 2000. Shortly after the Report appeared, we were contacted by the Securities and Exchange Commission ( SEC ) with respect to our option practices for the years mentioned in the Report. We have cooperated fully with the SEC 's informal inquiry. As a result of the

**Table of Contents**

appearance of the Report, and concurrent with the SEC's informal inquiry, the audit committee of the Board of Directors undertook an investigation into our option practices for the period 1999 to 2000 as well as for 2001 and 2002. The review was conducted with the assistance of outside legal counsel and outside accounting consultants. The audit committee has completed its investigation and has concluded that nothing has come to its attention that would cause it to believe that there were any instances where management of the Company or the compensation committee of the Company retroactively selected a date for the grant of stock options during the 1999 through 2002 period. Also, management reviewed its option grant practices for the period from 2003 to date. As a result of these reviews, we have restated our consolidated balance sheets as of March 31, 2006 and 2005, our consolidated statements of operations for the years ended March 31, 2005 and 2004, our consolidated statements of cash flows for the years ended March 31, 2005 and 2004, our consolidated statements of changes in stockholders equity for the years ended March 31, 2006, 2005 and 2004, and the related disclosures.

On October 10, 2006, a purported shareholder derivative lawsuit, captioned Thomas Bennett, III vs. Richard Pops et al. and docketed as CIV-06-3606, was filed ostensibly on our behalf in Middlesex County Superior Court, Massachusetts. The complaint in that lawsuit alleges, among other things, that, in connection with certain stock option grants made by us, certain of our directors and officers committed violations of state law, including breaches of fiduciary duty. The complaint names us as a nominal defendant, but does not seek monetary relief. The lawsuit seeks recovery of damages allegedly caused to us as well as certain other relief, including an order requiring us to take action to enhance our corporate governance and internal procedures.

We have received four letters, allegedly sent on behalf of owners of our securities, which claim, among other things, that certain of our officers and directors breached their fiduciary duties to us by, among other allegations, allegedly violating the terms of our stock option plans, allegedly violating generally accepted accounting principles by failing to recognize compensation expenses with respect to certain option grants during certain years, and allegedly publishing materially inaccurate financial statements relating to us. The letters demand, among other things, that our board of directors take action on our behalf to recover from the current and former officers and directors identified in the letters the damages allegedly sustained by us as a result of their alleged conduct, among other amounts. The letters do not seek any monetary recovery from us. Our board of directors appointed a special independent committee of the Board to investigate, assess and evaluate the allegations contained in these and any other demand letters relating to our stock option granting practices and to report its findings, conclusions and recommendations to the Board. See Part II, Item 1 (*Legal Proceedings*) in this Form 10-Q for additional information related to the investigation conducted by the special independent committee of our Board.

At this point we are unable to predict what, if any, consequences these issues relating to our option grants may have on us. The filing of our restated financial statements to correct the discovered accounting errors may not resolve the informal SEC inquiry into our grants of employee stock options, and the SEC may or may not agree with the adjustments we have made to our financial statements. There could be considerable legal and other expenses associated with the SEC inquiry and any private litigation, including that described above, that might be filed relating to these issues.

The above matters and any other similar matters could divert management's attention from other business concerns. Such matters could also result in harm to our reputation and significant monetary liability for the Company, and require that we take other actions not presently contemplated, any or all of which could have a material adverse effect on our business, results of operations, or financial condition.

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

A summary of our stock repurchase activity for the nine months ended December 31, 2006 is set forth in the table below:

Period	Total Number of Shares  Purchased(a)	Average Price Paid  per Share  (in thousands, except share and per share amounts)	Total Number of Shares	Approximate Dollar Value of Shares
			Purchased as Part of a Publicly Announced Program(a)	That May Yet be Purchased Under the Program
April 1 through June 30	134,630	\$ 19.52	134,630	\$ 12,373
July 1 through September 30	689,047	14.32	689,047	2,508
October 1 through October 31				2,508
November 1 through November 30				2,508
December 1 through December 31				2,508
Total as of December 31, 2006	823,677	\$ 15.17	823,677	

(a) In September 2005, our Board of Directors authorized a share repurchase program of up to \$15.0 million of common stock to be repurchased in the open market or through privately negotiated transactions. The repurchase program has no set expiration date and may be suspended or discontinued at any time. We publicly announced the share repurchase program in our press release for the fiscal 2006 second quarter financial results dated November 3, 2005.

In addition to the stock repurchases above, we purchased, by means of employee forfeitures, 31,307 shares during the nine months ended December 31, 2006 at an average price of \$18.11 to pay withholding taxes on employee stock awards.

**Item 6. Exhibits**

(a) List of Exhibits:

**Exhibit Index****Exhibit  
No.**

10.1 1998 Equity Incentive Plan.



- 10.2 1999 Stock Option Plan.
- 10.3 2002 Restricted Stock Award Plan.
- 31.1 Rule 13a-14(a)/15d-14(a) Certification (furnished herewith).
- 31.2 Rule 13a-14(a)/15d-14(a) Certification (furnished herewith).
- 32.1 Certification pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (furnished herewith).

**Table of Contents**

**SIGNATURES**

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

ALKERMES, INC.  
(Registrant)

By: /s/ Richard F. Pops

Richard F. Pops  
Chief Executive Officer and Director  
(Principal Executive Officer)

By: /s/ James M. Frates

James M. Frates  
Vice President, Chief Financial Officer and Treasurer  
(Principal Financial and Accounting Officer)

Date: February 8, 2007

**Table of Contents**

**EXHIBIT INDEX**

**Exhibit  
No.**

- 10.1 1998 Equity Incentive Plan.
- 10.2 1999 Stock Option Plan.
- 10.3 2002 Restricted Stock Award Plan.
- 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).