

ALKERMES INC  
Form 10-K  
May 30, 2008

**Table of Contents**

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

- ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934  
For the fiscal year ended March 31, 2008**
- OR**
- 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)*

**(617) 494-0171**

**(Registrant's telephone number, including area code)**

**Securities registered pursuant to Section 12(g) of the Act:**

Common Stock, par value \$.01 per share  
Series A Junior Participating Preferred Stock Purchase  
Rights

The NASDAQ Stock Market LLC

**Title of each class**

**Name of exchange on which registered**

**Securities registered pursuant to Section 12(b) of the Act:**

**None**

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes  No

## Edgar Filing: ALKERMES INC - Form 10-K

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Exchange Act. Yes  No

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 if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K.

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

Large accelerated filer  Accelerated filer  Non-accelerated filer  Smaller reporting Company   
(Do not check if a smaller reporting company)

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

As of September 28, 2007 (the last business day of the second fiscal quarter) the aggregate market value of the 100,688,198 outstanding shares of voting and non-voting common equity held by non-affiliates of the registrant was \$1,852,662,843. Such aggregate value was computed by reference to the closing price of the common stock reported on the NASDAQ Stock Market on September 28, 2007.

As of May 28, 2008, 95,168,528 shares of the Registrant's common stock were issued and outstanding and 382,632 shares of the Registrant's non-voting common stock were issued and outstanding.

### **DOCUMENTS INCORPORATED BY REFERENCE**

Portions of the Definitive Proxy Statement to be filed within 120 days after March 31, 2008 for the Registrant's Annual Shareholders Meeting are incorporated by reference into Part III of this Report on Form 10-K.

---

**ALKERMES, INC. AND SUBSIDIARIES**

**ANNUAL REPORT ON FORM 10-K  
FOR THE FISCAL YEAR ENDED MARCH 31, 2008**

**INDEX**

<b><u>PART I</u></b>		3
<u>Item 1.</u>	<u>Business</u>	3
<u>Item 1A.</u>	<u>Risk Factors</u>	16
<u>Item 2.</u>	<u>Properties</u>	34
<u>Item 3.</u>	<u>Legal Proceedings</u>	34
<u>Item 4.</u>	<u>Submission of Matters to a Vote of Security Holders</u>	35
	<b><u>PART II</u></b>	35
<u>Item 5.</u>	<u>Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities</u>	35
<u>Item 6.</u>	<u>Selected Financial Data</u>	38
<u>Item 7.</u>	<u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	40
<u>Item 7A.</u>	<u>Quantitative and Qualitative Disclosures about Market Risk</u>	57
<u>Item 8.</u>	<u>Financial Statements and Supplementary Data</u>	60
<u>Item 9.</u>	<u>Changes in and Disagreements with Accountants on Accounting and Financial Disclosure</u>	61
<u>Item 9A.</u>	<u>Controls and Procedures</u>	61
<u>Item 9B.</u>	<u>Other Information</u>	62
	<b><u>PART III</u></b>	63
<u>Item 10.</u>	<u>Directors and Executive Officers of the Registrant</u>	63
<u>Item 11.</u>	<u>Executive Compensation</u>	63
<u>Item 12.</u>	<u>Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters</u>	63
<u>Item 13.</u>	<u>Certain Relationships and Related Transactions</u>	63
<u>Item 14.</u>	<u>Principal Accounting Fees and Services</u>	63
	<b><u>PART IV</u></b>	63
<u>Item 15.</u>	<u>Exhibits and Financial Statement Schedules</u>	63
<b><u>SIGNATURES</u></b>		68
	<u>EX-10.15 Form of Covenant Not to Compete, of various dates, by and between the Registrant and each of Kathryn L. Biberstein and James M. Frates.</u>	
	<u>EX-10.15(a) Form of Covenant Not to Compete, of various dates, by and between the Registrant and each of Elliot W. Ehrich, M.D., Michael J. Landine, and Gordon G. Pugh.</u>	
	<u>EX-10.17 Accelerated Share Repurchase Agreement, dated as of February 7, 2008, between Morgan Stanley &amp; Co. Incorporated and Alkermes, Inc.</u>	
	<u>EX-21.1 Subsidiaries of the Registrant.</u>	
	<u>EX-23.1 Consent of Independent Registered Public Accounting Firm PriceWaterhousecoopers LLP.</u>	
	<u>EX-23.2 Consent of Independent Registered Public Accounting Firm Deloitte &amp; Touche LLP.</u>	
	<u>EX-31.1 Rule 13a-14(a)/15d-14(a) Certification.</u>	
	<u>EX-31.2 Rule 13a-14(a)/15d-14(a) Certification.</u>	

Edgar Filing: ALKERMES INC - Form 10-K

EX-32.1 Certification pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

**Table of Contents**

**PART I**

**Item 1. Business**

*The following business section contains forward-looking statements which involve risks and uncertainties. Our actual results could differ materially from those anticipated in these forward-looking statements as a result of certain factors. See Risk Factors and Management's Discussion and Analysis of Financial Condition and Results of Operations Forward-Looking Statements.*

**General**

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

**Our Strategy**

We leverage our unique formulation expertise and drug development technologies to develop, both with partners and on our own, innovative and competitively advantaged drug products that can enhance patient outcomes in major therapeutic areas. We enter into select collaborations with pharmaceutical and biotechnology companies to develop significant new product candidates, based on existing drugs and incorporating our technologies. In addition, we develop our own proprietary therapeutics by applying our innovative formulation expertise and drug development capabilities to create new pharmaceutical products. Each of these approaches is discussed in more detail in Products and Development Programs.

**Products and Development Programs**

***RISPERDAL CONSTA***

RISPERDAL CONSTA is a long-acting formulation of risperidone, a product of Janssen Pharmaceutica, Inc., a division of Ortho-McNeil-Janssen Pharmaceuticals, Inc. and Janssen Pharmaceutica International, a division of Cilag International (together, Janssen). RISPERDAL CONSTA is the first and only long-acting, atypical antipsychotic to be approved by the United States (U.S.) Food and Drug Administration (FDA). The medication uses our proprietary Medisorb® technology to deliver and maintain therapeutic medication levels in the body through just one injection every two weeks. Schizophrenia is a brain disorder characterized by disorganized thinking, delusions and hallucinations. Studies have demonstrated that as many as 75 percent of patients with schizophrenia have difficulty taking their oral medication on a regular basis, which can lead to worsening of symptoms. Clinical data has shown that treatment with RISPERDAL CONSTA may lead to improvements in symptoms, sustained remission and decreases in hospitalization. RISPERDAL CONSTA is marketed by Janssen and is exclusively manufactured by us. See Collaborative Arrangements Janssen for information about manufacturing fees and royalties received from Janssen.

RISPERDAL CONSTA was first approved by regulatory authorities in the United Kingdom (U.K.) and Germany in August 2002 and the FDA in October 2003. RISPERDAL CONSTA is approved in approximately 85 countries and marketed in approximately 60 countries, and Janssen continues to launch the product around the world. In May 2008,

we and Janssen agreed to begin development of a four week formulation of RISPERDAL CONSTA.

In April 2007, the FDA approved a new, smaller 12.5 mg dose of RISPERDAL CONSTA for the treatment of schizophrenia within specific patient populations, including those with renal and hepatic impairment.

## **Table of Contents**

In November 2007, Johnson & Johnson Pharmaceutical Research & Development, LLC ( J&J PRD ) submitted a Supplemental New Drug Application ( sNDA ) for RISPERDAL CONSTA for deltoid administration.

In April 2008, J&J PRD submitted a sNDA for RISPERDAL CONSTA to add an indication for the treatment of frequently relapsing bipolar disorder ( FRBD ). It is estimated that 27 million people worldwide suffer from bipolar disorder, also known as manic-depressive disorder. FRBD, defined as four or more manic or depressive episodes in the previous year that require a doctor's care, may affect up to 20 percent of the 27 million people with bipolar disorder worldwide. Bipolar disorder is characterized by debilitating mood swings, from extreme highs (mania) to extreme lows (depression). Signs of mania include euphoria, extreme irritability or rage, accelerated or disorganized thinking and an increase in risky behaviors. Signs of depression include intense sadness or despair, loss of energy, insomnia and suicidal thoughts.

In February 2008, the results of a study sponsored by Janssen were presented at the 14th Biennial Winter Workshop on Schizophrenia and Bipolar Disorders in Montreux, Switzerland. This one-year, phase 3 trial was the first placebo-controlled study to explore the use of a long-acting injectable medication in the maintenance treatment of FRBD. The study found that patients with FRBD had a significant delay in the time to an initial relapse when RISPERDAL CONSTA was combined with standard treatment. The study evaluated the time to the next mood episode, also known as a relapse, in FRBD patients receiving RISPERDAL CONSTA plus standard treatment compared to patients receiving placebo plus standard treatment. For most patients, standard treatment consisted of mood stabilizers, antidepressants, anxiolytics or combinations thereof. Time to relapse was significantly longer in patients receiving RISPERDAL CONSTA compared with placebo ( $p=0.004$ ), and the relative risk of relapse was 2.4 times higher with placebo. The relapse rates were 47.8 percent with placebo and 22.2 percent with RISPERDAL CONSTA.

## ***VIVITROL***

We developed VIVITROL, an extended-release Medisorb formulation of naltrexone, for the treatment of alcohol dependence in patients who are able to abstain from drinking in an outpatient setting and are not actively drinking prior to treatment initiation. Alcohol dependence is a serious and chronic brain disease characterized by cravings for alcohol, loss of control over drinking, withdrawal symptoms and an increased tolerance for alcohol. Adherence to medication is particularly challenging with this patient population. In clinical trials, when used in combination with psychosocial support, VIVITROL was shown to reduce the number of drinking days and heavy drinking days and to prolong abstinence in patients who abstained from alcohol the week prior to starting treatment. Each injection of VIVITROL provides medication for one month and alleviates the need for patients to make daily medication dosing decisions. Cephalon, Inc. ( Cephalon ) is primarily responsible for marketing VIVITROL in the U.S. We are the exclusive manufacturer of VIVITROL. See Collaborative Arrangements Cephalon for information about manufacturing fees received from Cephalon and the sharing of profits and losses relating to VIVITROL.

VIVITROL was approved by the FDA in April 2006 and launched in June 2006. In March 2007, we submitted a Marketing Authorization Application ( MAA ) for VIVITROL to regulatory authorities in the U.K. and Germany. The MAA for VIVITROL was submitted under a decentralized procedure, in which the U.K. will act as the Reference Member State and Germany will act as the Concerned Member State for the application. If successful, a filing under the decentralized procedure would result in a simultaneous approval of VIVITROL as a treatment for alcohol dependence in these two countries. The MAA submission reflects our targeted approach to commercialize VIVITROL in Europe on a country-by-country basis.

In December 2007, we entered into an exclusive agreement with Cilag GmbH International ( Cilag ), a subsidiary of Johnson & Johnson, to commercialize VIVITROL for the treatment of alcohol dependence and opioid dependence in Russia and other countries in the Commonwealth of Independent States ( CIS ). Cilag has primary responsibility for



filing the new drug application for VIVITROL in Russia and other countries in the CIS. Janssen-Cilag, an affiliate company of Cilag, will commercialize VIVITROL. We will retain exclusive development and marketing rights to VIVITROL in all markets outside the U.S., Russia and other countries in the CIS. We are responsible for manufacturing VIVITROL and will receive manufacturing fees and royalties

## **Table of Contents**

based on product sales. See Collaborative Arrangements Cilag GmbH International for information about manufacturing fees and royalties relating to VIVITROL. In April 2008, Cilag filed a new drug application for VIVITROL for the treatment of alcohol dependence with the Russian regulatory agency.

We are planning to commence a phase 3 clinical trial of VIVITROL for the treatment of opioid dependence within the first half of calendar 2008.

### ***Exenatide Once Weekly***

We are collaborating with Amylin Pharmaceuticals, Inc. ( Amylin ) on the development of exenatide once weekly for the treatment of type 2 diabetes. Exenatide once weekly is an injectable formulation of Amylin's BYETTA® (exenatide) which is an injection administered twice daily. Diabetes is a disease in which the body does not produce or properly use insulin. Diabetes can result in serious health complications, including cardiovascular, kidney and nerve disease. BYETTA was approved by the FDA in April 2005 as adjunctive therapy to improve blood sugar control in patients with type 2 diabetes who have not achieved adequate control on metformin and/or sulfonylurea; two commonly used oral diabetes medications. In December 2006, the FDA approved BYETTA as an add-on therapy for people with type 2 diabetes unable to achieve adequate glucose control on thiazolidinedione, a class of diabetes medications. Amylin has an agreement with Lilly for the development and commercialization of exenatide, including exenatide once weekly. Exenatide once weekly is being developed with the goal of providing patients with an effective and more patient-friendly treatment option.

In October 2007, we, Amylin and Eli Lilly and Company ( Lilly ) announced positive results from a 30-week comparator study of exenatide once weekly injection and BYETTA taken twice daily in patients with type 2 diabetes. Exenatide once weekly showed a statistically significant improvement in A1C of approximately 1.9 percentage points from baseline, compared to an improvement of approximately 1.5 percentage points for BYETTA. Approximately three out of four subjects treated with exenatide once weekly achieved an A1C of 7 percent or less. A1C of less than 7 percent is the target for good glucose control as recommended by the American Diabetes Association. After 30 weeks of treatment, both exenatide once weekly and BYETTA treatment resulted in an average weight loss of approximately eight pounds. Nearly 90 percent of subjects in both groups completed the study, which enrolled patients not achieving adequate glucose control with both diet and exercise or with use of oral glucose-lowering agents. The companies anticipate a regulatory submission to the FDA by the end of the first half of calendar 2009.

### ***AIR® Insulin***

On March 7, 2008, we received written notice from Lilly terminating the development and license agreement, dated April 1, 2001, between us and Lilly pursuant to which we and Lilly were collaborating to develop inhaled formulations of insulin and other potential products for the treatment of diabetes based on our AIR pulmonary technology. This termination will become effective 90 days from the date of written notice. Termination of our development and license agreement also results in the termination of our supply agreement with Lilly for AIR Insulin.

Upon the effective date of termination of the development and license agreement and the supply agreement, the license we granted to Lilly under the development and license agreement will revert to us, and we will have the option to purchase Lilly-owned manufacturing equipment at Lilly's then-current net book value or at a negotiated purchase price not to exceed Lilly's then-current net book value.

### ***ALKS 29***

We are developing ALKS 29, an oral compound for the treatment of alcohol dependence. In July 2007, we announced positive preliminary results from a phase 1/2 multi-center, randomized, double-blind, placebo-controlled, eight-week

study that was designed to assess the efficacy and safety of ALKS 29 in approximately 150 alcohol dependent patients. In the study, ALKS 29 was generally well tolerated and led to both a statistically significant increase in the percent of days abstinent and a decrease in drinking compared to placebo when combined with psychosocial therapy. The study endpoints included the percent of day s

**Table of Contents**

abstinent, percent of heavy drinking days and number of drinks per day. Heavy drinking was defined as five or more drinks per day for men and four or more drinks per day for women. We plan to initiate additional clinical studies to support ALKS 29 during the calendar year 2008.

***ALKS 27***

Using our AIR pulmonary technology, we are independently developing an inhaled tropium product for the treatment of chronic obstructive pulmonary disease ( COPD ). COPD is a serious, chronic disease characterized by a gradual loss of lung function.

On April 18, 2008, we confirmed, both orally and in writing, to Indevus Pharmaceuticals, Inc. ( Indevus ) that the feasibility agreement between us and Indevus, dated February 4, 2005, which related to the development of an inhaled formulation of tropium chloride using our proprietary AIR technology ( ALKS 27 ) for the treatment of COPD, had terminated in accordance with its terms. All patent rights contributed to the collaboration by the Company revert to us. We own all patent rights related to ALKS 27. Prior to the termination, we and Indevus shared equally all costs of developing ALKS 27.

In September 2007, we and Indevus announced positive preliminary results from a randomized, double-blind, placebo-controlled, phase 2a clinical study of ALKS 27 in patients with COPD. In the study, single doses of ALKS 27 demonstrated a rapid onset of action and produced a significant improvement in lung function ( $p < 0.0001$ ) over 24 hours compared to placebo. ALKS 27 was generally well tolerated, and all enrolled patients completed the study. No treatment related adverse events were reported in this study. Based on these positive results, we are moving forward with additional development of ALKS 27 and to identify a partner for the future development and commercialization of ALKS 27.

***ALKS 33***

ALKS 33 is a novel opioid modulator, identified from the library of compounds in-licensed from Rensselaer Polytechnic Institute ( RPI ). These compounds represent an opportunity for us to develop important therapeutics for a broad range of diseases and medical conditions, including addiction, pain and other central nervous system disorders. We plan to initiate clinical studies of ALKS 33 in the calendar year 2008.

***AIR Parathyroid Hormone***

We and Lilly completed a phase 1 study of inhaled formulations of parathyroid hormone ( PTH ) in healthy, post menopausal women. The data from the study indicated that additional feasibility and formulation work was required. At this time, we and Lilly are not planning to pursue further development of inhaled formulations of PTH. See Collaborative Arrangements Lilly AIR PTH for more information.

**Collaborative Arrangements**

Our business strategy includes forming collaborations to develop and commercialize our products and, in so doing, access technological, financial, marketing, manufacturing and other resources. We have entered into several collaborative arrangements, as described below.

**Janssen**

Under a product development agreement, we collaborated with Janssen on the development of RISPERDAL CONSTA. Under the development agreement, Janssen provided funding to us for the development of RISPERDAL

CONSTA, and Janssen is responsible for securing all necessary regulatory approvals for the product. RISPERDAL CONSTA has been approved in approximately 85 countries. RISPERDAL CONSTA has been launched in approximately 60 countries, including the U.S. and several major international markets. We exclusively manufacture RISPERDAL CONSTA for commercial sale. In addition, we and Janssen have recently agreed to begin work to develop a four week formulation of RISPERDAL CONSTA.

## **Table of Contents**

Under license agreements, we granted Janssen and an affiliate of Janssen exclusive worldwide licenses to use and sell RISPERDAL CONSTA. Under our license agreements with Janssen, we also record royalty revenues equal to 2.5 percent of Janssen's net sales of RISPERDAL CONSTA in the quarter when the product is sold by Janssen. Janssen can terminate the license agreements upon 30 days prior written notice to us.

Under our manufacturing and supply agreement with Janssen, we record manufacturing revenues when product is shipped to Janssen, based on 7.5% of Janssen's net unit sales price for RISPERDAL CONSTA for the calendar year.

The manufacturing and supply agreement terminates on expiration of the license agreements. In addition, either party may terminate the manufacturing and supply agreement upon a material breach by the other party which is not resolved within 60 days written notice or upon written notice in the event of the other party's insolvency or bankruptcy. Janssen may terminate the agreement upon six months written notice to us. In the event that Janssen terminates the manufacturing and supply agreement without terminating the license agreements, the royalty rate payable to us on Janssen's net sales of RISPERDAL CONSTA would increase from 2.5 percent to 5.0 percent.

## **Cephalon**

In June 2005, we entered into a license and collaboration agreement and supply agreement with Cephalon (together the Agreements) to jointly develop, manufacture and commercialize extended-release forms of naltrexone, including VIVITROL (the product or products), in the U.S. Under the terms of the Agreements, we provided Cephalon with a co-exclusive license to use and sell the product in the U.S. and a non-exclusive license to manufacture the product under certain circumstances, with the ability to sublicense. We were responsible for obtaining marketing approval for VIVITROL in the U.S. for the treatment of alcohol dependence, which we received from the FDA in April 2006, and for completing the first VIVITROL manufacturing line. The companies share responsibility for additional development of the products, which may include continuation of clinical trials, performance of new clinical trials, the development of new indications for the products and work to improve the manufacturing process and increase manufacturing yields. We and Cephalon also share responsibility for developing the commercial strategy for the products. Cephalon has primary responsibility for the commercialization, including distribution and marketing, of the products in the U.S., and we support this effort with a team of managers of market development. We have the option to staff our own field sales force in addition to our managers of market development at the time of the first sales force expansion, should one occur. We have responsibility for the manufacture of the products.

In June 2005, Cephalon made a nonrefundable payment of \$160.0 million to us upon signing the Agreements. In April 2006, Cephalon made a second nonrefundable payment of \$110.0 million to us upon FDA approval of VIVITROL. Cephalon will make additional nonrefundable milestone payments to us of up to \$220.0 million if calendar year net sales of the products exceed certain agreed-upon sales levels. Under the terms of the Agreements, we were responsible for the first \$120.0 million of net product losses incurred on VIVITROL through December 31, 2007 (the cumulative net loss cap). These net product losses excluded development costs incurred by us to obtain FDA approval of VIVITROL and costs to complete the first manufacturing line, both of which were our sole responsibility. Cephalon was responsible for all net product losses in excess of the cumulative net loss cap through December 31, 2007. After December 31, 2007, all net profits and losses earned on VIVITROL are divided between us and Cephalon in approximately equal shares.

In October 2006, we and Cephalon entered into binding amendments to the license and collaboration agreement and the supply agreement (the Amendments). Under the Amendments, the parties agreed that Cephalon would purchase from us two VIVITROL manufacturing lines (and related equipment) under construction, which will continue to be operated at our manufacturing facility. Cephalon also agreed to be responsible for its own losses related to the products during the period August 1, 2006 through December 31, 2006. In December 2006, we received a \$4.6 million payment from Cephalon as reimbursement for certain costs incurred by us prior to October 2006, which we had

charged to the collaboration and that were related to the construction of the VIVITROL manufacturing lines. These costs consisted primarily of internal or temporary employee time, billed at negotiated full-time equivalent ( FTE ) rates. We and Cephalon agreed to

## **Table of Contents**

increase the cumulative net loss cap from \$120.0 million to \$124.6 million to account for this reimbursement. During the years ended March 31, 2008 and 2007, we billed Cephalon \$1.6 million and \$21.6 million, respectively, for the sale of the two VIVITROL manufacturing lines, and we will bill Cephalon for future costs we incur related to the construction of the manufacturing lines. Beginning in October 2006, all FTE-related costs we incur that are reimbursable by Cephalon and related to the construction and validation of the two VIVITROL manufacturing lines are recorded as research and development revenue as incurred. Cephalon has granted us an option, exercisable after two years, to repurchase the two VIVITROL manufacturing lines at the then-current net book value of the assets. Because we continue to operate and maintain the equipment and intend to do so for the foreseeable future, the payments made by Cephalon for the assets have been treated as additional consideration under the Agreements. The assets remain on our books.

The Agreements and Amendments are in effect until the later of: (i) the expiration of certain patent rights; or (ii) 15 years from the date of the first commercial sale of the products in the U.S. Cephalon has the right to terminate the Agreements at any time by providing 180 days prior written notice to us, subject to certain continuing rights and obligations between the parties. The supply agreement terminates upon termination or expiration of the license and collaboration agreement or the later expiration of our obligations pursuant to the Agreements to continue to supply products to Cephalon. In addition, either party may terminate the license and collaboration agreement upon a material breach by the other party which is not cured within 90 days written notice of material breach or, in certain circumstances, a 30 day extension of that period, and either party may terminate the supply agreement upon a material breach by the other party which is not cured within 180 days written notice of material breach or, in certain circumstances, a 30 day extension of that period.

### ***Cilag GmbH International***

In December 2007, we entered into a license and commercialization agreement with Cilag to commercialize VIVITROL for the treatment of alcohol dependence and opioid dependence in Russia and other countries in the CIS. Under the terms of the agreement, Cilag will have primary responsibility for securing all necessary regulatory approvals for VIVITROL and Janssen-Cilag, an affiliate of Cilag, will commercialize the product. We will be responsible for the manufacture of VIVITROL and will receive manufacturing revenues and royalty revenues based upon product sales.

In December 2007, Cilag made a nonrefundable payment of \$5.0 million to us upon signing the agreement. Cilag will pay us up to an additional \$34.0 million upon the receipt of regulatory approvals for the product, the occurrence of certain agreed-upon events and levels of VIVITROL sales.

Commencing five years after the effective date of the agreement, Cilag will have the right to terminate the agreement at any time by providing 90 days written notice to us, subject to certain continuing rights and obligations between the parties. Cilag will also have the right to terminate the agreement at any time upon 90 days written notice to us if a change in the pricing and/or reimbursement of VIVITROL in Russia and other countries of the CIS has a material adverse effect on the underlying economic value of commercializing the product such that it is no longer reasonably profitable to Cilag. In addition, either party may terminate the agreement upon a material breach by the other party which is not cured within 90 days written notice of material breach or, in certain circumstances, a 30 day extension of that period.

### ***Amylin***

In May 2000, we entered into a development and license agreement with Amylin for the development of exenatide once weekly, which is under development for the treatment of type 2 diabetes. Pursuant to the development and license agreement, Amylin has an exclusive, worldwide license to the Medisorb technology for the development and



commercialization of injectable extended-release formulations of exendins and other related compounds. Amylin has entered into a collaboration agreement with Lilly for the development and commercialization of exenatide, including exenatide once weekly. We receive funding for research and development and milestone payments consisting of cash and warrants for Amylin common stock upon achieving certain development and commercialization goals and will also receive royalty payments based on

**Table of Contents**

future product sales, if any. We are responsible for formulation and non-clinical development of any products that may be developed pursuant to the agreement and for manufacturing these products for use in clinical trials and, in certain cases, for commercial sale. Subject to its arrangement with Lilly, Amylin is responsible for conducting clinical trials, securing regulatory approvals and marketing any products resulting from the collaboration on a worldwide basis.

In October 2005, we amended our existing development and license agreement with Amylin, and reached agreement regarding the construction of a manufacturing facility for exenatide once weekly and certain technology transfer related thereto. In December 2005, Amylin purchased a facility for the manufacture of exenatide once weekly and began construction in early calendar year 2006. Amylin is responsible for all costs and expenses associated with the design, construction and validation of the facility. The parties agreed that we will transfer our technology for the manufacture of exenatide once weekly to Amylin. Amylin reimburses us for any time, at an agreed-upon FTE rate, and materials we incur with respect to the transfer of technology. Following the completion of the technology transfer, Amylin will be responsible for the manufacture of exenatide once weekly and will operate the facility. Amylin will pay us royalties for commercial sales of this product, if approved, in accordance with the development and license agreement.

Amylin may terminate the development and license agreement for any reason upon 90 days written notice to us if such termination occurs before filing a New Drug Application ( NDA ) with the FDA for a product developed under the development and license agreement or upon 180 days written notice to us after such event. In addition, either party may terminate the development and license agreement upon a material default or breach by the other party that is not cured within 60 days after receipt of written notice specifying the default or breach.

**Lilly**

***AIR Insulin***

On March 7, 2008, we received written notice from Lilly terminating the development and license agreement, dated April 1, 2001, between us and Lilly pursuant to which we and Lilly were collaborating to develop inhaled formulations of insulin and other potential products for the treatment of diabetes based on our AIR pulmonary technology. This termination will become effective 90 days from the receipt of the notice. Termination of our development and license agreement also results in the termination of our supply agreement with Lilly for AIR Insulin.

Upon the effective date of termination of the development and license agreement and the supply agreement, the license we granted to Lilly under the development and license agreement will revert to us, and we will have the option to purchase Lilly-owned manufacturing equipment at a negotiated purchase price not to exceed Lilly's then-current net book value.

***AIR PTH***

On August 31, 2007, we received written notice from Lilly terminating the development and license agreement, dated December 16, 2005, between us and Lilly pursuant to which we and Lilly were collaborating to develop inhaled formulations of PTH. This termination became effective 90 days after our receipt of the written notice.

Upon the effective date of termination of the development and license agreement, the license we granted to Lilly under this agreement reverted to us.

***Indevus***

On April 18, 2008, we confirmed, both orally and in writing, to Indevus that the feasibility agreement between us and Indevus, dated February 4, 2005, which related to the development of ALKS 27 for the treatment of COPD, had terminated in accordance with its terms. All patent rights contributed to the collaboration by the Company revert to us. Prior to the termination, we and Indevus shared equally all costs of developing ALKS 27.

## **Table of Contents**

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

In September 2006, we and 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 therapeutics for a broad range of diseases and medical conditions, including addiction, pain and other central nervous system disorders.

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 of \$0.5 million and are obligated to pay annual fees of up to \$0.2 million, and tiered royalty payments of between 1% and 4% of annual net sales in the event any products developed under the agreement are commercialized. In addition, we are obligated to make milestone payments in the aggregate of up to \$9.1 million upon certain agreed-upon development events. All amounts paid to RPI under this license agreement have been expensed and are included in research and development expenses.

### **Drug Delivery Technology**

Our proprietary technologies address several important development opportunities, including injectable extended-release of proteins, peptides and small molecule pharmaceutical compounds and the pulmonary delivery of small molecules, proteins and peptides. We have used these technologies as a platform to establish drug development and regulatory expertise.

#### ***Injectable Extended-Release Technology***

Our proprietary injectable extended-release technology allows us to encapsulate traditional small molecule pharmaceuticals, peptides and proteins, in microspheres made of common medical polymers. The technology is designed to enable novel formulations of pharmaceuticals by providing controlled, extended-release of drugs over time. Drug release from the microsphere is controlled by diffusion of the drug through the microsphere and by biodegradation of the polymer. These processes can be modulated through a number of formulation and fabrication variables, including drug substance and microsphere particle sizing and choice of polymers and excipients.

#### ***Pulmonary Technology***

The AIR technology is our proprietary pulmonary technology that enables the delivery of both small molecules and macromolecules to the lungs. Our technology allows us to formulate drugs into dry powders made up of highly porous particles with low mass density. These particles can be efficiently delivered to the deep lung by a small, simple inhaler. The AIR technology is useful for small molecules, proteins or peptides and allows for both local delivery to the lungs and systemic delivery via the lungs.

AIR particles can be aerosolized and inhaled efficiently with simple inhaler devices because low forces of cohesion allow the particles to disaggregate easily. We have developed a family of relatively inexpensive, compact, easy-to-use inhalers. The AIR inhalers are breath activated and made from injection molded plastic. The powders are designed to quickly discharge from the device over a range of inhalation flow rates, which may lead to low patient-to-patient variability and high lung deposition of the inhaled dose. By varying the ratio and type of excipients used in the formulation, we believe we can deliver a range of drugs from the device that may provide both immediate and extended release.

### **Manufacturing**

We currently maintain a manufacturing facility in Ohio. We either purchase active drug product from third parties or receive it from our third party collaborators to formulate product using our technologies. The manufacture of our product for clinical trials and commercial use is subject to current good manufacturing practices ( cGMP ) and other regulatory agency regulations. We have been producing commercial product since 1999. For information about risks relating to the manufacture of our products and product candidates,

## **Table of Contents**

see the sections of Item 1A Risk Factors entitled We are subject to risks related to the manufacture of our products , We rely to a large extent on third parties in the manufacturing of our products , The manufacture of our products is subject to government regulation , and We rely heavily on collaborative partners.

### ***Injectable Extended-Release Technology***

We own and occupy a manufacturing, office and laboratory site in Wilmington, Ohio where we manufacture RISPERDAL CONSTA, VIVITROL and development-scale products such as exenatide once weekly. The facility is periodically inspected by U.S. and European regulatory authorities to ensure that the facility continues to meet required cGMP standards for continued commercial manufacturing. The facility is undergoing an expansion to increase the supply of RISPERDAL CONSTA. See Item 2. Properties, for details of the facility expansion.

### ***Pulmonary Technology***

We lease a 90,000 square foot facility located in Chelsea, Massachusetts that is designed to accommodate manufacturing of multiple products and that contains a 40,000 square foot clinical manufacturing facility. In March 2008, in connection with our restructuring of operations following the termination by Lilly of the AIR Insulin program, we announced the closure of this facility. See Item 2. Properties, for more information.

We have established and are operating clinical facilities, with the capability to produce clinical supplies of our pulmonary and injectable extended-release products, within our corporate headquarters in Cambridge, Massachusetts.

## **Marketing**

Under our collaboration agreements with Janssen, Cilag and Amylin, these companies are responsible for the commercialization of the products developed thereunder if, and when, regulatory approval is obtained. Under our collaboration agreement with Cephalon, Cephalon is primarily responsible for VIVITROL commercialization, however, we support the product commercialization effort with a team of managers of market development, whose responsibility it is to work in collaboration with the Cephalon field sales team to facilitate local and health care system level approaches to marketplace education and awareness and program support. Under the collaboration, we have the option to establish our own field sales force, in addition to the managers of market development, at the time of the first sales force expansion, should one occur.

## **Competition**

The biotechnology and pharmaceutical industries are subject to rapid and substantial technological change. We face intense competition in the development, manufacture, marketing and commercialization of our products and product candidates from many and varied sources academic institutions, government agencies, research institutions, biotechnology and pharmaceutical companies, including our collaborators, and other companies with similar technologies. Our success in the marketplace depends largely on our ability to identify and successfully commercialize products developed from our research activities or licensed through our collaboration activities, and to obtain financial resources necessary to fund our clinical trials, manufacturing, and commercialization activities. Competition for our marketed products and product candidates may be based on product efficacy, safety, convenience, reliability, availability and price, among other factors. The timing of entry of new pharmaceutical products in the market can be a significant factor in product success, and the speed with which we receive approval for products, bring them to market and produce commercial supplies may impact the competitive position of our products in the marketplace.

Many of our competitors and potential competitors have substantially more capital resources, human resources, manufacturing and marketing experience, research and development resources and production facilities than we do. Many of these competitors have significantly more experience than we do in undertaking preclinical testing and clinical trials of new pharmaceutical products and in obtaining FDA and other regulatory approvals. There can be no assurance that developments by our competitors will not render our

## **Table of Contents**

products, product candidates or our technologies obsolete or noncompetitive, or that our collaborators will not choose to use competing technologies or methods.

With respect to our injectable technology, we are aware that there are other companies developing extended-release delivery systems for pharmaceutical products. RISPERDAL CONSTA may compete with a number of other injectable products currently being developed, including paliperidone palmitate, an injectable, four-week, long-acting product being developed by Johnson & Johnson, and a number of new oral compounds for the treatment of schizophrenia.

VIVITROL competes with CAMPRAL<sup>®</sup> by Forest Laboratories, Inc. and ANTABUSE<sup>®</sup> by Odyssey Pharmaceuticals, Inc. as well as currently marketed drugs also formulated from naltrexone, such as REVIA<sup>®</sup> by Duramed Pharmaceuticals, Inc., NALOREX<sup>®</sup> by Bristol-Myers Squibb Pharmaceuticals Ltd. and DEPADE<sup>®</sup> by Mallinckrodt, Inc., a subsidiary of Tyco International Ltd. Other pharmaceutical companies are investigating product candidates that have shown some promise in treating alcohol dependence and that, if approved by the FDA, would compete with VIVITROL.

With respect to our AIR technology, we are aware that there are other companies marketing or developing pulmonary delivery systems for pharmaceutical products.

Other companies, including our collaborators, are developing new chemical entities or improved formulations of existing products which, if developed successfully, could compete against our products and product candidates. These chemical entities are being designed to have different mechanisms of action or improved safety and efficacy.

## **Patents and Proprietary Rights**

Our success will be dependent, in part, on our ability to obtain patent protection for our product candidates and those of our collaborators, to maintain trade secret protection and to operate without infringing upon the proprietary rights of others.

We have a proprietary portfolio of patent rights and exclusive licenses to patents and patent applications. We have filed numerous U.S. and foreign patent applications directed to compositions of matter as well as processes of preparation and methods of use, including applications relating to each of our delivery technologies. We own approximately 133 issued U.S. patents. The earliest date upon which a U.S. patent issued to us will expire, that is currently material to our business, is 2013. In the future, we plan to file further U.S. and foreign patent applications directed to new or improved products and processes. We intend to file additional patent applications when appropriate and defend our patent position aggressively.

We have exclusive rights through licensing agreements with third parties to approximately 35 issued U.S. patents, a number of U.S. patent applications and corresponding foreign patents and patent applications in many countries, subject in certain instances to the rights of the U.S. government to use the technology covered by such patents and patent applications. Under certain licensing agreements, we currently pay annual license fees and/or minimum annual royalties. During the year ended March 31, 2008, these fees totaled approximately \$0.3 million. In addition, under these licensing agreements, we are obligated to pay royalties on future sales of products, if any, covered by the licensed patents.

We know of several U.S. patents issued to other parties that may relate to our products and product candidates. The manufacture, use, offer for sale, sale or import of some of our product candidates might be found to infringe on the claims of these patents. A party might file an infringement action against us. Our cost of defending such an action is likely to be high and we might not receive a favorable ruling.



We also know of patent applications filed by other parties in the U.S. and various foreign countries that may relate to some of our product candidates if issued in their present form. The patent laws of the U.S. and foreign countries are distinct and decisions as to patenting, validity of patents and infringement of patents may be resolved differently in different countries. If patents are issued to any of these applicants, we or our collaborators may not be able to manufacture, use, offer for sale, or sell some of our product candidates without first getting a license from the patent holder. The patent holder may not grant us a license on

## **Table of Contents**

reasonable terms or it may refuse to grant us a license at all. This could delay or prevent us from developing, manufacturing or selling those of our product candidates that would require the license.

We try to protect our proprietary position by filing U.S. and foreign patent applications related to our proprietary technology, inventions and improvements that are important to the development of our business. Because the patent position of biotechnology and pharmaceutical companies involves complex legal and factual questions, enforceability of patents cannot be predicted with certainty. The ultimate degree of patent protection that will be afforded to biotechnology products and processes, including ours, in the U.S. and in other important markets remains uncertain and is dependent upon the scope of protection decided upon by the patent offices, courts and lawmakers in these countries. Patents, if issued, may be challenged, invalidated or circumvented. Thus, any patents that we own or license from others may not provide any protection against competitors. Our pending patent applications, those we may file in the future, or those we may license from third parties, may not result in patents being issued. If issued, they may not provide us with proprietary protection or competitive advantages against competitors with similar technology. Furthermore, others may independently develop similar technologies or duplicate any technology that we have developed outside the scope of our patents. The laws of certain foreign countries do not protect our intellectual property rights to the same extent as do the laws of the U.S.

We also rely on trade secrets, know-how and technology, which are not protected by patents, to maintain our competitive position. We try to protect this information by entering into confidentiality agreements with parties that have access to it, such as our corporate partners, collaborators, employees and consultants. Any of these parties may breach the agreements and disclose our confidential information or our competitors might learn of the information in some other way. If any trade secret, know-how or other technology not protected by a patent were to be disclosed to, or independently developed by, a competitor, our business, results of operations and financial condition could be materially adversely affected.

## **Government Regulation**

Before new pharmaceutical products may be sold in the U.S. and other countries, clinical trials of the products must be conducted and the results submitted to appropriate regulatory agencies for approval. The regulatory approval process requires a demonstration of product safety and efficacy and the ability to effectively manufacture such product. Generally, such demonstration of safety and efficacy includes preclinical testing and clinical trials of such product candidates. The testing, manufacture and marketing of pharmaceutical products in the U.S. requires the approval of the FDA. The FDA has established mandatory procedures and safety standards which apply to the preclinical testing and clinical trials, manufacture and marketing of these products. Similar standards are established by non-U.S. regulatory bodies for marketing approval of such products. Pharmaceutical marketing and manufacturing activities are also regulated by state, local and other authorities. The regulatory approval process in the U.S. is described in brief below.

As an initial step in the FDA regulatory approval process, preclinical studies are typically conducted in animal models to assess the drug's efficacy, identify potential safety problems and evaluate potential for harm to humans. The results of these studies must be submitted to the FDA as part of an investigational new drug application ( IND ), which must be reviewed by the FDA within 30 days of submission and before proposed clinical (human) testing can begin. If the FDA is not convinced of the product candidate's safety, it has the authority to place the program on hold at any time during the investigational stage and request additional animal data or changes to the study design. Studies supporting approval of products in the U.S. are typically accomplished under an IND.

Typically, clinical testing involves a three-phase process: phase 1 trials are conducted with a small number of healthy subjects and are designed to determine the early side effect profile and, perhaps, the pattern of drug distribution and metabolism; phase 2 trials are conducted on patients with a specific disease in order to determine appropriate dosages,

expand evidence of the safety profile and, perhaps, provide preliminary evidence of product efficacy; and phase 3 trials are large-scale, comparative studies conducted on patients with a target disease in order to generate enough data to provide statistical evidence of efficacy and safety required by national regulatory agencies. The results of the preclinical testing and clinical trials of a pharmaceutical

**Table of Contents**

product, as well as the information on the manufacturing of the product and proposed labeling, are then submitted to the FDA in the form of a NDA or, for a biological product, a biologics license application ( BLA ) for approval to commence commercial sales. Preparing such applications involves considerable data collection, verification, analysis and expense. In responding to an NDA or BLA, the FDA may grant marketing approval, request additional information or deny the application if it determines that the application does not satisfy its regulatory approval criteria. Submission of the application(s) for marketing authorization does not guarantee approval. At the same time, an FDA request for additional information does not mean the product will not be approved or that the FDA s review of the application will be significantly delayed. On occasion, regulatory authorities may require larger or additional studies, leading to unanticipated delay or expense. Even after initial FDA approval has been obtained, further clinical trials may be required to provide additional data on safety and efficacy. It is also possible that the labeling may be more limited than what was originally projected. Each marketing authorization application is unique and should be considered as such.

The receipt of regulatory approval often takes a number of years, involving the expenditure of substantial resources and depends on a number of factors, including the severity of the disease in question, the availability of alternative treatments and the risks and benefits demonstrated in clinical trials. Data obtained from preclinical testing and clinical trials are subject to varying interpretations, which can delay, limit or prevent FDA approval. In addition, changes in FDA approval policies or requirements may occur, or new regulations may be promulgated, which may result in delay or failure to receive FDA approval. Similar delays or failures may be encountered in foreign countries. Delays, increased costs and failures in obtaining regulatory approvals could have a material adverse effect on our business, results of operations and financial condition.

Regulatory authorities track information on side effects and adverse events reported during clinical studies and after marketing approval. Non-compliance with FDA safety reporting requirements may result in FDA regulatory action that may include civil action or criminal penalties. Side effects or adverse events that are reported during clinical trials can delay, impede or prevent marketing approval. Similarly, adverse events that are reported after marketing approval can result in additional limitations being placed on the product s use and, potentially, withdrawal or suspension of the product from the market. Furthermore, recently enacted legislation provides the FDA with expanded authority over drug products after approval. This legislation enhances the FDA s authority with respect to post-marketing safety surveillance including, among other things, the authority to require additional post-approval studies or clinical trials and mandate label changes as a result of safety findings.

If we seek to make certain changes to an approved product, such as adding a new indication, making certain manufacturing changes, or changing manufacturers or suppliers of certain ingredients or components, we will need review and approval of regulatory authorities, including the FDA and the European Medicines Agency ( EMEA ), before the changes can be implemented.

***Good Manufacturing Processes ( cGMP )***

Among the conditions for a NDA or BLA approval is the requirement that the prospective manufacturer s quality control and manufacturing procedures conform with cGMP. Before approval of an NDA or BLA, the FDA may perform a pre-approval inspection of a manufacturing facility to determine its compliance with cGMP and other rules and regulations. In complying with cGMP, manufacturers must continue to expend time, money and effort in the area of production and quality control to ensure full technical compliance. Similarly, NDA or BLA approval may be delayed or denied due to cGMP non-compliance or other issues at contract sites or suppliers included in the NDA or BLA, and the correction of these shortcomings may be beyond our control. Facilities are also subjected to the requirements of other government bodies, such as the U.S. Occupational Safety & Health Administration and the U.S. Environmental Protection Agency.

If, after receiving clearance from regulatory agencies, a company makes a material change in manufacturing equipment, location, or process, additional regulatory review and approval may be required. We also must adhere to cGMP and product-specific regulations enforced by the FDA following product approval. The FDA, the EMEA and other regulatory agencies also conduct regular, periodic visits to re-inspect equipment, facilities and processes following the initial approval of a product. If, as a result of these inspections, it is determined

**Table of Contents**

that our equipment, facilities or processes do not comply with applicable regulations and conditions of product approval, regulatory agencies may seek civil, criminal or administrative sanctions and/or remedies against us, including the suspension of our manufacturing operations.

***Advertising and Promotion***

The FDA regulates all advertising and promotion activities for products under its jurisdiction both prior to and after approval. A company can make only those claims relating to safety and efficacy that are approved by the FDA. Physicians may prescribe legally available drugs for uses that are not described in the drug's labeling and that differ from those tested by us and approved by the FDA. Such off-label uses are common across medical specialties, and often reflect a physician's belief that the off-label use is the best treatment for his patients. The FDA does not regulate the behavior of physicians in their choice of treatments, but the FDA regulations do impose stringent restrictions on manufacturers' communications regarding off-label uses. Failure to comply with applicable FDA requirements may subject a company to adverse publicity, enforcement action by the FDA, corrective advertising, and the full range of civil and criminal penalties available to the FDA.

***Regulation Outside the U.S.***

In the European Union ( E.U. ), regulatory requirements and approval processes are similar in principle to those in the U.S. depending on the type of drug for which approval is sought. There are currently three potential tracks for marketing approval in E.U. countries: mutual recognition; decentralized procedures; and centralized procedures. These review mechanisms may ultimately lead to approval in all E.U. countries, but each method grants all participating countries some decision-making authority in product approval.

***Sales and Marketing Regulations***

We are also subject to various federal and state laws pertaining to health care fraud and abuse, including anti-kickback laws and false claims laws. Anti-kickback laws make it illegal for a prescription drug manufacturer to solicit, offer, receive, or pay any remuneration in exchange for, or to induce, the referral of business, including the purchase or prescription of a particular drug. Due to the breadth of the statutory provisions and the absence of guidance in the form of regulations and very few court decisions addressing industry practices, it is possible that our practices might be challenged under anti-kickback or similar laws. False claims laws prohibit anyone from knowingly and willingly presenting, or causing to be presented for payment to third party payors (including Medicare and Medicaid) claims for reimbursed drugs or services that are false or fraudulent, claims for items or services not provided as claimed, or claims for medically unnecessary items or services. Our activities relating to the sale and marketing of our products may be subject to scrutiny under these laws. Violations of fraud and abuse laws may be punishable by criminal and/or civil sanctions, including fines and civil monetary penalties, as well as the possibility of exclusion from federal health care programs (including Medicare and Medicaid). If the government were to allege or convict us of violating these laws, our business could be harmed. In addition, there is ability for private individuals to bring similar actions. See the section of Item 1A Risk Factors entitled Failure to comply with government regulations regarding our products could harm our business and Our business is subject to extensive government regulation and oversight and changes in laws could adversely affect our revenues and profitability.

Our activities could be subject to challenge for the reasons discussed above and due to the broad scope of these laws and the increasing attention being given to them by law enforcement authorities. Further, there are an increasing number of state laws that require manufacturers to make reports to states on pricing and marketing information. Many of these laws contain ambiguities as to what is required to comply with the laws. Given the lack of clarity in laws and their implementation, our reporting actions could be subject to the penalty provisions of the pertinent state authorities.



## **Table of Contents**

### ***Other Regulations***

*Foreign Corrupt Practices Act.* We are also subject to the U.S. Foreign Corrupt Practices Act which prohibits corporations and individuals from paying, offering to pay, or authorizing the payment of anything of value to any foreign government official, government staff member, political party, or political candidate in an attempt to obtain or retain business or to otherwise influence a person working in an official capacity.

*Other Laws.* Our present and future business has been and will continue to be subject to various other laws and regulations. Various laws, regulations and recommendations relating to safe working conditions, laboratory practices, the experimental use of animals, and the purchase, storage, movement, import and export and use and disposal of hazardous or potentially hazardous substances used in connection with our research work are or may be applicable to our activities. To date, compliance with laws and regulations relating to the protection of the environment has not had a material effect on capital expenditures, earnings or our competitive position. However, the extent of government regulation which might result from any legislative or administrative action cannot be accurately predicted.

### **Employees**

As of May 28, 2008, we had approximately 610 full-time employees. A significant number of our management and professional employees have prior experience with pharmaceutical, biotechnology or medical product companies. We believe that we have been successful in attracting skilled and experienced scientific and senior management personnel, however, competition for such personnel is intense. None of our employees are covered by a collective bargaining agreement. We consider our relations with our employees to be good.

### **Available Information**

We are a Pennsylvania corporation with principal executive offices located at 88 Sidney Street, Cambridge, Massachusetts 02139. Our telephone number is (617) 494-0171 and our website address is [www.alkermes.com](http://www.alkermes.com). We make available free of charge through the Investor Relations section of our website our Annual Reports on Form 10-K and Form 10-K/A, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and all amendments to those reports as soon as reasonably practicable after such material is electronically filed with or furnished to the Securities and Exchange Commission ( SEC ). We include our website address in this Annual Report on Form 10-K only as an inactive textual reference and do not intend it to be an active link to our website. You may read and copy materials we file with the SEC at the SEC's Public Reference Room at 100 F Street, N.E., Washington, D.C. 20549. You may get information on the operation of the Public Reference Room by calling the SEC at 1-800-SEC-0330. The SEC maintains an Internet site that contains reports, proxy and information statements, and other information regarding issuers that file electronically with the SEC at [www.sec.gov](http://www.sec.gov).

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

*If any of the following risks actually occur, they could materially adversely affect our business, financial condition or operating results. In that case, the trading price of our common stock could decline.*

#### ***RISPERDAL CONSTA, VIVITROL and our product candidates may not generate significant revenues.***

Even if a product candidate receives regulatory approval for commercial sale, the revenues received or to be received from the sale of the product may not be significant and will depend on numerous factors, many of which are outside of our control, including but not limited to those factors set forth below:

#### ***RISPERDAL CONSTA***



We are not involved in the marketing or sales efforts for RISPERDAL CONSTA. Our revenues depend on manufacturing fees and royalties we receive from our partner for RISPERDAL CONSTA, each of which relates to sales of RISPERDAL CONSTA by our partner. For reasons outside of our control, including those mentioned below, sales of RISPERDAL CONSTA may not meet our partner's expectations.

**Table of Contents**

*VIVITROL*

In April 2006, the FDA approved VIVITROL for the treatment of alcohol dependence in patients able to refrain from drinking prior to, and not actively drinking at the time of, treatment initiation. In June 2005, we entered into an agreement with Cephalon to develop and commercialize VIVITROL for the treatment of alcohol dependence in the U.S. and its territories. Under this agreement, Cephalon is primarily responsible for the marketing and sale of VIVITROL, and we support their efforts with a team of managers of market development. We have very little sales and marketing experience. The revenues received or to be received from the sale of VIVITROL may not be significant and will depend on numerous factors, many of which are outside of our control, including but not limited to those specified below.

In December 2007, we entered into a license and commercialization agreement with Cilag to commercialize VIVITROL for the treatment of alcohol dependence and opioid dependence in Russia and other countries in the CIS. Under the terms of the agreement, Cilag will have primary responsibility for securing all necessary regulatory approvals for VIVITROL and Janssen-Cilag, an affiliate of Cilag, will commercialize the product. We will be responsible for the manufacture of VIVITROL and will receive manufacturing revenues and royalty revenues based upon product sales. If approved for sale in Russia and countries in the CIS, the revenues received or to be received from the sale of VIVITROL may not be significant and will depend on numerous factors, many of which are outside of our control, including but not limited to those specified below.

There can be no assurance that the phase 3 clinical trial results and other clinical and preclinical data will be sufficient to obtain regulatory approvals for VIVITROL elsewhere in the world, including Russia and countries of the CIS. Even if regulatory approvals are received in countries other than the U.S., Russia and countries of the CIS, we will have to market VIVITROL ourselves in these countries or enter into co-promotion or sales and marketing arrangements with other companies for VIVITROL sales and marketing activities in these countries.

We cannot be assured that RISPERDAL CONSTA and VIVITROL will be, or will continue to be, accepted in the U.S. or in any foreign markets or that sales of either of these products will not decline in the future or end. A number of factors may cause our revenues from RISPERDAL CONSTA and VIVITROL (and any of our product candidates that we develop, if and when approved) to grow at a slower than expected rate, or even to decrease or end, including:

- perception of physicians and other members of the health care community of their safety and efficacy relative to that of competing products;

- their cost-effectiveness;

- patient and physician satisfaction with these products;

- the ability to manufacture commercial products successfully and on a timely basis;

- the cost and availability of raw materials;

- the size of the markets for these products;

- reimbursement policies of government and third-party payors;

- unfavorable publicity concerning these products or similar drugs;

- the introduction, availability and acceptance of competing treatments, including those of our collaborators;

the reaction of companies that market competitive products;

adverse event information relating to these products;

changes to product labels to add significant warnings or restrictions on use;

the continued accessibility of third parties to vial, label and distribute these products on acceptable terms;

**Table of Contents**

the unfavorable outcome of patent litigation related to any of these products;

regulatory developments related to the manufacture or continued use of these products;

the extent and effectiveness of the sales and marketing and distribution support these products receive;

our collaborators' decisions as to the timing of product launches, pricing and discounting; and

any other material adverse developments with respect to the commercialization of these products.

Our revenues will fluctuate from quarter to quarter based on a number of factors, including the acceptance of RISPERDAL CONSTA and VIVITROL in the marketplace, our partners' orders, the timing of shipments, our ability to manufacture successfully, our yield and our production schedule. In addition, the costs to manufacture RISPERDAL CONSTA and VIVITROL may be higher than anticipated if certain volume levels are not achieved. In addition, we may not be able to supply the products in a timely manner. If RISPERDAL CONSTA and VIVITROL do not produce significant revenues or if we are unable to supply our partners' requirements, our business, results of operations and financial condition would be materially adversely affected.

***We are substantially dependent on revenues from our principal product.***

Our current and future revenues depend substantially upon continued sales of RISPERDAL CONSTA by our partner, Janssen. Any significant negative developments relating to this product, such as safety or efficacy issues, the introduction or greater acceptance of competing products or adverse regulatory or legislative developments, would have a material adverse effect on our results of operations. Although we have developed and continue to develop additional products for commercial introduction, we expect to be substantially dependent on sales from this product for the foreseeable future. A decline in sales from this product would adversely affect our business.

***We are subject to risks related to the manufacture of our products.***

We currently manufacture RISPERDAL CONSTA, VIVITROL and most of our other product candidates. The manufacture of drugs for clinical trials and for commercial sale is subject to regulation by the FDA under cGMP regulations and by other regulators under other laws and regulations. We have limited experience in manufacturing products for commercial sale. We cannot be assured that we can successfully manufacture our products under cGMP regulations or other laws and regulations in sufficient quantities for commercial sale, or in a timely or economical manner.

The manufacture of pharmaceutical products is a highly complex process in which a variety of difficulties may arise from time to time, including but not limited to product loss due to material equipment failure, or vendor or operator error. Problems with manufacturing processes could result in product defects or manufacturing failures, which could require us to delay shipment of products or recall products previously shipped, or could impair our ability to expand into new markets or supply products in existing markets. Any such problem would be exacerbated by unexpected demand for our products. We may not be able to resolve any such problems in a timely fashion, if at all. We are presently the sole manufacturer of RISPERDAL CONSTA and VIVITROL. Also, our manufacturing facility in Ohio is the sole source of supply for all of our injectable product candidates and products, including RISPERDAL CONSTA and VIVITROL. If we are not able to add additional capacity or if anything were to interfere with our continuing manufacturing operations in any of our facilities, it would materially adversely affect our business, results of operations and financial condition.

If we cannot produce sufficient commercial quantities of our products to meet demand, we would need to rely on third-party manufacturers, of which there are currently very few, if any, capable of manufacturing our products as contract suppliers. We cannot be certain that we could reach agreement on reasonable terms, if at all, with those manufacturers. Even if we were to reach agreement, the transition of the manufacturing process to a third party to enable commercial supplies could take a significant amount of time.

If more of our product candidates progress to mid-to-late-stage development, we may incur significant expenses in the expansion and/or construction of manufacturing facilities and increases in personnel in order

**Table of Contents**

to manufacture product candidates. The development of a commercial-scale manufacturing process is complex and expensive. We cannot be certain that we have the necessary funds or that we will be able to develop this manufacturing infrastructure in a timely or economical manner, or at all.

Currently, several of our product candidates are manufactured in small quantities for use in clinical trials. We cannot be assured that we will be able to successfully manufacture each of our product candidates at a commercial scale in a timely or economical manner, or at all. If any of these product candidates are approved by the FDA or other drug regulatory authorities for commercial sale, we will need to manufacture them in larger quantities. If we are unable to successfully increase our manufacturing scale or capacity, the regulatory approval or commercial launch of such product candidates may be delayed, there may be a shortage in supply of such product candidates or our margins may become uneconomical.

Our manufacturing facilities require specialized personnel and are expensive to operate and maintain. Any delay in the regulatory approval or market launch of product candidates, or suspension of the sale of our products, to be manufactured in these facilities will require us to continue to operate these expensive facilities and retain specialized personnel, which may cause operating losses.

If we fail to develop manufacturing capacity and experience, or fail to manufacture our products economically on a commercial scale or in commercial volumes, or in accordance with cGMP regulations, our development programs and our ability to commercialize any approved products will be materially adversely affected. This may result in delays in receiving FDA or foreign regulatory approval for one or more of our product candidates or delays in the commercial production of a product that has already been approved. Any such delays could materially adversely affect our business, results of operations and financial condition.

***We rely to a large extent on third parties in the manufacturing of our products.***

We are responsible for the entire supply chain for VIVITROL, up to manufacture of final product for sale, including the sourcing of raw materials and active pharmaceutical agents from third parties. We have limited experience in managing a complex, cGMP supply chain and issues with our supply sources may have a material adverse effect on our business, results of operations and financial condition. The manufacture of products and product components, including the procurement of bulk drug product, packaging, storage and distribution of our products require successful coordination among ourselves and multiple third party providers. Our inability to coordinate these efforts, the lack of capacity available at the third party contractor or any other problems with the operations of these third party contractors could require us to delay shipment of saleable products; recall products previously shipped or could impair our ability to supply products at all. This could increase our costs, cause us to lose revenue or market share and damage our reputation. Any third party we use to manufacture bulk drug product, package, store or distribute our products to be sold in the U.S. must be licensed by the FDA. As a result, alternative third party providers may not be readily available on a timely basis.

None of our drug delivery technologies can be commercialized as stand-alone products but must be combined with a drug. To develop any new proprietary product candidate using one of these technologies, we must obtain the drug substance from another party. We cannot be assured that we will be able to obtain any such drug substance on reasonable terms, if at all.

Due to the unique nature of the production of our products, there are several single source providers of our raw materials. We endeavor to qualify new vendors and to develop contingency plans so that production is not impacted by issues associated with single source providers. Nonetheless, our business could be materially impacted by issues associated with single source providers.

***The manufacture of our products is subject to government regulation.***

We and our third party providers are generally required to maintain compliance with cGMP, and are subject to inspections by the FDA or comparable agencies in other jurisdictions to confirm such compliance. Any changes of suppliers or modifications of methods of manufacturing require amending our application to the FDA and ultimate amendment acceptance by the FDA prior to release of product to the marketplace. Our

**Table of Contents**

inability or the inability of our third party service providers to demonstrate ongoing cGMP compliance could require us to withdraw or recall product and interrupt commercial supply of our products. Any delay, interruption or other issues that arise in the manufacture, formulation, packaging, or storage of our products as a result of a failure of our facilities or the facilities or operations of third parties to pass any regulatory agency inspection could significantly impair our ability to develop and commercialize our products. This could increase our costs, cause us to lose revenue or market share and damage our reputation.

The FDA and European regulatory authorities have inspected and approved our manufacturing facility for RISPERDAL CONSTA, and the FDA has inspected and approved the same manufacturing facility for VIVITROL. We cannot guarantee that the FDA or any foreign regulatory agencies will approve our other facilities or, once approved, that any of our facilities will remain in compliance with cGMP regulations. If we fail to gain or maintain FDA and foreign regulatory compliance, our business, results of operations and financial condition could be materially adversely affected.

***Our business involves environmental risks.***

Our business involves the controlled use of hazardous materials and chemicals. Although we believe that our safety procedures for handling and disposing of such materials comply with state and federal standards, there will always be the risk of accidental contamination or injury. If we were to become liable for an accident, or if we were to suffer an extended facility shutdown, we could incur significant costs, damages and penalties that could materially harm our business, results of operations and financial condition.

***We rely heavily on collaborative partners.***

Our arrangements with collaborative partners are critical to our success in bringing our products and product candidates to the market and promoting such marketed products profitably. We rely on these parties in various respects, including to conduct preclinical testing and clinical trials, to provide funding for product candidate development programs, raw materials, product forecasts, and sales and marketing services, to create and manage the distribution model for our commercial products, to commercialize our products, or to participate actively in or to manage the regulatory approval process. Most of our collaborative partners can terminate their agreements with us for no reason and on limited notice. We cannot guarantee that any of these relationships will continue. Failure to make or maintain these arrangements or a delay in a collaborative partner's performance or factors that may affect our partner's sales may materially adversely affect our business, results of operations and financial condition.

We cannot control our collaborative partners' performance or the resources they devote to our programs. Consequently, programs may be delayed or terminated or we may have to use funds, personnel, laboratories and other resources that we have not budgeted. A program delay or termination or unbudgeted use of our resources may materially adversely affect our business, results of operations and financial condition.

Disputes may arise between us and a collaborative partner and may involve the issue of which of us owns the technology that is developed during a collaboration or other issues arising out of the collaborative agreements. Such a dispute could delay the program on which the collaborative partner or we are working. It could also result in expensive arbitration or litigation, which may not be resolved in our favor.

A collaborative partner may choose to use its own or other technology to develop a way to deliver its drug and withdraw its support of our product candidate, or compete with our jointly developed product.

Our collaborative partners could merge with or be acquired by another company or experience financial or other setbacks unrelated to our collaboration that could, nevertheless, materially adversely affect our business, results of



operations and financial condition.

***We have very little sales and marketing experience and limited sales capabilities, which may make commercializing our products difficult.***

We currently have very little marketing experience and limited sales capabilities. Therefore, in order to commercialize our product candidates, we must either develop our own marketing and distribution sales

## **Table of Contents**

capabilities or collaborate with a third party to perform these functions. We may, in some instances, rely significantly on sales, marketing and distribution arrangements with our collaborative partners and other third parties. For example, we rely completely on Janssen to market, sell and distribute RISPEDAL CONSTA, and rely primarily upon Cephalon to market and distribute VIVITROL. In these instances, our future revenues will be materially dependent upon the success of the efforts of these third parties.

Under our agreement, Cephalon is primarily responsible for the marketing and sale of VIVITROL. We support Cephalon in its commercialization efforts with a small team of managers of market development. We have limited experience in the commercialization of pharmaceutical products. Therefore, the success of VIVITROL and our future profitability will depend in large part on the success of our collaborative partner in its sales and marketing efforts. We may not be able to attract and retain qualified personnel to serve in our sales and marketing organization, or to effectively support those commercialization activities provided by our collaborative partner. The cost of establishing and maintaining a sales and marketing organization may exceed its cost effectiveness. If we fail to develop sales and marketing capabilities, if our collaborative partners' sales efforts are not effective or if costs of developing sales and marketing capabilities exceed their cost effectiveness, our business, results of operations and financial condition would be materially adversely affected.

### ***Our delivery technologies or product development efforts may not produce safe, efficacious or commercially viable products.***

Many of our product candidates require significant additional research and development, as well as regulatory approval. To be profitable, we must develop, manufacture and market our products, either alone or by collaborating with others. It can take several years for a product candidate to be approved and we may not be successful in bringing additional product candidates to the market. A product candidate may appear promising at an early stage of development or after clinical trials and never reach the market, or it may reach the market and not sell, for a variety of reasons. The product candidate may:

- be shown to be ineffective or to cause harmful side effects during preclinical testing or clinical trials;

- fail to receive regulatory approval on a timely basis or at all;

- be difficult to manufacture on a large scale;

- be uneconomical; or

- infringe on proprietary rights of another party.

For factors that may affect the market acceptance of our products approved for sale, see risk factor "We face competition in the biotechnology and pharmaceutical industries, and others." If our delivery technologies or product development efforts fail to result in the successful development and commercialization of product candidates, if our collaborative partners decide not to pursue our product candidates or if new products do not perform as anticipated, our business, results of operations and financial condition will be materially adversely affected.

### ***Clinical trials for our product candidates are expensive and their outcome is uncertain.***

Conducting clinical trials is a lengthy, time-consuming and expensive process. Before obtaining regulatory approvals for the commercial sale of any products, we or our partners must demonstrate through preclinical testing and clinical trials that our product candidates are safe and effective for use in humans. We have incurred, and we will continue to incur, substantial expense for, and devote a significant amount of time to, preclinical testing and clinical trials.

Historically, the results from preclinical testing and early clinical trials often have not predicted results of later clinical trials. A number of new drugs have shown promising results in clinical trials, but subsequently failed to establish sufficient safety and efficacy data to obtain necessary regulatory approvals. Clinical trials conducted by us, by our collaborative partners or by third parties on our behalf may not demonstrate sufficient safety and efficacy to obtain the requisite regulatory approvals for our product candidates. Regulatory

**Table of Contents**

authorities may not permit us to undertake any additional clinical trials for our product candidates, and it may be difficult to design efficacy studies for product candidates in new indications.

Clinical trials of each of our product candidates involve a technology and a drug. This makes testing more complex because the outcome of the trials depends on the performance of technology in combination with a drug.

We have other product candidates in preclinical development. Preclinical and clinical development efforts performed by us may not be successfully completed. Completion of clinical trials may take several years or more. The length of time can vary substantially with the type, complexity, novelty and intended use of the product candidate. The commencement and rate of completion of clinical trials may be delayed by many factors, including:

- the potential delay by a collaborative partner in beginning the clinical trial;
- the inability to recruit clinical trial participants at the expected rate;
- the failure of clinical trials to demonstrate a product candidate's safety or efficacy;
- the inability to follow patients adequately after treatment;
- unforeseen safety issues;
- the inability to manufacture sufficient quantities of materials used for clinical trials; or
- unforeseen governmental or regulatory delays.

If a product candidate fails to demonstrate safety and efficacy in clinical trials, this failure may delay development of other product candidates and hinder our ability to conduct related preclinical testing and clinical trials. As a result of these failures, we may also be unable to find additional collaborative partners or to obtain additional financing. Our business, results of operations and financial condition may be materially adversely affected by any delays in, or termination of, our clinical trials.

***We depend on third parties in the conduct of our clinical trials for our product candidates and any failure of those parties to fulfill their obligations could adversely affect our development and commercialization plans.***

We depend on independent clinical investigators, contract research organizations and other third party service providers and our collaborators in the conduct of our clinical trials for our product candidates. We rely heavily on these parties for successful execution of our clinical trials but do not control many aspects of their activities. For example, the investigators are not our employees. However, we are responsible for ensuring that each of our clinical trials is conducted in accordance with the general investigational plan and protocols for the trial. Third parties may not complete activities on schedule or may not conduct our clinical trials in accordance with regulatory requirements or our stated protocols. The failure of these third parties to carry out their obligations could delay or prevent the development, approval and commercialization of our product candidates.

***We may not become profitable on a sustained basis.***

With the exception of fiscal years 2006 through 2008, we have had net operating losses since being founded in 1987. At March 31, 2008, our accumulated deficit was \$456.6 million. There can be no assurance we will achieve sustained profitability.

A major component of our revenue is dependent on our partners' ability to sell, and our ability to manufacture economically, our marketed products RISPERDAL CONSTA and VIVITROL. In addition, if VIVITROL sales are not sufficient, we could have significant losses in the future due to ongoing expenses to develop and commercialize VIVITROL.

**Table of Contents**

Our ability to achieve sustained profitability in the future depends, in part, on our ability to:

- obtain and maintain regulatory approval for our products and product candidates in the U.S. and in foreign countries;
- efficiently manufacture our commercial products;
- support the marketing and sale of RISPERDAL CONSTA by our partner Janssen;
- support the marketing and sale of VIVITROL by our partner Cephalon;
- support the regulatory approval and, if approved, the marketing and sale of VIVITROL by our partner Cilag GmbH;
- enter into agreements to develop and commercialize our products and product candidates;
- develop and expand our capacity to manufacture and market our products and product candidates;
- obtain adequate reimbursement coverage for our products from insurance companies, government programs and other third party payors;
- obtain additional research and development funding from collaborative partners or funding for our proprietary product candidates; or
- achieve certain product development milestones.

In addition, the amount we spend will impact our profitability. Our spending will depend, in part, on:

- the progress of our research and development programs for proprietary and collaborative product candidates, including clinical trials;
- the time and expense that will be required to pursue FDA and/or foreign regulatory approvals for our product candidates and whether such approvals are obtained;
- the time and expense required to prosecute, enforce and/or challenge patent and other intellectual property rights;
- the cost of building, operating and maintaining manufacturing and research facilities;
- the number of product candidates we pursue, particularly proprietary product candidates;
- how competing technological and market developments affect our product candidates;
- the cost of possible acquisitions of technologies, compounds, product rights or companies;
- the cost of obtaining licenses to use technology owned by others for proprietary products and otherwise; and
- the costs of potential litigation.

We may not achieve any or all of these goals and, thus, we cannot provide assurances that we will ever be profitable on a sustained basis or achieve significant revenues. Even if we do achieve some or all of these goals, we may not achieve significant commercial success.

***We may require additional funds to complete our programs and such funding may not be available on commercially favorable terms and may cause dilution to our existing shareholders.***

We may require additional funds to complete any of our programs, and may seek funds 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. If we are unable to raise additional funds on terms that are favorable to us, we may have to cut back significantly on one or more of our programs, give up some of our rights to our technologies, product candidates or licensed products or agree to reduced royalty rates from collaborative partners. If we issue additional equity securities or securities convertible into equity

**Table of Contents**

securities to raise funds, our shareholders will suffer dilution of their investment and it may adversely affect the market price of our common stock.

***The FDA or foreign regulatory agencies may not approve our product candidates.***

Approval from the FDA is required to manufacture and market pharmaceutical products in the U.S. Regulatory agencies in foreign countries have similar requirements. The process that pharmaceutical products must undergo to obtain this approval is extensive and includes preclinical testing and clinical trials to demonstrate safety and efficacy and a review of the manufacturing process to ensure compliance with cGMP regulations. The FDA or foreign regulatory agencies may choose not to communicate with or update us during clinical testing and regulatory review periods. The ultimate decision by the FDA or foreign regulatory agencies regarding drug approval may not be consistent with prior communications. See risk factor RISPARDAL CONSTA, VIVITROL and our product candidates may not generate significant revenues.

This process can last many years, be very costly and still be unsuccessful. FDA or foreign regulatory approval can be delayed, limited or not granted at all for many reasons, including:

a product candidate may not be safe or effective;

data from preclinical testing and clinical trials may be interpreted by the FDA or foreign regulatory agencies in different ways than we or our partners interpret it;

the FDA or foreign regulatory agencies might not approve our manufacturing processes or facilities;

the FDA or foreign regulatory agencies may change their approval policies or adopt new regulations;

a product candidate may not be approved for all the indications we or our partners request; or

the FDA or foreign regulatory agencies may not agree with our or our partners regulatory approval strategies or components of our or our partners filings, such as clinical trial designs.

For some product candidates utilizing our drug delivery technologies, the drug used has not been approved at all or has not been approved for every indication for which it is being tested. Any delay in the approval process for any of our product candidates will result in increased costs that could materially adversely affect our business, results of operations and financial condition.

Regulatory approval of a product candidate generally is limited to specific therapeutic uses for which the product has demonstrated safety and efficacy in clinical testing. Approval of a product candidate could also be contingent on post-marketing studies. In addition, any marketed drug and its manufacturer continue to be subject to strict regulation after approval. Any unforeseen problems with an approved drug or any violation of regulations could result in restrictions on the drug, including its withdrawal from the market.

***Our business is subject to extensive governmental regulation and oversight and changes in laws could adversely affect our revenues and profitability.***

Our business is subject to extensive government regulation and oversight. As a result, we may become subject to governmental actions which could materially adversely affect our business, results of operations and financial condition, including:



Edgar Filing: ALKERMES INC - Form 10-K

new laws, regulations or judicial decisions, or new interpretations of existing laws, regulations or decisions, related to patent protection and enforcement, health care availability, method of delivery and payment for health care products and services or our business operations generally;

changes in the FDA and foreign regulatory approval processes that may delay or prevent the approval of new products and result in lost market opportunity;

new laws, regulations and judicial decisions affecting pricing or marketing; and

changes in the tax laws relating to our operations.

**Table of Contents**

In addition, the Food and Drug Administration Amendments Act of 2007 included new authorization for the FDA to require post-market safety monitoring, along with a clinical trials registry, and expanded authority for FDA to impose civil monetary penalties on companies that fail to meet certain commitments.

***Our revenues depend on payment and reimbursement from third party payors, and a reduction in payment rate or reimbursement could result in decreased use or sales of our products.***

In both domestic and foreign markets, sales of our products are dependent, in part, on the availability of reimbursement from third party payors such as state and federal governments, under programs such as Medicare and Medicaid in the U.S., and private insurance plans. In certain foreign markets, the pricing and profitability of our products, such as RISPERDAL CONSTA, generally are subject to government controls. In the U.S., there have been, there are, and we expect there will continue to be, a number of state and federal proposals that could limit the amount that state or federal governments will pay to reimburse the cost of pharmaceutical products. Legislation or regulatory action that reduces reimbursement for our products could materially adversely impact our business. In addition, we believe that private insurers, such as managed care organizations, may adopt their own reimbursement reductions unilaterally, or in response to any such federal legislation. Reduction in reimbursement for our products could have a material adverse effect on our results of operations and financial condition. Also, we believe the increasing emphasis on management of the utilization and cost of healthcare in the U.S. has and will continue to put pressure on the price and usage of our products, which may materially adversely impact product sales. Further, when a new therapeutic product is approved, the availability of governmental and/or private reimbursement for that product is uncertain, as is the amount for which that product will be reimbursed. We cannot predict the availability or amount of reimbursement for our approved products or product candidates, including those at any stage of development, and current reimbursement policies for marketed products may change at any time.

If reimbursement for our products changes adversely or if we fail to obtain adequate reimbursement for our other current or future products, healthcare providers may limit how much or under what circumstances they will prescribe or administer them, which could reduce the use of our products or cause us to reduce the price of our products.

***Failure to comply with government regulations regarding our products could harm our business.***

Our activities, including the sale and marketing of our products, are subject to extensive government regulation and oversight, including regulation under the federal Food, Drug and Cosmetic Act and other federal and state statutes. We are also subject to the provisions of the Federal Anti-Kickback Statute, and several similar state laws, which prohibit payments intended to induce physicians or others either to purchase or arrange for or recommend the purchase of healthcare products or services. While the federal law applies only to products or services for which payment may be made by a federal healthcare program, state laws may apply regardless of whether federal funds may be involved. These laws constrain the sales, marketing and other promotional activities of manufacturers of drugs and biologicals, such as us, by limiting the kinds of financial arrangements, including sales programs, with hospitals, physicians, and other potential purchasers of drugs and biologicals. Other federal and state laws generally prohibit individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid, or other third party payors that are false or fraudulent, or are for items or services that were not provided as claimed. Anti-kickback and false claims laws prescribe civil and criminal penalties for noncompliance that can be substantial, including the possibility of exclusion from federal healthcare programs (including Medicare and Medicaid).

Pharmaceutical and biotechnology companies have been the target of lawsuits and investigations alleging violations of government regulation, including claims asserting antitrust violations, violations of the Federal False Claim Act, the Anti-Kickback Statute, the Prescription Drug Marketing Act and other violations in connection with off-label

promotion of products and Medicare and/or Medicaid reimbursement or related to environmental matters and claims under state laws, including state anti-kickback and fraud laws.

While we continually strive to comply with these complex requirements, interpretations of the applicability of these laws to marketing practices are ever evolving. If any such actions are instituted against us or our

**Table of Contents**

collaboration partners and we are not successful in defending ourselves or asserting our rights, those actions could have a significant and material impact on our business, including the imposition of significant fines or other sanctions. Even an unsuccessful challenge could cause adverse publicity and be costly to respond to, and thus could have a material adverse effect on our business, results of operations and financial condition.

***If and when approved, the commercial use of our products may cause unintended side effects or adverse reactions or incidence of misuse may occur.***

We cannot predict whether the commercial use of products (or product candidates in development, if and when they are approved for commercial use) will produce undesirable or unintended side effects that have not been evident in the use of, or in clinical trials conducted for, such products (and product candidates) to date. Additionally, incidents of product misuse may occur. These events, among others, could result in product recalls, product liability actions or withdrawals or additional regulatory controls, all of which could have a material adverse effect on our business, results of operations and financial condition.

***Patent protection for our products is important and uncertain.***

The following factors are important to our success:

receiving and maintaining patent protection for our products and product candidates, including those which are the subject of collaborations with our collaborative partners;

maintaining our trade secrets;

not infringing the proprietary rights of others; and

preventing others from infringing our proprietary rights.

Patent protection only provides rights of exclusivity for the term of the patent. We will be able to protect our proprietary rights from unauthorized use by third parties only to the extent that our proprietary rights are covered by valid and enforceable patents or are effectively maintained as trade secrets.

We know of several U.S. patents issued to third parties that may relate to our product candidates. We also know of patent applications filed by other parties in the U.S. and various foreign countries that may relate to some of our product candidates if such patents are issued in their present form. If patents are issued that cover our product candidates, we may not be able to manufacture, use, offer for sale, import or sell some of them without first getting a license from the patent holder. The patent holder may not grant us a license on reasonable terms or it may refuse to grant us a license at all. This could delay or prevent us from developing, manufacturing or selling those of our product candidates that would require the license. A patent holder might also file an infringement action against us claiming that the manufacture, use, offer for sale, import or sale of our product candidates infringed one or more of its patents. Our cost of defending such an action is likely to be high and we might not receive a favorable ruling.

We try to protect our proprietary position by filing U.S. and foreign patent applications related to our proprietary technology, inventions and improvements that are important to the development of our business. Our pending patent applications, together with those we may file in the future, or those we may license from third parties, may not result in patents being issued. Even if issued, such patents may not provide us with sufficient proprietary protection or competitive advantages against competitors with similar technology. Because the patent position of pharmaceutical and biotechnology companies involves complex legal and factual questions, enforceability of patents cannot be predicted with certainty. The ultimate degree of patent protection that will be afforded to biotechnology products and

processes, including ours, in the U.S. and in other important markets remains uncertain and is dependent upon the scope of protection decided upon by the patent offices, courts and lawmakers in these countries, including, within the U.S., possible new patent legislation. Patents, if issued, may be challenged, invalidated or circumvented. The laws of certain foreign countries may not protect our intellectual property rights to the same extent as do the laws of the U.S. Thus, any patents that we own or license from others may not provide any protection against competitors. Furthermore, others may independently develop similar technologies outside the scope of our patent coverage.

**Table of Contents**

We also rely on trade secrets, know-how and technology, which are not protected by patents, to maintain our competitive position. We try to protect this information by entering into confidentiality agreements with parties that have access to it, such as our collaborative partners, licensees, employees and consultants. Any of these parties may breach the agreements and disclose our confidential information or our competitors might learn of the information in some other way. If any trade secret, know-how or other technology not protected by a patent were to be disclosed to, or independently developed by, a competitor, our business, results of operations and financial condition could be materially adversely affected.

As more products are commercialized using our technologies, or as any product achieves greater commercial success, our patents become more likely to be subject to challenge by potential competitors.

***Uncertainty over intellectual property in the biotechnology industry has been the source of litigation, which is inherently costly and unpredictable.***

We are aware that others, including various universities and companies working in the biotechnology field, have filed patent applications and have been granted patents in the U.S. and in other countries claiming subject matter potentially useful to our business. Some of those patents and patent applications claim only specific products or methods of making such products, while others claim more general processes or techniques useful or now used in the biotechnology industry. There is considerable uncertainty within the biotechnology industry about the validity, scope and enforceability of many issued patents in the U.S. and elsewhere in the world, and, to date, there is no consistent policy regarding the breadth of claims allowed in biotechnology patents. We cannot currently determine the ultimate scope and validity of patents which may be granted to third parties in the future or which patents might be asserted to be infringed by the manufacture, use and sale of our products.

There has been, and we expect that there may continue to be, significant litigation in the industry regarding patents and other intellectual property rights. Litigation and administrative proceedings concerning patents and other intellectual property rights may be protracted, expensive and distracting to management. Competitors may sue us as a way of delaying the introduction of our products. Any litigation, including any interference proceedings to determine priority of inventions, oppositions to patents in foreign countries or litigation against our partners may be costly and time consuming and could harm our business. We expect that litigation may be necessary in some instances to determine the validity and scope of certain of our proprietary rights. Litigation may be necessary in other instances to determine the validity, scope and/or noninfringement of certain patent rights claimed by third parties to be pertinent to the manufacture, use or sale of our products. Ultimately, the outcome of such litigation could adversely affect the validity and scope of our patent or other proprietary rights, or, conversely, hinder our ability to manufacture and market our products.

***If we do not realize the expected benefits from the restructuring plan we announced in March 2008, our operating results and financial conditions will be negatively impacted.***

On March 19, 2008, following the termination by Lilly of the AIR Insulin program, we announced a restructuring of our operations designed to align our cost structure with near-term revenues. Accordingly, we reduced our workforce by approximately 150 employees and closed our AIR commercial manufacturing facility in Chelsea, Massachusetts. We announced that we were taking a restructuring charge in the fourth quarter of fiscal 2008 associated with the reduction in workforce and facility-related expenses, and an impairment charge in the fourth quarter of fiscal 2008 related to fixed assets at our Chelsea facility. We also announced expected cost savings from the restructuring in fiscal 2009. If we are unable to realize the expected operational efficiencies from our restructuring, our results of operations and financial condition will be adversely affected.

***We may be exposed to product liability claims and recalls.***

We may be exposed to product liability claims arising from the commercial sale of RISPERDAL CONSTA and VIVITROL, or the use of our product candidates in clinical trials or commercially, once approved. These claims may be brought by consumers, clinical trial participants, our collaborative partners or third parties selling the products. We currently carry product liability insurance coverage in such amounts as

**Table of Contents**

we believe are sufficient for our business. However, we cannot provide any assurance that this coverage will be sufficient to satisfy any liabilities that may arise. As our development activities progress and we continue to have commercial sales, this coverage may be inadequate, we may be unable to obtain adequate coverage at an acceptable cost or we may be unable to get adequate coverage at all or our insurer may disclaim coverage as to a future claim. This could prevent or limit our commercialization of our product candidates or commercial sales of our products. Even if we are able to maintain insurance that we believe is adequate, our results of operations and financial condition may be materially adversely affected by a product liability claim.

Additionally, product recalls may be issued at our discretion or at the direction of the FDA, other government agencies or other companies having regulatory control for pharmaceutical product sales. We cannot assure you that product recalls will not occur in the future or that, if such recalls occur, such recalls will not adversely affect our business, results of operations and financial condition or reputation.

***We may not be successful in the development of products for our own account.***

In addition to our development work with collaborative partners, we are developing proprietary product candidates for our own account by applying our technologies to off-patent drugs as well as developing our own proprietary molecules. Because we will be funding the development of such programs, there is a risk that we may not be able to continue to fund all such programs to completion or to provide the support necessary to perform the clinical trials, obtain regulatory approvals or market any approved products on a worldwide basis. We expect the development of products for our own account to consume substantial resources. If we are able to develop commercial products on our own, the risks associated with these programs may be greater than those associated with our programs with collaborative partners.

***If we are not able to develop new products, our business may suffer.***

We compete with other biotechnology and pharmaceutical companies with financial resources and capabilities substantially greater than our resources and capabilities, in the development of new products. We cannot assure you that we will be able to:

- develop or successfully commercialize new products on a timely basis or at all; or
- develop new products in a cost effective manner.

Further, other companies, including our collaborators, may develop products or may acquire technology for the development of products that are the same as or similar to our platform technologies or to the product candidates we have in development. Because there is rapid technological change in the industry and because other companies have more resources than we do, other companies may:

- develop their products more rapidly than we can;
- complete any applicable regulatory approval process sooner than we can; or
- offer their newly developed products at prices lower than our prices.

Any of the foregoing may negatively impact our sales of newly developed products. Technological developments or the FDA's approval of new therapeutic indications for existing products may make our existing products, or those product candidates we are developing, obsolete or may make them more difficult to market successfully, any of which could have a material adverse effect on our business, results of operations and financial condition.



***Potential tax liabilities could adversely affect our results.***

We are subject to both federal and state taxes on income. Significant judgment is required in determining our provision for income taxes. Although we believe our tax estimates are reasonable, the final determination of tax audits and any related litigation could be materially different than that which is reflected in historical income tax provisions and accruals. In such case, the potential exists for audit findings to have a material effect on our income tax provision and net income in the period or periods in which that determination is made.

**Table of Contents**

***Foreign currency exchange rates may affect revenue.***

We derive more than fifty percent (50%) of our RISPERDAL CONSTA revenues from sales in foreign countries. Such revenues may fluctuate when translated to U.S. dollars as a result of changes in foreign currency exchange rates. We currently do not hedge this exposure. An increase in the U.S. dollar relative to other currencies in which we have revenues will cause our revenues to be lower than with a stable exchange rate. A large increase in the value of the U.S. dollar relative to such foreign currencies could have a material adverse affect on our revenues, results of operations and financial condition.

***We face competition in the biotechnology and pharmaceutical industries, and others.***

We can provide no assurance that we will be able to compete successfully in developing our products and product candidates.

We face intense competition in the development, manufacture, marketing and commercialization of our products and product candidates from many and varied sources from academic institutions, government agencies, research institutions and biotechnology and pharmaceutical companies, including other companies with similar technologies. Some of these competitors are also our collaborative partners. These competitors are working to develop and market other systems, products, vaccines and other methods of preventing or reducing disease, and new small-molecule and other classes of drugs that can be used without a drug delivery system.

There are other companies developing extended-release and pulmonary technologies. In many cases, there are products on the market or in development that may be in direct competition with our products or product candidates. In addition, we know of new chemical entities that are being developed that, if successful, could compete against our product candidates. These chemical entities are being designed to work differently than our product candidates and may turn out to be safer or to be more effective than our product candidates. Among the many experimental therapies being tested around the world, there may be some that we do not now know of that may compete with our technologies or product candidates. Our collaborative partners could choose a competing technology to use with their drugs instead of one of our technologies and could develop products that compete with our products.

With respect to our injectable technology, we are aware that there are other companies developing extended-release delivery systems for pharmaceutical products. RISPERDAL CONSTA may compete with a number of other injectable products being developed, including paliperidone palmitate, an injectable, four-week, long-acting product being developed by Johnson & Johnson, and a number of new oral compounds for the treatment of schizophrenia.

VIVITROL competes with CAMPRAL by Forest Laboratories, Inc. and ANTABUSE by Odyssey Pharmaceuticals, Inc. as well as currently marketed drugs also formulated from naltrexone, such as REVIA by Duramed Pharmaceuticals, Inc., NALOREX by Bristol-Myers Squibb Co. and DEPADE by Mallinckrodt. Other pharmaceutical companies are investigating product candidates that have shown some promise in treating alcohol dependence and that, if approved by the FDA, would compete with VIVITROL.

With respect to our AIR technology, we are aware that there are other companies marketing or developing pulmonary delivery systems for pharmaceutical products.

Many of our competitors have much greater capital resources, manufacturing, research and development resources and production facilities than we do. Many of them also have much more experience than we do in preclinical testing and clinical trials of new drugs and in obtaining FDA and foreign regulatory approvals.

Major technological changes can happen quickly in the biotechnology and pharmaceutical industries, and the development of technologically improved or different products or technologies may make our product candidates or platform technologies obsolete or noncompetitive.

Our product candidates if successfully developed and approved for commercial sale, will compete with a number of drugs and therapies currently manufactured and marketed by major pharmaceutical and other biotechnology companies. Our product candidates may also compete with new products currently under development by others or with products which may cost less than our product candidates. Physicians, patients,

**Table of Contents**

third party payors and the medical community may not accept or utilize any of our product candidates that may be approved. If our product candidates, if and when approved, do not achieve significant market acceptance, our business, results of operations and financial condition may be materially adversely affected. For more information on other factors that would impact the market acceptance of our product candidates, if and when approved, see the risk factor RISPARDAL CONSTA, VIVITROL and our product candidates may not generate significant revenues.

***RISPARDAL CONSTA revenues may not be sufficient to repay RC Royalty Sub, LLC's obligations for the non-recourse RISPARDAL CONSTA secured 7% notes (the 7% Notes).***

Pursuant to the terms of a purchase and sales agreement between Alkermes and its wholly-owned subsidiary, RC Royalty Sub, LLC ( Royalty Sub ), Royalty Sub is obligated to repay certain obligations to holders of the 7% Notes. There can be no assurance that Royalty Sub will have sufficient funds to satisfy these obligations. If revenues from RISPARDAL CONSTA are not sufficient to repay Royalty Sub's obligations on the 7% notes at maturity, then the note holders may have the right to take control of Royalty Sub and all of its assets. If Janssen terminates the manufacturing and supply agreement and the license agreements with us, whether or not due to a lack of revenues, and revenues on RISPARDAL CONSTA are not sufficient to repay Royalty Sub's obligations on the 7% Notes, the note holders may be entitled to certain of our rights to RISPARDAL CONSTA.

***We may not be able to retain our key personnel.***

Our success depends largely upon the continued service of our management and scientific staff and our ability to attract retain and motivate highly skilled technical, scientific, management, regulatory compliance and marketing personnel. The loss of key personnel or our inability to hire and retain personnel who have technical, scientific or regulatory compliance backgrounds could materially adversely affect our research and development efforts and our business.

***Future transactions may harm our business or the market price of our stock.***

We regularly review potential transactions related to technologies, products or product rights and businesses complementary to our business. These transactions could include:

- mergers;
- acquisitions;
- strategic alliances;
- licensing agreements; and
- co-promotion agreements.

We may choose to enter into one or more of these transactions at any time, which may cause substantial fluctuations in the market price of our stock. Moreover, depending upon the nature of any transaction, we may experience a charge to earnings, which could also materially adversely affect our results of operations and could harm the market price of our stock.

***If we issue additional common stock, shareholders may suffer dilution of their investment and a decline in stock price.***

As discussed above under the risk factor We may require additional funds to complete our programs and such funding may not be available on commercially favorable terms and may cause dilution to our existing shareholders, we may issue additional equity securities or securities convertible into equity securities to raise funds, thus reducing the ownership share of the current holders of our common stock, which may adversely affect the market price of the common stock. As of March 31, 2008, we were obligated to issue 19,059,655 shares of common stock upon the vesting and exercise of stock options and vesting of stock

**Table of Contents**

awards. In addition, any of our shareholders could sell all or a large number of their shares, which could adversely affect the market price of our common stock.

***Funds associated with certain of our auction rate securities may not be accessible for in excess of 12 months and our auction rate securities may experience an other-than-temporary decline in value, which would adversely affect our results of operations and financial condition.***

Our marketable securities portfolio, which totals \$357.1 million at March 31, 2008, includes auction rate securities of \$10.0 million (at cost). The auction rate securities are structured with short-term interest rate reset dates of generally 30 days and with long-term contractual maturities. At the end of each interest rate reset period, investors can sell or continue to hold the securities at par. In the fourth quarter of fiscal year 2008, each of the two auction rate securities we invested in failed auction due to sell orders exceeding buy orders. Based on our impairment analysis, we recorded a temporary impairment on these investments within other comprehensive income, a component of shareholders equity, of approximately \$0.7 million at March 31, 2008. Although we believe that the decline in the value of these securities is temporary, there is a risk that the decline in value may ultimately be deemed to be other-than-temporary. In the future, should we determine that the decline in value of these auction rate securities is other-than-temporary, it would result in a loss being recorded in our consolidated statement of income, which could be material to our results of operations. The funds associated with failed auctions may not be accessible until a successful auction occurs, a buyer is found outside of the auction process or the underlying securities have matured. As a result, we have classified these securities as Investments Long-Term in our consolidated balance sheets.

***Our common stock price is highly volatile.***

The realization of any of the risks described in these risk factors or other unforeseen risks could have a dramatic and adverse effect on the market price of our common stock. Additionally, market prices for securities of biotechnology and pharmaceutical companies, including ours, have historically been very volatile. The market for these securities has from time to time experienced significant price and volume fluctuations for reasons that were unrelated to the operating performance of any one company. In particular, and in addition to circumstances described elsewhere under these risk factors, the following risk factors can adversely affect the market price of our common stock:

non-approval, set-backs or delays in the development or manufacture of our product candidates and success of our research and development programs;

public concern as to the safety of drugs developed by us or others;

announcements of issuances of common stock or acquisitions by us;

the announcement and timing of new product introductions by us or others;

material public announcements;

events related to our products or those of our competitors, including the withdrawal or suspension of products from the market;

availability and level of third party reimbursement;

political developments or proposed legislation in the pharmaceutical or healthcare industry;

economic or other external factors, disaster or crisis;

developments of our corporate partners;

termination or delay of development program(s) by our corporate partners;

announcements of technological innovations or new therapeutic products or methods by us or others;

changes in government regulations or policies or patent decisions;

changes in patent legislation or adverse changes to patent law;

**Table of Contents**

changes in key members of management;

failure to meet our financial expectations or changes in opinions of analysts who follow our stock; or

general market conditions.

***We may undertake additional strategic acquisitions in the future, and difficulties integrating such acquisitions could damage our ability to sustain profitability.***

Although we have limited experience in acquiring businesses, we may acquire additional businesses that complement or augment our existing business. If we acquire businesses with promising drug candidates or technologies, we may not be able to realize the benefit of acquiring such businesses if we are unable to move one or more drug candidates through preclinical and/or clinical development to regulatory approval and commercialization. Integrating any newly acquired businesses or technologies could be expensive and time-consuming, resulting in the diversion of resources from our current business. We may not be able to integrate any acquired business successfully. We cannot assure you that, following an acquisition, we will achieve revenues, specific net income or loss levels that justify the acquisition or that the acquisition will result in increased earnings, or reduced losses, for the combined company in any future period. Moreover, we may need to raise additional funds through public or private debt or equity financing to acquire any businesses, which would result in dilution for shareholders or the incurrence of indebtedness. We may not be able to operate acquired businesses profitably or otherwise implement our growth strategy successfully.

***Anti-takeover provisions may not benefit shareholders.***

We are a Pennsylvania corporation and Pennsylvania law contains strong anti-takeover provisions. In February 2003, our board of directors adopted a shareholder rights plan. The shareholder rights plan is designed to cause substantial dilution to a person who attempts to acquire us on terms not approved by our board of directors. The shareholder rights plan and Pennsylvania law could make it more difficult for a person or group to, or discourage a person or group from attempting to, acquire control of us, even if the change in control would be beneficial to shareholders. Our articles of incorporation and bylaws also contain certain provisions that could have a similar effect. The articles provide that our board of directors may issue, without shareholder approval, preferred stock having such voting rights, preferences and special rights as the board of directors may determine. The issuance of such preferred stock could make it more difficult for a third party to acquire us.

***Litigation and/or arbitration may result in financial losses or harm our reputation and may divert management resources.***

We may be the subject of certain claims, including those asserting violations of securities laws and derivative actions. In addition, the administration of drugs in humans, whether in clinical studies or commercially, carries the inherent risk of product liability claims whether or not the drugs are actually the cause of an injury.

We cannot predict with certainty the eventual outcome of any future litigation, arbitration or third party inquiry. We may not be successful in defending ourselves or asserting our rights in new lawsuits, investigations or claims that may be brought against us, and, as a result, our business could be materially harmed. These lawsuits, arbitrations, investigations or claims may result in large judgments or settlements against us, any of which could have a negative effect on our financial performance and business. Additionally, lawsuits, arbitrations and investigations can be expensive to defend, whether or not the lawsuit, arbitration or investigation has merit, and the defense of these actions may divert the attention of our management and other resources that would otherwise be engaged in running our business.



*We face risks related to 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 our employees of the

**Table of Contents**

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. In a letter dated May 22, 2007, the Boston District Office of the SEC informed us that its informal investigation related to our issuance of stock options has been completed, and that the SEC does not intend to recommend that any enforcement action against us be taken by the SEC. As a result of the appearance of the Report, and concurrent with the SEC 's informal inquiry, the audit committee of our 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 our management 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, in August 2006 we restated our consolidated balance sheets as of March 31, 2006 and 2005, our consolidated statements of income 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. The defendants moved to dismiss the lawsuit and, following oral argument, the Massachusetts Superior Court issued a decision dated July 10, 2007 granting the defendants' motion to dismiss the lawsuit in its entirety. The plaintiff did not appeal the Court's decision and the plaintiff's time to appeal has expired.

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 of directors 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 our board of directors. 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 our board of directors 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 our management 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 our board of directors have been presented to and adopted by our board of directors.

At this point we are unable to predict what, if any, consequences these issues relating to our option grants may have on us. There could be considerable legal and other expenses associated with any private litigation, including that described above, that might be filed relating to these issues.

**Table of Contents**

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 us, 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 and financial condition.

**Item 2. *Properties***

We lease space in Cambridge, Massachusetts under several leases, the original terms of which are effective through calendar year 2012. These leases contain provisions permitting us to extend their terms for up to two ten-year periods. Our corporate headquarters, administration areas and laboratories are located in this space. We have established and are operating clinical facilities, with the capability to produce clinical supplies of our pulmonary and injectable extended-release products, at this location.

We also lease a building in Chelsea, Massachusetts for clinical and commercial manufacturing of inhaled products based on our AIR pulmonary technology. The lease term is for fifteen years, expiring in 2015, with an option to extend the term for up to two five-year periods. The facility and equipment, which is partially funded and owned by Lilly, is designed to accommodate the manufacture of multiple products. On March 19, 2008, in connection with our restructuring of operations following the termination by Lilly of the AIR Insulin program, we announced our plans to close this facility. See Collaborative Arrangements Lilly AIR Insulin for more information about our contractual rights upon termination of the AIR Insulin program.

We own a 15-acre manufacturing, office and laboratory site in Wilmington, Ohio. The site produces RISPERDAL CONSTA, VIVITROL and clinical supplies of exenatide once weekly. We are currently operating two RISPERDAL CONSTA lines and one VIVITROL line at commercial scale, and an additional line is under construction for RISPERDAL CONSTA which is being funded by Janssen. Janssen and Cephalon own all purchased equipment that they have funded. Cephalon has granted us an option, exercisable after two years, to purchase two manufacturing lines which Cephalon funded at their then-current net book value. Janssen has granted us an option, exercisable upon 30 days advance written notice, to purchase the additional RISPERDAL CONSTA manufacturing line under construction at its then-current net book value.

We lease a commercial manufacturing facility in Cambridge, Massachusetts that we are not currently utilizing. The lease term is for fifteen years, expiring in August 2008, with an option to extend the term for one five year period. We exited this facility in connection with a restructuring of operations in June 2004 and have subleased a portion of the facility through the lease expiration date. We have no plans to extend the lease beyond its expiration date.

We believe that our current and planned facilities are adequate for our current and near-term preclinical, clinical and commercial manufacturing requirements.

**Item 3. *Legal Proceedings***

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. The defendants moved to dismiss the lawsuit and, following oral argument, the Massachusetts Superior Court issued a decision dated July 10, 2007 granting the defendants' motion to dismiss the lawsuit in its entirety. The plaintiff did not appeal the Court's decision and the

plaintiff's time to appeal has expired.

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

**Table of Contents**

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 of directors 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 our board of directors. 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 our board of directors 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 our management 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 our board of directors have been presented to and adopted by our board of directors.

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

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

No matters were submitted to a vote of our security holders, through the solicitation of proxies or otherwise, during the last quarter of the fiscal year ended March 31, 2008.

**PART II****Item 5. *Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities*****(a) *Market Information***

Our common stock is traded on the NASDAQ Stock Market under the symbol ALKS. We have 382,632 shares of our non-voting common stock issued and outstanding. There is no established public trading market for our non-voting common stock. Set forth below for the indicated periods are the high and low bid prices for our common stock:

	Fiscal 2008		Fiscal 2007	
	High	Low	High	Low
1st Quarter	\$ 17.85	\$ 14.38	\$ 22.05	\$ 17.91
2nd Quarter	18.51	14.00	19.11	13.18
3rd Quarter	18.78	12.30	17.48	13.37
4th Quarter	16.00	10.32	17.83	13.09

The last reported sale price of our common stock as reported on the NASDAQ Stock Market on May 28, 2008 was \$12.13.

**(b) *Stockholders***

There were 352 shareholders of record for our common stock and one shareholder of record for our non-voting common stock on May 28, 2008.

**Table of Contents****(c) Dividends**

No dividends have been paid on the common stock or non-voting common stock to date, and we do not expect to pay cash dividends thereon in the foreseeable future. We anticipate that we will retain all earnings, if any, to support our operations and our proprietary drug development programs. Any future determination as to the payment of dividends will be at the sole discretion of our board of directors and will depend on our financial condition, results of operations, capital requirements and other factors our board of directors deems relevant.

**(d) Securities authorized for issuance under equity compensation plans**

See Part III, Item 12 for information regarding securities authorized for issuance under our equity compensation plans.

**(e) Repurchase of equity securities**

A summary of our stock repurchase activity for the fiscal year ended March 31, 2008 is as follows:

Period	Total Number of Shares Purchased(a)	Average Price Paid per Share	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 October 31		\$		\$ 2,508
November 1 through November 30	379,600	13.85	379,600	169,743
December 1 through December 31	1,539,727	14.55	1,539,727	147,334
January 1 through January 31	358,867	15.84	358,867	141,649
February 1 through February 29	3,373,313	12.79	3,373,313	98,499
March 1 through March 31	1,317,229	12.79	1,317,229	\$ 81,649
Total	6,968,736	\$ 13.39	6,968,736	

(a) In November 2007, our board of directors authorized a program to repurchase up to \$175.0 million of our common stock to be repurchased at the discretion of management from time to time in the open market or through privately negotiated transactions. The repurchase program has no set expiration date and may be suspended or discontinued at any time. We publicly announced the share repurchase program in our press release dated November 21, 2007. We purchased 6,968,736 shares at a cost of approximately \$93.4 million under this program during the year ended March 31, 2008 by means of a prepaid stock repurchase program and open market purchases. The approximate dollar value of shares that may yet be purchased under this program is \$81.6 million as of March 31, 2008.

In September 2005, our board of directors authorized a program to repurchase up to \$15.0 million of our common stock to be repurchased at the discretion of management from time to time in the open market or through privately



negotiated transactions. We publicly announced the share repurchase program in our press release for the fiscal year 2006 second quarter financial results dated November 3, 2005. Upon the adoption of the \$175.0 million share repurchase program in November 2007, the repurchase authorization of \$2.5 million remaining under this program was superceded, and no repurchase authorization remains outstanding under this program.

In addition to the stock repurchases above, during the year ended March 31, 2008, we acquired, by means of net share settlements, 77,094 shares of Alkermes common stock, at an average price of \$17.31 per share, related to the vesting of employee stock awards to satisfy withholding tax obligations. In addition, during the year ended March 31, 2008, we acquired 8,675 shares of Alkermes common stock, at an average price of \$16.77 per share, tendered by employees as payment of the exercise price of stock options granted under our equity compensation plans.

**Table of Contents****Performance Graph**

The following graph compares the yearly percentage change in the cumulative total shareholder return on our common stock for the last five fiscal years, with the cumulative total return on the Nasdaq Stock Market Index and the Nasdaq Biotechnology Index. The comparison assumes \$100 was invested on March 31, 2003 in our common stock and in each of the foregoing indices and further assumes reinvestment of any dividends. We did not declare or pay any dividends on our common stock during the comparison period.

**Comparison of Cumulative Total Returns**

	<b>2003</b>	<b>2004</b>	<b>2005</b>	<b>2006</b>	<b>2007</b>	<b>2008</b>
Alkermes, Inc.	100	176	114	242	170	131
NASDAQ Stock Market Index	100	148	149	175	182	170
NASDAQ Biotechnology Index	100	152	127	164	152	152

**Table of Contents****Item 6. Selected Financial Data**

The following financial data should be read in conjunction with our consolidated financial statements and related notes appearing elsewhere in this Form 10-K, beginning on page F-1.

**Alkermes, Inc. and Subsidiaries**

	<b>2008</b>	<b>Year Ended March 31,</b>			<b>2004</b>
		<b>2007</b>	<b>2006</b>	<b>2005</b>	
	<b>(In thousands, except per share data)</b>				
<b>Consolidated Statements of Operations Data:</b>					
<b>REVENUES:</b>					
Manufacturing revenues	\$ 101,700	\$ 105,416	\$ 64,901	\$ 40,488	\$ 25,736
Royalty revenues	29,457	23,151	16,532	9,636	3,790
Research and development revenue under collaborative arrangements	89,510	74,483	45,883	26,002	9,528
Net collaborative profit	20,050	36,915	39,285		
<b>Total revenues</b>	<b>240,717</b>	<b>239,965</b>	<b>166,601</b>	<b>76,126</b>	<b>39,054</b>
<b>EXPENSES:</b>					
Cost of goods manufactured(1)	40,677	45,209	23,489	16,834	19,037
Research and development(1)	125,268	117,315	89,068	91,641	92,101
Selling, general and administrative(1)	59,508	66,399	40,383	29,499	27,206
Impairment of long-lived assets	11,630				
Restructuring(2)	6,423			11,527	(208)
<b>Total expenses</b>	<b>243,506</b>	<b>228,923</b>	<b>152,940</b>	<b>149,501</b>	<b>138,136</b>
<b>OPERATING (LOSS) INCOME</b>	<b>(2,789)</b>	<b>11,042</b>	<b>13,661</b>	<b>(73,375)</b>	<b>(99,082)</b>
<b>OTHER INCOME (EXPENSE):</b>					
Gain on sale of investment in Reliant Pharmaceuticals, Inc.	174,631				
Interest income	17,834	17,707	11,569	3,005	3,409
Interest expense	(16,370)	(17,725)	(20,661)	(7,394)	(6,497)
Derivative (loss) income related to convertible subordinated notes(3)			(1,084)	4,385	(4,514)
Other income (expense), net(4)(5)	(476)	(481)	333	(1,789)	2,118
<b>Total other income (expense)</b>	<b>175,619</b>	<b>(499)</b>	<b>(9,843)</b>	<b>(1,793)</b>	<b>(5,484)</b>
<b>INCOME (LOSS) BEFORE INCOME TAXES</b>	<b>172,830</b>	<b>10,543</b>	<b>3,818</b>	<b>(75,168)</b>	<b>(104,566)</b>
<b>INCOME TAXES</b>	<b>5,851</b>	<b>1,098</b>			

Edgar Filing: ALKERMES INC - Form 10-K

NET INCOME (LOSS)	\$ 166,979	\$ 9,445	\$ 3,818	\$ (75,168)	\$ (104,566)
EARNINGS (LOSS) PER COMMON SHARE:					
BASIC	\$ 1.66	\$ 0.10	\$ 0.04	\$ (0.83)	\$ (1.27)
DILUTED	\$ 1.62	\$ 0.09	\$ 0.04	\$ (0.83)	\$ (1.27)
WEIGHTED AVERAGE NUMBER OF COMMON SHARES OUTSTANDING:					
BASIC	100,742	99,242	91,022	90,094	82,083
DILUTED	102,923	103,351	97,377	90,094	82,083

**Table of Contents**

	2008	2007	March 31, 2006 (In thousands)	2005	2004
<b>Consolidated Balance Sheet Data:</b>					
Cash, cash equivalents and investments	\$ 460,361	\$ 357,466	\$ 303,112	\$ 202,567	\$ 143,936
Total assets	656,311	568,621	477,163	338,874	270,030
Long-term debt(6)	160,324	156,898	279,518	276,485	122,584
Unearned milestone revenue – current and long-term portions	117,657	128,750	99,536		
Redeemable convertible preferred stock			15,000	30,000	30,000
Shareholders' equity	305,314	203,461	33,216	4,112	75,930

- (1) Includes share-based compensation expense as a result of the adoption of Statement of Financial Accounting Standard ( SFAS ) No. 123(R), *Share-Based Payment* on April 1, 2006 (see Note 9 in the notes to the consolidated financial statements included in this Annual Report on Form 10-K).
- (2) Represents charges (recoveries) in connection with our March 2008, June 2004 and August 2002 restructurings of operations. The June 2004 and August 2002 restructuring programs were substantially completed during fiscal 2005 and 2003, respectively. Certain closure costs related to the leased facilities exited in connection with the March 2008 restructuring of operations will continue to be paid through December 2015.
- (3) Represents noncash (loss) income in connection with derivative liabilities associated with the two-year interest make-whole ( Two-Year Interest Make-Whole ) payment provision of our 6.52% convertible senior subordinated notes ( 6.52% Senior Notes ) and the three-year interest make-whole ( Three-Year Interest Make-Whole ) payment provision of our 2.5% convertible subordinated notes ( 2.5% Subordinated Notes ). The derivative liability is recorded at fair value in the consolidated balance sheets.
- (4) Primarily represents income (expense) recognized on the changes in the fair value of warrants of public companies held by us in connection with collaboration and licensing arrangements, which are recorded as derivatives under Other assets in the 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.
- (5) Includes a charge of approximately \$0.3 million in fiscal 2006 for recognizing the cumulative effect of initially applying Financial Accounting Standards Board ( FASB ) interpretation No. 47, *Accounting for Conditional Asset Retirement Obligations* ( FIN No. 47 ).
- (6) Includes the 7% Notes which were issued by Royalty Sub and are non-recourse to Alkermes.

**Table of Contents**

**Item 7. *Management's Discussion and Analysis of Financial Condition and Results of Operations***

**Introduction**

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

**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; recognition of milestone payments from our partner Cilag related to the future sales of VIVITROL in Russia and the countries of the CIS; the successful continuation of development activities for our programs, including exenatide once weekly; the successful manufacture of our products and product candidates, including RISPERDAL CONSTA and VIVITROL at a commercial scale, and the successful manufacture of exenatide once weekly by Amylin; 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 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 requirements or the requirements of our partners Cephalon and Cilag, 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/or 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/or our partner Cephalon may be unable to commercialize VIVITROL successfully; (vi) Cilag may be unable to receive approval for, and if approved commercialize successfully, VIVITROL in Russia and the countries of the CIS; (vii) VIVITROL may not produce significant revenues; (viii) 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.; (ix) third party payors may not cover or reimburse

## **Table of Contents**

VIVITROL; (x) we may be unable to scale-up and manufacture our product candidates, including exenatide once weekly, ALKS 27, ALKS 29 and extended-release naltrexone, commercially or economically; (xi) we may not be able to source raw materials for our production processes from third parties; (xii) we may not be able to successfully transfer manufacturing technology and related systems for exenatide once weekly to Amylin, and Amylin may not be able to successfully operate the manufacturing facility for exenatide once weekly; (xiii) 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; (xiv) we rely on our partners to determine the regulatory and marketing strategies for RISPERDAL CONSTA and our other partnered, non-proprietary programs; (xv) RISPERDAL CONSTA, VIVITROL and our product candidates in commercial use may have unintended side effects, adverse reactions or incidents of misuse and the FDA or other health authorities could require post approval studies or require removal of our products from the market; (xvi) 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; (xvii) clinical trials may take more time or consume more resources than initially envisioned; (xviii) results of earlier clinical trials may not necessarily be predictive of the safety and efficacy results in larger clinical trials; (xix) 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; (xx) 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; (xxi) 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; (xxii) technological change in the biotechnology or pharmaceutical industries could render our products and/or product candidates obsolete or non-competitive; (xxiii) difficulties or set-backs in obtaining and enforcing our patents and difficulties with the patent rights of others could occur; (xxiv) we may incur losses in the future; (xxv) we face potential liabilities and diversion of management's attention as a result of private litigation relating to our past practices with respect to equity incentives; and (xxvi) we may need to raise substantial additional funding to continue research and development programs and clinical trials and other operations and could incur difficulties or setbacks in raising such funds.

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.

## **Critical Accounting Policies**

While our significant accounting policies are more fully described in Note 2 to our consolidated financial statements included in this Form 10-K, we believe the following accounting policies are important to the portrayal of our financial condition and results of operations and can require estimates from time to time.

### ***Manufacturing and Royalty Revenues***

We recognize revenue from manufacturing under certain manufacturing and supply arrangements when the product has been shipped, title and risk of loss have passed to the customer and collection from the customer is reasonably assured. We recognize manufacturing revenue from Janssen based on information they supply to us, which may require estimates to be made. We receive royalties related to the sale of RISPERDAL CONSTA in the period the product is sold by Janssen.



***Research and Development Revenue Under Collaborative Arrangements***

Our research and development revenue consists of nonrefundable research and development funding under collaborative arrangements with various collaborative partners. We are generally compensated for formulation,

**Table of Contents**

preclinical and clinical testing related to the collaborative research programs using a negotiated full-time equivalent or hourly rate for hours worked by our employees, plus any direct external research costs, if any. We recognize research and development revenue under collaborative arrangements over the term of the applicable agreements through the application of a proportional performance model where revenue is recognized in an amount equal to the lesser of the amount due under the agreements or an amount based on the proportional performance to date. We recognize nonrefundable payments and fees for the licensing of technology or intellectual property rights over the related performance period or when there is no remaining performance recorded. Nonrefundable payments and fees are recorded as deferred revenue or unearned milestone revenue upon receipt and may require deferral of revenue recognition to future periods.

At times, we enter into arrangements with customers or collaborators that have multiple elements. To recognize a delivered item in a multiple element arrangement, delivered items must have value to the customer on a stand-alone basis, there must be objective and reliable evidence of fair value of the undelivered items and that delivery or performance is probable and within our control for any delivered items that have a right of return.

***Revenue related to the License and Collaboration Agreement and Supply Agreement (together, the Agreements ) with Cephalon***

For purposes of revenue recognition, the deliverables under these Agreements are generally separated into three units of accounting: (i) net losses on the products; (ii) manufacturing of the products; and (iii) the product license.

Under the terms of the Agreements, we were responsible for the first \$120.0 million of net product losses through December 31, 2007, which increased pursuant to the Amendments (see below) to \$124.6 million (the cumulative net loss cap ). The net product losses excluded development costs incurred by us to obtain FDA approval of VIVITROL and costs incurred by us to complete the first VIVITROL manufacturing line, both of which were our sole responsibility. Cephalon was responsible to pay all net product losses in excess of the cumulative net loss cap through December 31, 2007. After December 31, 2007, all net profits and losses earned on the product are divided between us and Cephalon in approximately equal shares. Cumulative net product losses since inception of the Agreements through March 31, 2008 were \$174.8 million.

Cephalon records net sales from the products in the U.S. We and Cephalon reconcile the costs incurred in the period by each party to develop, commercialize and manufacture the products against revenues earned on the products in the period, to determine net profits or losses on the products in the period. To the extent that the cash earned or expended by either of the parties exceeds or is less than its proportional share of net profit or loss for the period, the parties settle by delivering cash such that the net cash earned or expended equals each party's proportional share. The cash flow between the companies related to our share of net profits or losses is recorded in the period in which it was made as Net collaborative profit in the consolidated statements of income and comprehensive income.

The costs incurred by us and Cephalon with respect to the development and commercialization of the products, and which are charged into the collaboration, include employee time, which is billed to the collaboration at negotiated full-time equivalent ( FTE ) rates, and external expenses incurred by the parties with respect to the products. FTE rates vary depending on the nature of the activity performed (such as development and sales) and are intended to approximate our actual costs. Cost of goods manufactured related to the products is based on a fully burdened manufacturing cost, determined in accordance with accounting standards generally accepted in the United States ( GAAP ).

The nonrefundable payments of \$160.0 million and \$110.0 million we received from Cephalon in June 2005 and April 2006, respectively, and the \$4.6 million payment we received from Cephalon in December 2006, pursuant to the Amendments (see below), have been deemed to be arrangement consideration in accordance with Emerging Issues

Task Force Issue No. 00-21, *Revenue Arrangements with Multiple Deliverables* ( EITF No. 00-21 ). This arrangement consideration is recognized as milestone revenue across the three accounting units referred to above. The allocation of the arrangement consideration to each of the accounting units was based initially on the fair value of each unit as determined at the date the consideration

**Table of Contents**

was received. Of the initial \$160.0 million nonrefundable payment we received from Cephalon upon signing the Agreements, we allocated \$144.4 million to the accounting unit net losses on the products , comprising the \$124.6 million of net product losses for which we were responsible and the \$19.8 million of expenses we incurred in obtaining FDA approval of VIVITROL and completing the first manufacturing line. The remaining \$20.2 million of the \$160.0 million payment was allocated to the accounting unit product license . Of the \$110.0 million nonrefundable payment we received from Cephalon upon VIVITROL approval, we allocated \$77.8 million to the accounting unit manufacturing of the products and applied the remaining \$32.2 million to the accounting unit product license . The \$4.6 million payment we received from Cephalon pursuant to the Amendments has been allocated to the accounting unit net losses on the products . The fair values of the accounting units are reviewed periodically and adjusted, as appropriate. The above payments were recorded in the consolidated balance sheets as Unearned milestone revenue current portion and Unearned milestone revenue long-term portion prior to being earned. The classification between the current and long-term portions is based on our best estimate of whether the milestone revenue will be recognized during or after the 12-month period following the reporting period, respectively.

In October 2006, we and Cephalon entered into binding amendments to the license and collaboration agreement and the supply agreement (the Amendments ). Under the Amendments, the parties agreed that Cephalon would purchase from us two VIVITROL manufacturing lines (and related equipment) under construction. Amounts we received from Cephalon for the sale of the two VIVITROL manufacturing lines were recorded as Deferred revenue long-term portion in the consolidated balance sheets and will be recorded as revenue over the depreciable life of the assets in amounts equal to the related asset depreciation once the assets are placed in service. Future purchases of physical assets by Cephalon will be accounted for in a consistent way. Beginning October 2006, all FTE-related costs we incur that are reimbursable by Cephalon related to the construction and validation of the two additional VIVITROL manufacturing lines are recorded as research and development revenue as incurred. In December 2006, we received a \$4.6 million payment from Cephalon as reimbursement for certain costs we incurred prior to October 2006, which we had charged to the collaboration and that were related to the construction of the VIVITROL manufacturing lines. These costs consisted primarily of internal or temporary employee time, billed at negotiated FTE rates. We and Cephalon agreed to increase the cumulative net loss cap from \$120.0 million to \$124.6 million to account for this reimbursement.

*Manufacturing Revenues Related to the Agreements with Cephalon*

Under the terms of the Agreements, we are responsible for the manufacture of clinical and commercial supplies of the products for sale in the U.S. Under the terms of the Agreements, we bill Cephalon at cost for finished product shipped to them. We record this manufacturing revenue as Manufacturing revenues in the consolidated statements of income and comprehensive income. An amount equal to this manufacturing revenue is recorded as cost of goods manufactured in the consolidated statements of income and comprehensive income. Manufacturing revenue and cost of goods manufactured related to VIVITROL were recorded for the first time in the year ended March 31, 2007, as we began shipping VIVITROL to Cephalon.

The amount of the arrangement consideration allocated to the accounting unit manufacturing of the products is based on the estimated fair value of manufacturing profit to be earned over the expected ten year life of VIVITROL.

Manufacturing profit is estimated at 10% of the forecasted cost of goods manufactured over the expected life of VIVITROL. This profit margin was determined by reference to margins on other products we produce for partners, an analysis of margins enjoyed by other pharmaceutical contract manufacturers and other available data. The forecast of units to be manufactured was negotiated between us and Cephalon. Our obligation to manufacture VIVITROL is limited to volumes that we are capable of supplying at our manufacturing facility, and the units to be manufactured in the forecast are in line with, and do not exceed, this maximum anticipated capacity. We estimate the fair value of this accounting unit to be \$77.8 million, and this amount was allocated out of the \$110.0 million in consideration we

received from Cephalon upon FDA approval of VIVITROL. We record the earned portion of the arrangement consideration allocated to this accounting unit to revenue in proportion to the units of finished VIVITROL shipped during the reporting

**Table of Contents**

period, to the total expected units of finished VIVITROL to be shipped over the expected life of VIVITROL. This milestone revenue is recorded as *Manufacturing revenues* in the consolidated statements of income and comprehensive income. During the years ended March 31, 2008, 2007 and 2006, we recorded \$0.6 million, \$1.5 million and \$0 of milestone revenue, respectively, related to this accounting unit.

*Net Collaborative Profit Related to the Agreements with Cephalon*

The amount of the arrangement consideration allocated to the accounting unit *net losses on the products* represents our best estimate of the net product losses that we were responsible for through December 31, 2007, plus those development costs incurred by us to obtain FDA approval of VIVITROL and to complete the first manufacturing line, both of which were our sole responsibility. We estimate the fair value of this accounting unit to be approximately \$144.4 million and this amount was allocated out of the \$160.0 million in consideration we received from Cephalon upon signing the Agreements. We record the earned portion of the arrangement consideration allocated to this accounting unit to revenue in the period that we were responsible for product losses, being the period ending December 31, 2007. This milestone revenue directly offsets our expenses incurred on VIVITROL and Cephalon's net losses on VIVITROL and is recorded as *Net collaborative profit* in the consolidated statements of income and comprehensive income. During the years ended March 31, 2008, 2007 and 2006, we recorded \$5.3 million, \$78.8 million and \$60.5 million, respectively, of milestone revenue related to this accounting unit. In the years ended March 31, 2008, 2007 and 2006, because a portion of these amounts related to cash returned to Cephalon as reimbursement for its net losses up to the cumulative net loss cap, those net payments, which totaled \$5.2 million, \$47.0 million and \$21.2 million, respectively, were netted against the milestone revenue. In addition, in the year ended March 31, 2008, we received cash of \$14.8 million from Cephalon as reimbursement for our net product losses that exceeded the cumulative net loss cap through December 31, 2007 and to reimburse us for expenses that exceeded our share of net product losses after December 31, 2007.

Under the terms of the Agreements, we granted Cephalon a co-exclusive license to our patents and know-how necessary to use, sell, offer for sale and import the products for all current and future indications in the U.S. The arrangement consideration allocated to the product license is based on the residual method of allocation as outlined in EITF No. 00-21, because fair value evidence exists separately for the undelivered obligations under the Agreements. The arrangement consideration allocated to this accounting unit equals the total arrangement consideration received from Cephalon less the fair value of the manufacturing obligations and the net losses on VIVITROL. We estimate the fair value of this accounting unit to be approximately \$52.4 million of the \$274.6 million in total consideration we received to date. We record the earned portion of the arrangement consideration allocated to the product license to revenue on a straight-line basis over the expected life of VIVITROL, being ten years. This revenue is recorded as *Net collaborative profit* in the consolidated statements of income and comprehensive income. We began to recognize milestone revenue related to this accounting unit upon FDA approval of VIVITROL in April 2006. During the years ended March 31, 2008, 2007 and 2006, we recorded \$5.2 million, \$5.1 million and \$0 of milestone revenue, respectively, related to the product license.

If there are significant changes in our estimates of the fair value of an accounting unit, we would reallocate the arrangement consideration to the accounting units based on the revised fair values. This revision would be recognized prospectively in the consolidated statements of income and comprehensive income over the remaining terms of the affected accounting units.

Under the terms of the Agreements, Cephalon will pay us up to \$220.0 million in nonrefundable milestone payments if calendar year net sales of the products exceed certain agreed-upon sales levels. Under current accounting guidance, we expect to recognize these milestone payments in the period earned as *Net collaborative profit* in the consolidated statements of income and comprehensive income.

***Restructuring Charges***

We have, at times, announced restructuring programs and, accordingly, recorded certain charges in connection with implementing such programs. These charges generally include employee separation costs,

**Table of Contents**

including severance and related benefits, as well as facility consolidation and closure costs. Actual costs may differ from those estimates, and in the event that we under-or over-estimate the restructuring charges and related accruals, our reported expenses for a reporting period may be overstated or understated and may require adjustment in the future.

***Impairment of Long-Lived Assets***

Our long-lived assets to be held and used, including property plant and equipment, are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of the assets may not be recoverable. Conditions that would necessitate an impairment assessment include a significant decline in the observable market value of an asset, a significant change in the extent or manner in which an asset is used, or a significant adverse change that would indicate that the carrying amount of an asset or group of assets is not recoverable. Determination of recoverability is based on an estimate of undiscounted future cash flows resulting from the use of the asset and its eventual disposition. In the event that such cash flows are not expected to be sufficient to recover the carrying amount of the assets, the assets are written-down to their estimated fair values. Long-lived assets to be disposed of are carried at fair value less costs to sell.

***Income Taxes***

We use the asset and liability method of accounting for deferred income taxes. Our most significant tax jurisdictions are the U.S. federal government and states. Significant judgments, estimates and assumptions regarding future events, such as the amount, timing and character of income, deductions and tax credits, are required in the determination of our provision for income taxes and whether valuation allowances are required against deferred tax assets. In evaluating our ability to recover our deferred tax assets, we consider all available positive and negative evidence including our past operating results, the existence of cumulative income in the most recent fiscal years, changes in the business in which we operate and our forecast of future taxable income. In determining future taxable income, we are responsible for assumptions utilized including the amount of state, federal and international pre-tax operating income, the reversal of temporary differences and the implementation of feasible and prudent tax planning strategies. These assumptions require significant judgment about the forecasts of future taxable income and are consistent with the plans and estimates that we are using to manage the underlying businesses. As of March 31, 2008, we determined that it is more likely than not that the deferred tax assets will not be realized and a full valuation allowance has been recorded.

We account for uncertain tax positions in accordance with FASB Interpretation No. 48, *Accounting for Uncertainty in Income Taxes* an Interpretation of FASB Statement No. 109 ( FIN No. 48 ). FIN No. 48 prescribes a recognition threshold and measurement attribute for financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return and also provides guidance on various related matters such as derecognition, interest and penalties, and disclosure. We also recognize interest and penalties, if any, related to unrecognized tax benefits in income tax expense.

***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. The assumptions used to estimate the fair value of stock options include the expected option term, which takes into account both the contractual term of the option and the effect of our employees' expected exercise and post-vesting termination behavior; expected volatility of our common stock over the



option's expected term; the risk-free interest rate over the option's expected term; and our expected annual dividend yield. Certain of these assumptions are

**Table of Contents**

highly subjective and require the exercise of management judgment. For the year ended March 31, 2008, these weighted-average assumptions were as follows:

Expected option term	4 - 7 years
Expected stock volatility	38% - 50%
Risk-free interest rate	2.78% - 5.07%
Expected annual dividend yield	

In addition, our management must also apply judgment in developing an estimate of awards that may be forfeited. For the year ended March 31, 2008, we used a forfeiture estimate of 4.75% for members of our senior management and 12% for the rest of our employees. For all of the assumptions used in determining the fair value and forfeiture estimates, our historical experience is generally the starting point for developing our expectations, which may be modified to reflect information available at the time of grant that would indicate that the future is reasonably expected to differ from the past.

***Investments***

We invest our excess cash balances in short-term and long-term investments consisting of U.S. government obligations, investment grade corporate notes, commercial paper and student loan backed auction rate securities issued by major financial institutions in accordance with documented corporate policies and we limit the amount of credit exposure to any one financial institution or corporate issuer. The earnings on our investment portfolios may be adversely affected by changes in interest rates, credit ratings, collateral value, the overall strength of credit markets and other factors that may result in other-than-temporary declines in the value of the securities. On a quarterly basis, we review the fair market value of our investments in comparison to historical cost. If the fair market value of a security is significantly less than its carrying value, we consider all available evidence in assessing when and if the value of the investment can be expected to recover to at least its historical cost. This evidence would include:

the extent and duration to which fair value is less than cost;

historical operating performance and financial condition of the issuer, including industry and sector performance;

short and long-term prospects of the issuer and its industry;

specific events that occurred affecting the issuer;

overall market conditions and trends; and

our ability and intent to retain the investment for a period of time sufficient to allow for a recovery in value.

If our review indicates that the decline in value is other-than-temporary, we write down our investment to the then current market value and record an impairment charge to our consolidated statements of income and comprehensive income. The determination of whether an unrealized loss is other-than-temporary requires significant judgment, and can have a material impact on our reported earnings.

At March 31, 2008, we had available-for-sale, long-term investments with maturities in excess of one year that had gross unrealized losses of \$2.7 million. These investments were in a continuous unrealized loss position for less than twelve months, and we believe these losses are temporary and we have the intent and ability to hold these securities to

recovery, which may be at maturity. The investments consisted of investment grade corporate debt securities, auction rate debt securities and asset backed debt securities.

**Results of Operations**

Net income for the year ended March 31, 2008 was \$167.0 million, or \$1.66 per common share basic and \$1.62 per common share diluted, as compared net income for the year ended March 31, 2007 of \$9.4 million, or \$0.10 per common share basic and \$0.09 per common share diluted, and net income of \$3.8 million, or \$0.04 per common share basic and diluted, for the year ended March 31, 2006. Net income



VIVITROL to Cephalon for the first time during the quarter ended June 30, 2006, and during the remainder of the fiscal year ended March 31, 2007 we shipped quantities sufficient to build inventory to support the commercial launch of the product. We are currently managing our manufacturing volumes of VIVITROL to avoid excess inventory and shipped a small quantity of product to Cephalon during the year ended March 31, 2008. VIVITROL manufacturing revenues for the year ended March 31, 2008 and 2007 included \$2.2 million and \$3.7 million, respectively, of billings for idle capacity costs. VIVITROL manufacturing revenues for the year ended March 31, 2008 and 2007 included \$0.6 million and \$1.5 million, respectively, of milestone revenue related to manufacturing profit on VIVITROL, which equals a 10% markup on VIVITROL cost of goods manufactured and draws down unearned milestone revenue. See Note 2 to the

**Table of Contents**

consolidated financial statements included in this Form 10-K, *Revenue Recognition, Manufacturing Revenues Related to the Agreements with Cephalon* for additional information related to manufacturing profit on VIVITROL.

All of our royalty revenues for the years ended March 31, 2008, 2007 and 2006 were related to sales of RISPERDAL CONSTA. Under our license agreements with Janssen, we record royalty revenues equal to 2.5% of Janssen's net sales of RISPERDAL CONSTA in the period that the product is sold by Janssen. Royalty revenues for the years ended March 31, 2008, 2007 and 2006 were based on RISPERDAL CONSTA sales of \$1,176.5 million, \$924.2 million and \$659.4 million, respectively. The increase in sales of RISPERDAL CONSTA for the years ended March 31, 2008 and 2007 was due in part to fluctuations in the exchange ratio of the U.S. dollar and the foreign currencies of the countries in which the product was sold.

The increase in research and development revenue under collaborative arrangements ( R&D Revenue ) for the year ended March 31, 2008, as compared to the year ended March 31, 2007, was primarily due to an increase in revenues on the exenatide once weekly and AIR Insulin development programs, partially offset by reductions in revenues on other development programs and to reduced revenues related to work we performed on construction and validation of additional VIVITROL manufacturing lines at our Ohio manufacturing facility, which were constructed under the Amendments with Cephalon. For the years ended March 31, 2008, 2007 and 2006, R&D revenue related to the work we performed on the VIVITROL manufacturing lines totaled \$1.2 million, \$4.6 million and \$0, respectively. In addition, R&D revenue for the year ended March 31, 2008 included recognition of a \$5.0 million payment we received from Amylin in December 2007 related to the phase 3 clinical program for exenatide once weekly. Upon achievement of the milestone, we recalculated the amounts due under the proportional performance model, and based on the proportional performance to date, adjusted revenues to the lesser of the amount due under the contract or the amount based on the proportional performance to date, and based on the amount of effort that had been expended to date, we were able to recognize the full amount as revenue in the period received.

The increase in research and development revenue under collaborative arrangements for the year ended March 31, 2007, as compared to the year ended March 31, 2006, was primarily due to increases in revenues related to work performed on the exenatide once weekly, AIR Insulin and AIR PTH programs and revenues related to work performed on the construction and validation of additional VIVITROL manufacturing lines at our Ohio manufacturing facility, which were constructed under the Amendments with Cephalon. R&D revenue related to the work we performed on the VIVITROL manufacturing lines totaled \$4.6 million and \$0 for the years ended March 31, 2007 and 2006, respectively.

Net collaborative profit for the years ended March 31 was as follows:

	2008	2007	2006
	(In millions)		
Milestone revenue cost recovery	\$ 5.3	\$ 78.8	\$ 60.5
Milestone revenue license	5.2	5.1	
Total milestone revenue cost recovery and license	10.5	83.9	60.5
Payments made to Cephalon(1)	(5.2)	(47.0)	(21.2)
Payments from Cephalon(1)	14.8		
Net collaborative profit	\$ 20.1	\$ 36.9	\$ 39.3

- (1) Through March 31, 2008, the cumulative net losses on VIVITROL were \$174.8 million, of which \$68.8 million was incurred by us on behalf of the collaboration and \$106.0 million was incurred by Cephalon on behalf of the collaboration.

Gross sales of VIVITROL by Cephalon were \$18.0 million, \$6.5 million and \$0 for the years ended March 31, 2008, 2007 and 2006, respectively.

For the years ended March 31, 2008, 2007 and 2006, we recognized \$5.3 million, \$78.8 million and \$60.5 million of milestone revenue cost recovery, respectively, to offset net losses on VIVITROL that we





The decrease in cost of goods manufactured for VIVITROL in the year ended March 31, 2008, as compared to the year ended March 31, 2007, was due to lower manufacturing activity and shipments of VIVITROL. We began shipping VIVITROL to Cephalon for the first time during the quarter ended June 30, 2006, and during the remainder of the fiscal year ended March 31, 2007, we shipped quantities sufficient to build inventory to support the commercial launch of the product. We are currently managing our manufacturing volumes of VIVITROL to avoid excess inventory and shipped a small quantity of product to Cephalon during the year ended March 31, 2008. Cost of goods manufactured for VIVITROL for the years ended March 31, 2008 and 2007 included \$2.7 million and \$3.7 million of idle capacity costs, respectively. These costs consisted of current year manufacturing costs allocated to cost of goods manufactured which were

**Table of Contents**

related to underutilized VIVITROL manufacturing capacity. For the years ended March 31, 2008, 2007 and 2006, cost of goods manufactured for VIVITROL included \$0.2 million, \$0.8 million and \$0, respectively, of share-based compensation expense.

The increase in research and development expenses for the year ended March 31, 2008, as compared to the year ended March 31, 2007, was primarily due to increased costs on the exenatide once weekly and AIR Insulin development programs, partially offset by decreased external costs related to legacy clinical trials for VIVITROL and decreased share-based compensation expense. The increase in research and development expenses for the year ended March 31, 2007, as compared to the year ended March 31, 2006, was primarily due to increased personnel-related costs, raw materials used during work we performed on our product candidates, increased cost for third party packaging of clinical drug product and to share-based compensation expense resulting from the adoption of SFAS No. 123(R) beginning April 1, 2006. For the years ended March 31, 2008, 2007 and 2006, research and development expenses included \$7.0 million, \$8.6 million and \$0.2 million, respectively, of share-based compensation expense.

A significant portion of our research and development expenses (including laboratory supplies, travel, dues and subscriptions, recruiting costs, temporary help costs, consulting costs and allocable costs such as occupancy and depreciation) are not tracked by project as they benefit multiple projects or our technologies in general. Expenses incurred to purchase specific services from third parties to support our collaborative research and development activities are tracked by project and are reimbursed to us by our partners. We generally bill our partners under collaborative arrangements using a negotiated FTE or hourly rate. This rate has been established by us based on our annual budget of employee compensation, employee benefits and the billable non-project-specific costs mentioned above and is generally increased annually based on increases in the consumer price index. Each collaborative partner is billed using a negotiated FTE or hourly rate for the hours worked by our employees on a particular project, plus direct external costs, if any. We account for our research and development expenses on a departmental and functional basis in accordance with our budget and management practices.

The decrease in selling, general and administrative expenses for the year ended March 31, 2008, as compared to the year ended March 31, 2007, was primarily due to decreased share-based compensation expense. The increase in selling, general and administrative expenses for the year ended March 31, 2007, as compared to the year ended March 31, 2006, was primarily due to increases in selling and marketing costs related to VIVITROL, legal fees and to share-based compensation expense resulting from the adoption of SFAS No. 123(R) beginning April 1, 2006. For the years ended March 31, 2008, 2007 and 2006, selling, general and administrative expenses included \$10.6 million, \$16.4 million and \$0.2 million, respectively, of share-based compensation expense.

In March 2008, our collaborative partner Lilly announced the decision to terminate the AIR Insulin development program. In connection with the program termination, in March 2008, our board of directors approved a plan (the 2008 Restructuring ) to reduce our workforce by approximately 150 employees and to cease operations at our AIR commercial manufacturing facility located in Chelsea, Massachusetts. As a result, we recorded a restructuring charge of \$6.9 million, made up of the following components (in millions):

Severance, continuation of benefits and outplacement services	\$ 2.9
Leasehold costs	3.9
Other contract losses	0.1
Total restructuring expenses	\$ 6.9

Restructuring charges for the year ended March 31, 2008 were reduced by \$0.5 million due to an adjustment to the accrual for restructuring charges related to restructuring activities in fiscal 2004.

We expect to pay approximately \$4.0 million of the restructuring costs related to the 2008 Restructuring in fiscal 2009. The remaining \$2.9 million primarily relates to leasehold costs and is expected to be paid out through fiscal 2015. We expect to realize a reduction in expense in the range of \$15.0 million to \$20.0 million

**Table of Contents**

from the 2008 Restructuring in fiscal 2009, primarily due to reduced employee expenses and reduced depreciation.

In connection with the termination of the AIR Insulin development program, we performed an impairment analysis on the assets that supported the production of AIR Insulin, which consisted of machinery and equipment and leasehold improvements at the AIR commercial manufacturing facility. We determined that the carrying value of the assets exceeded their fair value and recorded an impairment charge of \$11.6 million during the three months ended March 31, 2008. Fair value was based on internally established estimates and the selling prices of similar assets.

***Other Income (Expense)***

	2008	2007	2006	Change Favorable/(Unfavorable)	
				2008-2007	2007-2006
	(In millions)				
Gain on sale of investment in Reliant Pharmaceuticals, Inc.	\$ 174.6	\$	\$	\$ 174.6	\$
Interest income	17.8	17.7	11.6	0.1	6.1
Interest expense	(16.4)	(17.7)	(20.6)	1.3	2.9
Derivative loss related to convertible subordinated notes			(1.1)		1.1
Other income (expense), net	(0.4)	(0.5)	0.3	0.1	(0.8)
Total other income (expense)	\$ 175.6	\$ (0.5)	\$ (9.8)	\$ 176.1	\$ 9.3

We recorded a gain on sale of investment in Reliant of \$174.6 million in the year ended March 31, 2008. In November 2007, Reliant was acquired by GlaxoSmithKline ( GSK ) and under the terms of the acquisition we received \$166.9 million upon the closing of the transaction in exchange for our investment in Series C convertible, redeemable preferred stock of Reliant. We are entitled to receive up to an additional \$7.7 million of funds held in escrow subject to the terms of an escrow agreement between GSK and Reliant. We purchased the Series C convertible, redeemable preferred stock of Reliant for \$100.0 million in December 2001, and our investment in Reliant had a carrying value of \$0 at the time of the sale.

The increase in interest income for the year ended March 31, 2008, as compared to the year ended March 31, 2007, was primarily due to higher average cash and investment balances held, partially offset by lower interest rates earned during the year ended March 31, 2008. The increase for the year ended March 31, 2007, as compared to the year ended March 31, 2006, was primarily due to higher average cash and investment balances held and higher interest rates earned during the year ended March 31, 2007.

The decrease in interest expense for the year ended March 31, 2008, as compared to the year ended March 31, 2007, 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 year ended March 31, 2007 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. The decrease in interest expense for the year ended March 31, 2007, as compared to the year ended March 31, 2006, was also due to the conversion of our 2.5% Subordinated Notes. We incur approximately \$4.0 million of interest expense each quarter on the 7% Notes through the period until principal repayment starts on April 1, 2009.

The elimination of derivative loss related to convertible subordinated notes for the years ended March 31, 2008 and 2007 is due to the adoption of Derivative Implementation Group ( DIG ) Issue B39. Starting January 1, 2006, we no longer recorded changes in the estimated fair value of the embedded derivatives in our statement of income and comprehensive income. In June 2005, the FASB released DIG Issue B39, which modified accounting guidance for determining whether an embedded call option held by the issuer of a debt contract requires separate accounting recognition. We adopted the provisions of DIG Issue B39 in the reporting

**Table of Contents**

period beginning January 1, 2006, at which time the carrying value of the embedded derivative contained in our 2.5% Subordinated Notes was combined with the carrying value of the host contract.

Other income (expense), net consists primarily of income or expense recognized on the changes in the fair value of warrants and realized losses on available-for-sale securities and other strategic investments, which are recorded as other assets and investments long-term, respectively, in the consolidated balance sheets, and the accretion of discounts related to restructurings and asset retirement obligations. The recorded value of warrants we hold can fluctuate significantly based on fluctuations in the market value of the underlying securities. In September 2007, we exercised warrants to purchase common stock of a collaborative partner, which are considered marketable equity securities under SFAS No. 115, *Accounting for Certain Investments in Debt and Equity Securities* and are recorded as investments long-term in the accompanying consolidated balance sheets as of March 31, 2008 and 2007. As a result of our September 2007 warrant exercise, future recorded income or expense on changes in the fair value of our remaining holdings of warrants of public companies is expected to be less than the amounts recorded in previous reporting periods. In the years ended March 31, 2008, 2007 and 2006, we recorded other-than-temporary impairments on common stock holdings of our collaborators of \$1.6 million, \$0, and \$0.6 million, respectively. Future changes in the fair value of the common stock of our collaborators will be recorded in other comprehensive income until realized.

**Provision for Income Taxes**

	2008	2007	2006	2008-2007	Change Favorable / (Unfavorable) 2007-2006
	(In millions)				
Income taxes	\$ 5.9	\$ 1.1	\$	\$ (4.8)	\$ (1.1)

The provision for income taxes for the years ended March 31, 2008 and 2007 related to the U.S. alternative minimum tax ( AMT ). Utilization of tax loss carryforwards is limited in the calculation of AMT. As a result, a federal tax charge was recorded in the years ended March 31, 2008 and 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 did not record a provision for income taxes for the year ended March 31, 2006.

As of March 31, 2008, we had approximately \$249.0 million of federal net operating loss ( NOL ) carryforwards, \$158.8 million of state operating loss carryforwards, and \$27.7 million of foreign NOL and foreign capital loss carryforwards, which expire on various dates through the year 2026 or can be carried forward indefinitely. These loss carryforwards are available to reduce future federal and foreign taxable income, if any, and are subject to review and possible adjustment by the applicable taxing authorities. The available loss carryforwards that may be utilized in any future period may be subject to limitation based upon historical changes in the ownership of our stock. The valuation allowance of \$169.1 million relates to our U.S. net operating losses and deferred tax assets and certain other foreign deferred tax assets and is recorded based upon the uncertainty surrounding future utilization.

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

**Table of Contents****Capital Resources and Liquidity**

Our financial condition is summarized as follows:

	<b>March 31, 2008</b>	<b>March 31, 2007</b>
	<b>(In millions)</b>	
Cash and cash equivalents	\$ 101.2	\$ 80.5
Investments short-term	240.1	271.1
Investments long-term	119.1	5.9
Total cash, cash equivalents and investments	\$ 460.4	\$ 357.5
Working capital	\$ 371.1	\$ 370.8
Outstanding borrowings current and long-term	\$ 160.4	\$ 158.4

We invest in short-term and long-term investments consisting of U.S. government obligations, investment grade corporate notes, commercial paper and student loan backed auction rate securities issued by major financial institutions in accordance with our documented corporate policies. Our investment objectives are, first, to assure liquidity and conservation of capital and, second, to obtain investment income. We performed an analysis of our investment portfolio at March 31, 2008 for impairment and determined that we had a temporary impairment, attributed primarily to corporate debt investments, auction rate and asset backed securities, of \$2.7 million and an other-than-temporary impairment of \$1.6 million attributed to certain strategic investments in the common stock of our collaborative partners. The fair value of the investments in our strategic partners exceeds our cost basis in these investments. Temporary impairments are unrealized and are recorded in accumulated other comprehensive income, a component of shareholders' equity, and other-than-temporary impairments are realized and recorded in our statement of income.

We have reclassified \$112.4 million of our investments in securities with temporary losses at March 31, 2008, which we believe recovery of the losses will extend beyond one year, to Investments Long-Term in the accompanying consolidated balance sheet as we have the intent and ability to hold them to recovery, which may be maturity.

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 promotional expenses for any future products to be marketed by us or our collaborators, if any, may exceed revenues in the future, which may result in losses from operations. We believe that our current cash and cash equivalents and short-term investments, combined with our unused equipment lease line, anticipated interest income and anticipated revenues will generate sufficient cash flows to meet our anticipated liquidity and capital requirements through at least March 31, 2009.

***Operating Activities***

Cash provided by operating activities was \$42.4 million, \$83.5 million and \$116.7 million in the years ended March 31, 2008, 2007 and 2006, respectively. Cash provided by operating activities in the year ended March 31, 2008 decreased by \$41.1 million, as compared to the year ended March 31, 2007, primarily due to a decrease in cash flows from unearned milestone revenue. In the year ended March 31, 2007, we received nonrefundable payments of \$110.0 million from Cephalon upon FDA approval of VIVITROL and \$4.6 million from Cephalon under our Amendments. In the year ended March 31, 2008, we did not receive any such payments under our Agreements and Amendments with Cephalon.

Cash provided by operating activities in the year ended March 31, 2007 decreased by \$33.2 million, as compared to the year ended March 31, 2006, primarily due to a decrease in the cash flows from unearned milestone revenue, partially offset by an increase in cash flows from deferred revenue. In the year ended



**Table of Contents**

March 31, 2006, we received a nonrefundable payment of \$160.0 million upon signing the Agreements with Cephalon. In the year ended March 31, 2007, we received nonrefundable payments of \$110.0 million from Cephalon upon FDA approval of VIVITROL and \$4.6 million from Cephalon under our Amendments. During the years ended March 31, 2007 and 2006 we billed Cephalon \$21.6 million and \$0, respectively, for the sale of the two VIVITROL manufacturing lines, which was recorded as deferred revenue.

***Investing Activities***

Cash provided by investing activities was \$62.0 million in the year ended March 31, 2008, and cash used in investing activities was \$30.0 million and \$138.0 million in the years ended March 31, 2007 and 2006, respectively. Cash provided by investing activities in the year ended March 31, 2008 was due to the \$166.9 million we received in exchange for our investment in Series C convertible, redeemable preferred stock of Reliant, partially offset by net purchases of investments of \$83.0 million and capital expenditures of \$21.9 million.

Cash used for investing activities in the year ended March 31, 2007 was due to capital expenditures of \$36.3 million and net purchases of investments of \$6.2 million, partially offset by \$12.6 million in proceeds we received from Lilly for the sale of equipment under our supply agreement for AIR Insulin.

Cash used for investing activities in the year ended March 31, 2006 was due to capital expenditures of \$28.7 million and \$109.5 million for net purchases of investments.

***Financing Activities***

Cash used in financing activities was \$83.6 million and \$6.6 million in the years ended March 31, 2008 and 2007, respectively, and cash provided by financing activities was \$7.4 million in the year ended March 31, 2006. In the year ended March 31, 2008, we purchased our common stock for treasury at a cost of \$93.4 million, which consisted of \$33.4 million of purchases made on the open market and \$60.0 million purchased through a structured stock repurchase arrangement with a large financial institution in order to lower the average cost to acquire these shares. In the year ended March 31, 2007, we purchased \$12.5 million of our common stock for treasury on the open market. In the years ended March 31, 2008, 2007 and 2006, cash provided from the issuance of common stock in connection with our share-based compensation arrangements was \$11.2 million, \$7.5 million and \$8.6 million, respectively.

***Borrowings***

At March 31, 2008, our borrowings consisted of \$160.3 million of the 7% Notes and \$0.1 million related to a capital lease with Johnson & Johnson Finance Corporation. We are currently making interest payments on the 7% Notes, with principal payments scheduled to begin in fiscal 2010. The Johnson & Johnson capital lease will be paid in full in fiscal 2009.

Our capital expenditures 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. In connection with our arrangement with GE, we have an equipment lease line that provides us with the ability to finance up to \$18.3 million of new equipment purchases. The equipment financing would be secured by the purchased equipment and will be subject to a financial covenant and this lease line expires in December 2008. As of March 31, 2008, there were no amounts outstanding under this lease line.

We may continue to pursue opportunities to obtain additional financing in the future. Such financing may be sought through various sources, including debt and equity offerings, corporate collaborations, bank borrowings, arrangements

relating to assets or other financing methods or structures. The source, timing and availability of any financings will depend on market conditions, interest rates and other factors. Our future capital requirements will also depend on many factors, including continued scientific progress in our research and development programs (including our proprietary product candidates), the size of these programs, progress with preclinical testing and clinical trials, the time and costs involved in obtaining regulatory approvals, the

**Table of Contents**

costs involved in filing, prosecuting and enforcing patent claims, competing technological and market developments, the establishment of additional collaborative arrangements, the cost of manufacturing facilities and of commercialization activities and arrangements and the cost of product in-licensing and any possible acquisitions and, for any future proprietary products, the sales, marketing and promotion expenses associated with marketing such products. We may from time to time seek to retire or purchase our outstanding debt through cash purchases and/or exchanges for equity securities, in open market purchases, privately negotiated transactions or otherwise. Such repurchases or exchanges, if any, will depend on prevailing market conditions, our liquidity requirements, contractual restrictions and other factors. The amounts involved may be material.

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

**Contractual Obligations**

The following table summarizes our obligations to make future payments under current contracts at March 31, 2008.

Contractual Cash Obligations	Total	Less Than	One to Three	Three to Five	More than
		One Year	Years	Years	Five Years
		(Fiscal 2009)	(Fiscal 2010-2011)	(Fiscal 2012-2013)	(After Fiscal 2013)
(In thousands)					
7% Notes principal(1)	\$ 170,000	\$	\$ 113,334	\$ 56,666	\$
7% Notes interest(1)	31,237	11,900	16,858	2,479	
Capital lease obligations	48	48			
Operating lease obligations	151,353	10,136	20,488	21,605	99,124
Purchase obligations	15,052	15,052			
Capital expansion programs	804	804			
Total contractual cash obligations	\$ 368,494	\$ 37,940	\$ 150,680	\$ 80,750	\$ 99,124

(1) The 7% Notes were issued by RC Royalty Sub LLC, a wholly-owned subsidiary of Alkermes, Inc. The 7% Notes are non-recourse to Alkermes, Inc. (see Note 7 to the consolidated financial statements included in this Form 10-K).

We enter into license agreements with third parties that may require us to make royalty, milestone or other payments that are contingent upon the occurrence of certain future events linked to the successful development and commercialization of pharmaceutical products. Certain of the payments may be contingent upon the successful achievement of an important event in the development life cycle of these pharmaceutical products, which may or may

not occur. If required by the agreements, we may make royalty payments based upon a percentage of the sales of a pharmaceutical product if regulatory approval to market this product is obtained and the product is commercialized. Because of the contingent nature of these payments, we have not attempted to predict the amount or period in which such payments would possibly be made and thus they are not included in the table of contractual obligations.

This table also excludes any liabilities pertaining to uncertain tax positions as we cannot make a reliable estimate of the period of cash settlement with the respective taxing authorities. In connection with the adoption of FIN No. 48, we have approximately \$0.1 million of long term liabilities associated with uncertain tax positions at March 31, 2008.

In September 2006, we and RPI entered into a license agreement granting us exclusive rights to a family of opioid receptor compounds discovered at RPI. Under the terms of the agreement, RPI granted us an

## **Table of Contents**

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 of \$0.5 million and are obligated to pay annual fees of up to \$0.2 million, and tiered royalty payments of between 1% and 4% of annual net sales in the event any products developed under the agreement are commercialized. In addition, we are obligated to make milestone payments in the aggregate of up to \$9.1 million upon certain agreed-upon development events. All amounts paid to RPI under this license agreement have been expensed and are included in research and development expenses.

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

## **Off-Balance Sheet Arrangements**

As of March 31, 2008, we were not a party to any off-balance sheet financing arrangements, other than operating leases.

## **Recent Accounting Pronouncements**

In September 2006, the FASB issued 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 us on a prospective basis for the reporting period beginning April 1, 2008 for our financial assets and liabilities. In February 2008, the FASB issued FASB Staff Position ( FSP ) SFAS No. 157-2, which delayed the effective date of SFAS No. 157 for all nonrecurring fair value measurements of nonfinancial assets and nonfinancial liabilities until the period beginning April 1, 2009. We do not expect the adoption of SFAS No. 157 to have a significant impact on our consolidated financial statements.

In February 2007, the FASB issued SFAS No. 159, *The Fair Value Option for Financial Assets and Financial Liabilities Including an Amendment of FASB Statement No. 115* ( SFAS No. 159 ). SFAS No. 159 permits entities to elect to measure selected financial instruments and certain other items at fair value. Unrealized gains and losses on items for which the fair value option has been elected are recognized in earnings at each reporting period. SFAS No. 159 is effective for our fiscal year beginning April 1, 2008. We do not expect the adoption of SFAS No. 159 to have a significant impact on our consolidated financial statements.

In June 2007, the EITF reached a final consensus on EITF Issue No. 07-3, *Accounting for Nonrefundable Advance Payments for Goods or Services to Be Used in Future Research and Development Activities* ( EITF No. 07-3 ). EITF No. 07-3 is effective for our fiscal year beginning April 1, 2008. EITF No. 07-3 requires nonrefundable advance payments for future research and development activities to be capitalized until the goods have been delivered or related services have been performed. Adoption is on a prospective basis and could impact the timing of expense recognition for agreements entered into after March 31, 2008. We do not expect the adoption of EITF No. 07-3 to

have a significant impact on our consolidated financial statements.

In November 2007, the EITF reached a final consensus on EITF Issue No. 07-1, *Accounting for Collaborative Arrangements Related to the Development and Commercialization of Intellectual Property*

**Table of Contents**

( EITF No. 07-1 ). EITF No. 07-1 is effective for our fiscal year beginning April 1, 2009. Adoption is on a retrospective basis to all prior periods presented for all collaborative arrangements existing as of the effective date. We are currently evaluating the impact of the adoption of EITF No. 07-1 on our consolidated financial statements.

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

In May 2008, the FASB issued FASB Staff Position ( FSP ) No. APB 14-1, *Accounting for Convertible Debt Instruments That May Be Settled in Cash upon Conversion (Including Partial Cash Settlement)* ( FSP No. APB 14-1 ), which is effective for our fiscal year beginning on April 1, 2009. FSP No. APB 14-1 requires that proceeds from the issuance of such instruments be allocated between a liability and equity component in a manner that will reflect the Company's nonconvertible debt borrowing rate when interest cost is recognized in subsequent periods. Adoption is on a retrospective basis to all prior periods presented for all convertible debt instruments within the scope of the FSP existing as of the effective date. We do not expect the adoption of FSP No. APB 14-1 to have a significant impact on our consolidated financial statements.

**Item 7A. *Quantitative and Qualitative Disclosures about Market Risk***

We hold financial instruments in our investment portfolio that are sensitive to market risks. Our investment portfolio, excluding warrants and equity securities we hold in connection with our collaborations and licensing activities, is used to preserve capital until it is required to fund operations. Our held-to-maturity investments are restricted and are held as collateral under certain letters of credit related to our lease agreements. Our short-term and long-term investments consist of U.S. government obligations, investment grade corporate notes, commercial paper, auction rate securities and asset backed securities. These debt securities are: (i) classified as available-for-sale; (ii) are recorded at fair value; and (iii) are subject to interest rate risk, and could decline in value if interest rates increase. Fixed rate interest securities may have their market value adversely impacted by a rise in interest rates, while floating rate securities may produce less income than expected if interest rates fall. Due in part to these factors, our future investment income may fall short of expectation due to a fall in interest rates or we may suffer losses in principal if we are forced to sell securities that decline in the market value due to changes in interest rates. However, because we classify our investments in debt securities as available-for-sale, no gains or losses are recognized due to changes in interest rates unless such securities are sold prior to maturity or declines in fair value are determined to be other-than-temporary. Should interest rates fluctuate by 10%, our interest income would change by approximately \$2.0 million over an annual period, and the value of our marketable securities would have changed by approximately \$0.1 million as of March 31, 2008. Due to the conservative nature of our short-term and long-term investments and our investment policy, we do not believe that we have a material exposure to interest rate risk. Although our investments are subject to credit risk, our investment policies specify credit quality standards for our investments and limit the amount of credit exposure from any single issue, issuer or type of investment.

We hold investments in auction rate securities with a cost of \$10.0 million, which invest in taxable student loan revenue bonds issued by state higher education authorities which service student loans under the Federal Family Education Loan Program ( FFELP ). The bonds were AAA rated at the date of purchase and are collateralized by student loans purchased by the authorities which are guaranteed by state sponsored agencies and reinsured by the U.S. Department of Education. Liquidity for these securities is typically provided by an auction process that resets the applicable interest rate at pre-determined intervals. Each of these securities had been subject to auction processes for which there had been insufficient bidders on the scheduled auction dates and the auctions subsequently failed. We are

not able to liquidate our investments in auction rate securities until future auctions are successful, a buyer is found outside of the auction process or



**Table of Contents**

the notes are redeemed by the issuer. The securities continue to pay interest at predetermined interest rates during the periods in which the auctions have failed.

Typically, auction rate securities trade at their par value due to the short interest rate reset period and the availability of buyers of sellers of the securities at recurring auctions. However, since the security auctions have failed and fair value cannot be derived from quoted prices, we used a discounted cash flow model to determine the estimated fair value of the securities as of March 31, 2008. Our valuation analyses consider, among other items, assumptions that market participants would use in their estimates of fair value such as the collateral underlying the security, the creditworthiness of the issuer and any associated guarantees, the timing of expected future cash flows, and the expectation of the next time the security will have a successful auction or when callability features may be exercised by the issuer. These securities were also compared, when possible, to other observable market data with similar characteristics to the securities held by us. Based upon this methodology, we have recorded an unrealized loss related to our auction rate securities of approximately \$0.7 million to accumulated other comprehensive income as of March 31, 2008. We believe there are several significant assumptions that are utilized in our valuation analysis, the two most critical of which are the discount rate and the average expected term. Holding all other factors constant, if we were to increase the discount rate utilized in our valuation analysis by 50 basis points (one-half of a percentage point), this change would have the effect of reducing the fair value of our auction rate securities by approximately \$0.2 million as of March 31, 2008. Similarly, holding all other factors constant, if we were to increase the average expected term utilized in our fair value calculation by one year, this change would have the effect of reducing the fair value of our auction rate securities by approximately \$0.1 million as of March 31, 2008.

As of March 31, 2008, we determined that the securities had been temporarily impaired due to the length of time each security was in an unrealized loss position, the extent to which fair value was less than cost, financial condition and near term prospects of the issuers and our intent and ability to hold each security for a period of time sufficient to allow for any anticipated recovery in fair value. We do not expect the estimated fair value of these securities to decrease significantly in the future unless credit market conditions deteriorate significantly.

We hold investments in asset backed securities with a cost of \$9.5 million, that invest in AAA rated medium term floating rate notes ( MTN ) of Aleutian Investments, LLC ( Aleutian ) and Meridian Funding Company, LLC ( Meridian ) which are qualified special purpose entities ( QSPE ) of Ambac Financial Group, Inc. ( Ambac ) and MBIA, Inc. ( MBIA ), respectively. Ambac and MBIA are guarantors of financial obligations and are referred to as monoline financial guarantee insurance companies. The QSPE s, which purchase pools of assets or securities and fund the purchase through the issuance of MTN s, have been established to provide a vehicle to access the capital markets for asset backed securities and corporate borrowers. The MTN s include a sinking fund redemption feature which match-fund the terms of redemptions to the maturity dates of the underlying pools of assets or securities in order to mitigate potential liquidity risk to the QSPE s. As of March 31, 2008, a substantial portion of our initial investment in the Meridian MTN s had been redeemed by MBIA through scheduled sinking fund redemptions at par value, and the first sinking fund redemption on the Aleutian MTN is scheduled for June 2009.

The liquidity and fair value of these securities has been negatively impacted by the uncertainty in the credit markets, and the exposure of these securities to the financial condition of monoline financial guarantee insurance companies, including Ambac and MBIA. We may not be able to liquidate our investment in the securities before the scheduled redemptions or until trading in the securities resumes in the credit markets, which may not occur. Because the MTN s are not actively trading in the credit markets and fair value cannot be derived from quoted prices, we used a discounted cash flow model to determine the estimated fair value of the securities as of March 31, 2008. Our valuation analyses consider, among other items, assumptions that market participants would use in their estimates of fair value such as the collateral underlying the security, the creditworthiness of the issuer and the associated guarantees by Ambac and MBIA, the timing of expected future cash flows, including whether the callability features of these investments may be exercised by the issuer. Based upon this methodology, we have recorded an unrealized loss

related to these asset backed securities of approximately \$0.5 million to accumulated other comprehensive income as of March 31, 2008. We believe there are several significant assumptions that are utilized in our valuation analysis, the two most

**Table of Contents**

critical of which are the discount rate and the average expected term. Holding all other factors constant, if we were to increase the discount rate utilized in our valuation analysis by 50 basis points (one-half of a percentage point), this change would have the effect of reducing the fair value of these asset backed securities by approximately \$0.1 million as of March 31, 2008. Similarly, holding all other factors constant, if we were to assume that the expected term of these securities was the full contractual maturity, which could be through the year 2012, this change would have the effect of reducing the fair value of these asset back securities by approximately \$0.3 million as of March 31, 2008.

As of March 31, 2008, we determined that the securities had been temporarily impaired due to the length of time each security was in an unrealized loss position, the extent to which fair value was less than cost, the financial condition and near term prospects of the issuers and our intent and ability to hold each security for a period of time sufficient to allow for any anticipated recovery in fair value or until scheduled redemption. We do not expect the estimated fair value of these securities to decrease significantly in the future unless credit market conditions deteriorate significantly or the credit ratings of the issuers is downgraded.

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

As of March 31, 2008, the fair value of our 7% Notes approximates the carrying value. The interest rate 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 our consolidated financial statements.

**Foreign Currency Exchange Rate Risk**

The manufacturing and royalty revenues we receive on RISPERDAL CONSTA are a percentage of the net sales made by our collaborative partner, Janssen. Janssen derives more than fifty percent (50%) of its RISPERDAL CONSTA revenues from sales in foreign countries, and as a result, our revenues are impacted by changes in the exchange rates and their impact on Janssen sales. The manufacturing and royalty payments on these foreign sales is calculated initially in the foreign currency in which the sale is made and is then converted into U.S. dollars to determine the amount that Janssen pays us for manufacturing and royalty revenues. Fluctuations in the exchange ratio of the U.S. dollar and these foreign currencies will have the effect of increasing or decreasing our manufacturing and royalty revenues even if there is a constant amount of sales in foreign currencies. For example, if the U.S. dollar weakens against a foreign currency, then our manufacturing and royalty revenues will increase given a constant amount of sales in such foreign currency.

The impact on our 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.

**Table of Contents****Item 8. Financial Statements and Supplementary Data****Unaudited Quarterly Financial Data Year Ended March 31, 2008**

	<b>June 30, 2007</b>	<b>Three Months Ended</b>		<b>March 31, 2008</b>
		<b>September 30, 2007</b>	<b>December 31, 2007</b>	
	(In thousands, except per share data)			
<b>REVENUES:</b>				
Manufacturing revenues	\$ 31,517	\$ 24,137	\$ 14,275	\$ 31,771
Royalty revenues	6,982	7,348	7,384	7,743
Research and development revenue under collaborative arrangements	23,450	21,206	23,985	20,869
Net collaborative profit	6,989	5,909	5,127	2,025
<b>Total revenues</b>	<b>68,938</b>	<b>58,600</b>	<b>50,771</b>	<b>62,408</b>
<b>EXPENSES:</b>				
Cost of goods manufactured	10,145	9,218	7,499	13,815
Research and development	32,619	28,317	30,395	33,937
Selling, general and administrative	15,400	14,487	15,249	14,372
Impairment of long-lived assets				11,630
Restructuring				6,423
<b>Total expenses</b>	<b>58,164</b>	<b>52,022</b>	<b>53,143</b>	<b>80,177</b>
<b>OPERATING INCOME (LOSS)</b>	<b>10,774</b>	<b>6,578</b>	<b>(2,372)</b>	<b>(17,769)</b>
<b>OTHER INCOME (EXPENSE):</b>				
Gain on sale of investment in Reliant Pharmaceuticals, Inc.			174,631	
Interest income	4,402	4,246	4,292	4,894
Interest expense	(4,073)	(4,077)	(4,088)	(4,132)
Other income (expense), net	26	1,151	(393)	(1,260)
<b>Total other income (expense)</b>	<b>355</b>	<b>1,320</b>	<b>174,442</b>	<b>(498)</b>
<b>INCOME (LOSS) BEFORE INCOME TAXES</b>	<b>11,129</b>	<b>7,898</b>	<b>172,070</b>	<b>(18,267)</b>
<b>INCOME TAXES</b>	<b>2,382</b>	<b>200</b>	<b>3,189</b>	<b>80</b>
<b>NET INCOME (LOSS)</b>	<b>\$ 8,747</b>	<b>\$ 7,698</b>	<b>\$ 168,881</b>	<b>\$ (18,347)</b>
<b>EARNINGS (LOSS) PER COMMON SHARE:</b>				
<b>BASIC</b>	<b>\$ 0.09</b>	<b>\$ 0.08</b>	<b>\$ 1.66</b>	<b>\$ (0.19)</b>
<b>DILUTED</b>	<b>\$ 0.08</b>	<b>\$ 0.07</b>	<b>\$ 1.63</b>	<b>\$ (0.19)</b>

WEIGHTED AVERAGE NUMBER OF  
COMMON SHARES OUTSTANDING:

BASIC	101,324	101,595	101,703	97,919
DILUTED	104,191	104,315	103,914	97,919

**Table of Contents****Unaudited Quarterly Financial Data Year Ended March 31, 2007**

	<b>Three Months Ended</b>			
	<b>June 30,</b>	<b>September 30,</b>	<b>December 31,</b>	<b>March 31,</b>
	<b>2006</b>	<b>2006</b>	<b>2006</b>	<b>2007</b>
	<b>(In thousands, except per share data)</b>			
<b>REVENUES:</b>				
Manufacturing revenues	\$ 22,193	\$ 26,122	\$ 28,763	\$ 28,338
Royalty revenues	5,139	5,813	5,673	6,526
Research and development revenue under collaborative arrangements	14,464	17,624	19,532	22,863
Net collaborative profit	9,742	11,611	8,445	7,117
<b>Total revenues</b>	<b>51,538</b>	<b>61,170</b>	<b>62,413</b>	<b>64,844</b>
<b>EXPENSES:</b>				
Cost of goods manufactured	9,338	11,822	12,989	11,060
Research and development	25,863	29,817	29,908	31,727
Selling, general and administrative	16,530	15,677	16,365	17,827
<b>Total expenses</b>	<b>51,731</b>	<b>57,316</b>	<b>59,262</b>	<b>60,614</b>
<b>OPERATING (LOSS) INCOME</b>	<b>(193)</b>	<b>3,854</b>	<b>3,151</b>	<b>4,230</b>
<b>OTHER INCOME (EXPENSE):</b>				
Interest income	4,335	4,734	4,260	4,378
Interest expense	(5,473)	(4,034)	(4,141)	(4,077)
Other income (expense), net	787	(664)	89	(693)
<b>Total other income (expense)</b>	<b>(351)</b>	<b>36</b>	<b>208</b>	<b>(392)</b>
<b>(LOSS) INCOME BEFORE INCOME TAXES</b>	<b>(544)</b>	<b>3,890</b>	<b>3,359</b>	<b>3,838</b>
<b>INCOME TAXES</b>	<b>171</b>	<b>164</b>	<b>426</b>	<b>337</b>
<b>NET (LOSS) INCOME</b>	<b>\$ (715)</b>	<b>\$ 3,726</b>	<b>\$ 2,933</b>	<b>\$ 3,501</b>
<b>(LOSS) EARNINGS PER COMMON SHARE:</b>				
<b>BASIC</b>	<b>\$ (0.01)</b>	<b>\$ 0.04</b>	<b>\$ 0.03</b>	<b>\$ 0.03</b>
<b>DILUTED</b>	<b>\$ (0.01)</b>	<b>\$ 0.04</b>	<b>\$ 0.03</b>	<b>\$ 0.03</b>
<b>WEIGHTED AVERAGE NUMBER OF COMMON SHARES OUTSTANDING:</b>				
<b>BASIC</b>	<b>93,784</b>	<b>101,331</b>	<b>100,896</b>	<b>101,025</b>
<b>DILUTED</b>	<b>93,784</b>	<b>105,543</b>	<b>104,746</b>	<b>104,034</b>

All financial statements, other than the quarterly financial data as required by Item 302 of Regulation S-K summarized above, required to be filed hereunder, are filed as an exhibit hereto, are listed under Item 15(a) (1) and (2), and are incorporated herein by reference.

**Item 9. *Changes in and Disagreements with Accountants on Accounting and Financial Disclosure***

The information required by this item is incorporated herein by reference to Form 8-K dated and filed on July 10, 2007.

**Item 9A. *Controls and Procedures***

(a) Evaluation of disclosure controls and procedures

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) of the

**Table of Contents**

Securities Exchange Act of 1934) as of March 31, 2008. This evaluation included consideration of the controls, processes and procedures that comprise our internal control over financial reporting. Based on such evaluation, our Chief Executive Officer and Chief Financial Officer concluded that, as of March 31, 2008, our disclosure controls and procedures were effective to provide reasonable assurance that information required to be disclosed by us in the reports that we file under the Securities Exchange Act of 1934 is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms and that such information is accumulated and communicated to our management as appropriate to allow timely decisions regarding required disclosure.

(b) Evaluation of internal control over financial reporting

Management's Annual Report on Internal Control over Financial Reporting

Management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Exchange Act Rules 13a-15(f). Under the supervision and with the participation of management, including our Chief Executive Officer and Chief Financial Officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting as of March 31, 2008, based on the framework in Internal Control Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission ( COSO ).

In completing our assessment, no material weaknesses in our internal controls over financial reporting as of March 31, 2008 were identified. In addition, based on such assessment, our Chief Executive Officer and Chief Financial Officer concluded that, as of March 31, 2008, our disclosure controls and procedures were effective to provide reasonable assurance that information required to be disclosed by us in the reports that we file under the Securities Exchange Act of 1934 is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms and that such information is accumulated and communicated to our management as appropriate to allow timely decisions regarding required disclosure.

Management's assessment of the effectiveness of our internal control over financial reporting as of March 31, 2008 has been attested to by PricewaterhouseCoopers LLP, an independent registered public accounting firm, as stated in their report which is included herein.

(c) Changes in internal controls

No change in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) occurred during the quarter ended March 31, 2008 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

(d) Inherent Limitations of Disclosure Controls and Internal Control Over Financial Reporting

The effectiveness of our disclosure controls and procedures and our internal control over financial reporting is subject to various inherent limitations, including cost limitations, judgments used in decision making, assumptions about the likelihood of future events, the soundness of our systems, the possibility of human error, and the risk of fraud. Moreover, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions and the risk that the degree of compliance with policies or procedures may deteriorate over time. Because of these limitations, there can be no assurance that any system of disclosure controls and procedures or internal control over financial reporting will be successful in preventing all errors or fraud or in making all material information known in a timely manner to the appropriate levels of management.

**Item 9B. Other Information**



Our policy governing transactions in our securities by our directors, officers and employees permits our officers, directors and employees to enter into trading plans in accordance with Rule 10b5-1 under the Exchange Act. During the year ending March 31, 2008, Mr. Floyd E. Bloom and Mr. Paul J. Mitchell, directors of the Company, entered into trading plans in accordance with Rule 10b5-1 and our policy governing transactions in our securities by our directors, officers and employees. We undertake no obligation to update or revise the information provided herein, including for revision or termination of an established trading plan.

**Table of Contents**

**PART III**

**Item 10. *Directors and Executive Officers of the Registrant***

The information required by this item is incorporated herein by reference to our Proxy Statement for our annual shareholders meeting (the 2008 Proxy Statement ).

**Item 11. *Executive Compensation***

The information required by this item is incorporated herein by reference to the 2008 Proxy Statement.

**Item 12. *Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters***

The information required by this item is incorporated herein by reference to the 2008 Proxy Statement.

**Item 13. *Certain Relationships and Related Transactions***

The information required by this item is incorporated herein by reference to the 2008 Proxy Statement.

**Item 14. *Principal Accounting Fees and Services***

The information required by this item is incorporated herein by reference to the 2008 Proxy Statement.

**PART IV**

**Item 15. *Exhibits and Financial Statement Schedules***

(a) (1) *Consolidated Financial Statements* The consolidated financial statements of Alkermes, Inc. required by this item are submitted in a separate section beginning on page F-1 of this Form 10-K.

(2) *Financial Statement Schedules* All schedules have been omitted because of the absence of conditions under which they are required or because the required information is included in the consolidated financial statements or notes thereto.

**EXHIBIT INDEX**

**Exhibit  
No.**

- 3.1 Third Amended and Restated Articles of Incorporation as filed with the Pennsylvania Secretary of State on June 7, 2001. (Incorporated by reference to Exhibit 3.1 to the Registrant's Report on Form 10-K for the fiscal year ended March 31, 2001 (File No. 001-14131).)
- 3.1(a) Amendment to Third Amended and Restated Articles of Incorporation as filed with the Pennsylvania Secretary of State on December 16, 2002 (2002 Preferred Stock Terms). (Incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K filed on December 16, 2002 (File No. 001-14131).)

Edgar Filing: ALKERMES INC - Form 10-K

- 3.1(b) Amendment to Third Amended and Restated Articles of Incorporation as filed with the Pennsylvania Secretary of State on May 14, 2003 (Incorporated by reference to Exhibit A to Exhibit 4.1 to the Registrant's Report on Form 8-A filed on May 2, 2003 (File No. 000-19267).)
- 3.2 Second Amended and Restated By-Laws of Alkermes, Inc. (Incorporated by reference to Exhibit 3.2 to the Registrant's Current Report on Form 8-K filed on September 28, 2005.)
- 4.1 Specimen of Common Stock Certificate of Alkermes, Inc. (Incorporated by reference to Exhibit 4 to the Registrant's Registration Statement on Form S-1, as amended (File No. 033-40250).)
- 4.2 Specimen of Non-Voting Common Stock Certificate of Alkermes, Inc. (Incorporated by reference to Exhibit 4.4 to the Registrant's Report on Form 10-K for the fiscal year ended March 31, 1999 (File No. 001-14131).)

**Table of Contents****Exhibit  
No.**

- 4.3 Rights Agreement, dated as of February 7, 2003, as amended, between Alkermes, Inc. and EquiServe Trust Co., N.A., as Rights Agent. (Incorporated by reference to Exhibit 4.1 to the Registrant's Report on Form 8-A filed on May 2, 2003 (File No. 000-19267).)
- 4.4 Indenture, dated as of February 1, 2005, between RC Royalty Sub LLC and U.S. Bank National Association, as Trustee. (Incorporated by reference to Exhibit 4.1 to the Registrant's Current Report on Form 8-K filed on February 3, 2005.)
- 4.5 Form of Risperdal Consta<sup>®</sup> PhaRMA<sup>sm</sup> Secured 7% Notes due 2018. (Incorporated by reference to Exhibit 4.1 to the Registrant's Current Report on Form 8-K filed on February 3, 2005.)
- 10.1 Amended and Restated 1990 Omnibus Stock Option Plan, as amended. (Incorporated by reference to Exhibit 10.2 to the Registrant's Report on Form 10-K for the fiscal year ended March 31, 1998 (File No. 001-14131).)+
- 10.2 Stock Option Plan for Non-Employee Directors, as amended. (Incorporated by reference to Exhibit 99.2 to the Registrant's Registration Statement on Form S-8 filed on October 1, 2003 (File No. 333-109376).)+
- 10.3 Lease, dated as of October 26, 2000, between FC88 Sidney, Inc. and Alkermes, Inc. (Incorporated by reference to Exhibit 10.3 to the Registrant's Report on Form 10-Q for the quarter ended December 31, 2000 (File No. 001-14131).)
- 10.4 Lease, dated as of October 26, 2000, between Forest City 64 Sidney Street, Inc. and Alkermes, Inc. (Incorporated by reference to Exhibit 10.4 to the Registrant's Report on Form 10-Q for the quarter ended December 31, 2000 (File No. 001-14131).)
- 10.5 License Agreement, dated as of February 13, 1996, between Medisorb Technologies International L.P. and Janssen Pharmaceutica Inc. (U.S.) (assigned to Alkermes Inc. in July 2006). (Incorporated by reference to Exhibit 10.19 to the Registrant's Report on Form 10-K for the fiscal year ended March 31, 1996 (File No. 000-19267).)\*
- 10.6 License Agreement, dated as of February 21, 1996, between Medisorb Technologies International L.P. and Janssen Pharmaceutica International (worldwide except U.S.) (assigned to Alkermes Inc. in July 2006). (Incorporated by reference to Exhibit 10.20 to the Registrant's Report on Form 10-K for the fiscal year ended March 31, 1996 (File No. 000-19267).)\*
- 10.7 Manufacturing and Supply Agreement, dated August 6, 1997, by and among Alkermes Controlled Therapeutics Inc. II, Janssen Pharmaceutica International and Janssen Pharmaceutica, Inc. (assigned to Alkermes Inc. in July 2006)(Incorporated by reference to Exhibit 10.19 to the Registrant's Report on Form 10-K for the fiscal year ended March 31, 2002 (File No. 001-14131).)\*\*\*
- 10.7(a) Third Amendment To Development Agreement, Second Amendment To Manufacturing and Supply Agreement and First Amendment To License Agreements by and between Janssen Pharmaceutica International Inc. and Alkermes Controlled Therapeutics Inc. II, dated April 1, 2000 (assigned to Alkermes Inc. in July 2006) (with certain confidential information deleted) (Incorporated by reference to Exhibit 10.5 to the Registrant's Report on Form 10-Q for the quarter ended December 31, 2004.)\*\*\*\*
- 10.7(b) Fourth Amendment To Development Agreement and First Amendment To Manufacturing and Supply Agreement by and between Janssen Pharmaceutica International Inc. and Alkermes Controlled Therapeutics Inc. II, dated December 20, 2000 (assigned to Alkermes Inc. in July 2006) (with certain confidential information deleted) (Incorporated by reference to Exhibit 10.4 to the Registrant's Report on Form 10-Q for the quarter ended December 31, 2004.)\*\*\*\*
- 10.7(c) Addendum to Manufacturing and Supply Agreement, dated August 2001, by and among Alkermes Controlled Therapeutics Inc. II, Janssen Pharmaceutica International and Janssen Pharmaceutica, Inc. (assigned to Alkermes Inc. in July 2006) (Incorporated by reference to Exhibit 10.19(b) to

the Registrant's Report on Form 10-K for the fiscal year ended March 31, 2002 (File No. 001-14131).\*\*\*

**Table of Contents****Exhibit  
No.**

- 10.7(d) Letter Agreement and Exhibits to Manufacturing and Supply Agreement, dated February 1, 2002, by and among Alkermes Controlled Therapeutics Inc. II, Janssen Pharmaceutica International and Janssen Pharmaceutica, Inc. (assigned to Alkermes Inc. in July 2006)(Incorporated by reference to Exhibit 10.19(a) to the Registrant's Report on Form 10-K for the fiscal year ended March 31, 2002.)\*\*\*
- 10.7(e) Amendment to Manufacturing and Supply Agreement by and between JPI Pharmaceutica International, Janssen Pharmaceutica Inc. and Alkermes Controlled Therapeutics Inc. II, dated December 22, 2003 (assigned to Alkermes Inc. in July 2006) (with certain confidential information deleted) (Incorporated by reference to Exhibit 10.8 to the Registrant's Report on Form 10-Q for the quarter ended December 31, 2004.)\*\*\*\*
- 10.7(f) Fourth Amendment To Manufacturing and Supply Agreement by and between JPI Pharmaceutica International, Janssen Pharmaceutica Inc. and Alkermes Controlled Therapeutics Inc. II, dated January 10, 2005 (assigned to Alkermes Inc. in July 2006) (with certain confidential information deleted) (Incorporated by reference to Exhibit 10.9 to the Registrant's Report on Form 10-Q for the quarter ended December 31, 2004.)\*\*\*\*
- 10.8 Agreement by and between JPI Pharmaceutica International, Janssen Pharmaceutica Inc. and Alkermes Controlled Therapeutics Inc. II, dated December 21, 2002 (assigned to Alkermes Inc. in July 2006) (with certain confidential information deleted) (Incorporated by reference to Exhibit 10.6 to the Registrant's Report on Form 10-Q for the quarter ended December 31, 2004.)\*\*\*\*
- 10.8(a) Amendment to Agreement by and between JPI Pharmaceutica International, Janssen Pharmaceutica Inc. and Alkermes Controlled Therapeutics Inc. II, dated December 16, 2003 (assigned to Alkermes Inc. in July 2006) (with certain confidential information deleted) (Incorporated by reference to Exhibit 10.7 to the Registrant's Report on Form 10-Q for the quarter ended December 31, 2004.)\*\*\*\*
- 10.9 Patent License Agreement, dated as of August 11, 1997, between Massachusetts Institute of Technology and Advanced Inhalation Research, Inc. (assigned to Alkermes, Inc. in March 2007), as amended. (Incorporated by reference to Exhibit 10.25 to the Registrant's Report on Form 10-K for the fiscal year ended March 31, 1999 (File No. 001-14131).)\*\*
- 10.10 Promissory Note by and between Alkermes, Inc. and General Electric Capital Corporation, dated December 22, 2004. (Incorporated by reference to Exhibit 10.1 to the Registrant's Report on Form 10-Q for the quarter ended December 31, 2004.)
- 10.11 Master Security Agreement by and between Alkermes, Inc. and General Electric Capital Corporation dated December 22, 2004. (Incorporated by reference to Exhibit 10.2 to the Registrant's Report on Form 10-Q for the quarter ended December 31, 2004.)
- 10.11(a) Addendum No. 001 To Master Security Agreement by and between Alkermes, Inc. and General Electric Capital Corporation, dated December 22, 2004. (Incorporated by reference to Exhibit 10.3 to the Registrant's Report on Form 10-Q for the quarter ended December 31, 2004.)
- 10.12 Employment agreement, dated as of December 12, 2007, by and between Richard F. Pops and the Registrant. (Incorporated by reference to Exhibit 10.1 to the Registrant's Report on Form 10-Q for the quarter ended December 31, 2007.)+
- 10.13 Employment agreement, dated as of December 12, 2007, by and between David A. Broecker and the Registrant. (Incorporated by reference to Exhibit 10.2 to the Registrant's Report on Form 10-Q for the quarter ended December 31, 2007.)+
- 10.14 Form of Employment Agreement, dated as of December 12, 2007, by and between the Registrant and each of Kathryn L. Biberstein, Elliot W. Ehrich, M.D., James M. Frates, Michael J. Landine, Gordon G. Pugh. (Incorporated by reference to Exhibit 10.3 to the Registrant's Report on Form 10-Q for the

Edgar Filing: ALKERMES INC - Form 10-K

quarter ended December 31, 2007.)+

10.15 Form of Covenant Not to Compete, of various dates, by and between the Registrant and each of Kathryn L. Biberstein and James M. Frates.+#

10.15(a) Form of Covenant Not to Compete, of various dates, by and between the Registrant and each of Elliot W. Ehrich, M.D., Michael J. Landine, and Gordon G. Pugh.+#

65

---

**Table of Contents**

**Exhibit  
No.**

- 10.16 License and Collaboration Agreement between Alkermes, Inc. and Cephalon, Inc. dated as of June 23, 2005. (Incorporated by reference to Exhibit 10.1 to the Registrant's Report on Form 10-Q for the quarter ended June 30, 2005.)\*\*\*\*\*
- 10.16(a) Supply Agreement between Alkermes, Inc. and Cephalon, Inc. dated as of June 23, 2005. (Incorporated by reference to Exhibit 10.2 to the Registrant's Report on Form 10-Q for the quarter ended June 30, 2005.)\*\*\*\*\*
- 10.16(b) Amendment to the License and Collaboration Agreement between Alkermes, Inc. and Cephalon, Inc. dated as of December 21, 2006. (Incorporated by reference to Exhibit 10.16(b) to the Registrant's Report on Form 10-K for the year ended March 31, 2007.)\*\*\*\*\*
- 10.16(c) Amendment to the Supply Agreement between Alkermes, Inc. and Cephalon, Inc. dated as of December 21, 2006. (Incorporated by reference to Exhibit 10.16(c) to the Registrant's Report on Form 10-K for the year ended March 31, 2007.)\*\*\*\*\*
- 10.17 Accelerated Share Repurchase Agreement, dated as of February 7, 2008, between Morgan Stanley & Co. Incorporated and Alkermes, Inc.#
- 10.18 Alkermes, Inc. 1998 Equity Incentive Plan as Amended and Approved on November 2, 2006. (Incorporated by reference to Exhibit 10.1 to the Registrant's Report on Form 10-Q for the fiscal quarter ended December 31, 2006.)+
- 10.18(a) Form of Stock Option Certificate pursuant to Alkermes, Inc. 1998 Equity Incentive Plan. (Incorporated by reference to Exhibit 10.37 to the Registrant's Report on Form 10-K for the fiscal year ended March 31, 2006.)+
- 10.19 Alkermes, Inc. Amended and Restated 1999 Stock Option Plan. (Incorporated by reference to Appendix A to the Registrant's Definitive Proxy Statement on Form DEF 14/A filed on July 27, 2007.)+
- 10.19(a) Form of Incentive Stock Option Certificate pursuant to the 1999 Stock Option Plan, as amended. (Incorporated by reference to Exhibit 10.35 to the Registrant's Report on Form 10-K for the fiscal year ended March 31, 2006.)+
- 10.19(b) Form of Non-Qualified Stock Option Certificate pursuant to the 1999 Stock Option Plan, as amended. (Incorporated by reference to Exhibit 10.36 to the Registrant's Report on Form 10-K for the fiscal year ended March 31, 2006.)+
- 10.20 Alkermes, Inc. 2002 Restricted Stock Award Plan as Amended and Approved on November 2, 2006. (Incorporated by reference to Exhibit 10.3 to the Registrant's Report on Form 10-Q for the fiscal quarter ended December 31, 2006.)+
- 10.20(a) Amendment to Alkermes, Inc. 2002 Restricted Stock Award Plan. (Incorporated by reference to Appendix B to the Registrant's Definitive Proxy Statement on Form DEF 14/A filed on July 27, 2007.)+
- 10.21 2006 Stock Option Plan for Non-Employee Directors. (Incorporated by reference to Exhibit 10.4 to the Registrant's Report on Form 10-Q for the fiscal quarter ended September 30, 2006.)+
- 10.21(a) Amendment to 2006 Stock Option Plan for Non-Employee Directors. (Incorporated by reference to Appendix C to the Registrant's Definitive Proxy Statement on Form DEF 14/A filed on July 27, 2007.)+
- 10.22 Alkermes Fiscal 2008 Named-Executive Bonus Plan. (Incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed on April 26, 2007.)+
- 10.23 Alkermes Fiscal Year 2009 Reporting Officer Performance Pay Plan. (Incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed on May 16, 2008.)+
- 21.1 Subsidiaries of the Registrant.#



Edgar Filing: ALKERMES INC - Form 10-K

23.1	Consent of Independent Registered Public Accounting Firm PriceWaterhousecoopers LLP.#
23.2	Consent of Independent Registered Public Accounting Firm Deloitte & Touche LLP.#
24.1	Power of Attorney (included on signature pages).#
31.1	Rule 13a-14(a)/15d-14(a) Certification.#

**Table of Contents**

**Exhibit**

**No.**

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

\* Confidential status has been granted for certain portions thereof pursuant to a Commission Order granted September 3, 1996. Such provisions have been filed separately with the Commission.

\*\* Confidential status has been granted for certain portions thereof pursuant to a Commission Order granted August 19, 1999. Such provisions have been filed separately with the Commission.

\*\*\* Confidential status has been granted for certain portions thereof pursuant to a Commission Order granted September 16, 2002. Such provisions have been separately filed with the Commission.

\*\*\*\* Confidential status has been granted for certain portions thereof pursuant to a Commission Order granted September 26, 2005. Such provisions have been filed separately with the Commission.

\*\*\*\*\* Confidential status has been granted for certain portions thereof pursuant to a Commission Order granted July 31, 2006. Such provisions have been filed separately with the Commission.

\*\*\*\*\* Confidential status has been granted for certain portions thereof pursuant to a Commission Order granted April 15, 2008. Such provisions have been filed separately with the Commission.

+ Indicates a management contract or any compensatory plan, contract or arrangement.

# Filed herewith.

**Table of Contents**

**SIGNATURES**

Pursuant to the requirements of Section 13 or 15(d) 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.

By: /s/ David A. Broecker

David A. Broecker  
President and Chief Executive Officer

May 30, 2008

**POWER OF ATTORNEY**

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the Registrant and in the capacities and on the dates indicated.

Each person whose signature appears below in so signing also makes, constitutes and appoints David A. Broecker and James M. Frates, and each of them, his true and lawful attorney-in-fact, with full power of substitution, for him in any and all capacities, to execute and cause to be filed with the Securities and Exchange Commission any and all amendments to this Form 10-K, with exhibits thereto and other documents in connection therewith, and hereby ratifies and confirms all that said attorney-in-fact or his substitute or substitutes may do or cause to be done by virtue hereof.

<b>Signature</b>	<b>Title</b>	<b>Date</b>
/s/ David A. Broecker David A. Broecker	President and Chief Executive Officer and Director (Principal Executive Officer)	May 30, 2008
/s/ James M. Frates James M. Frates	Senior Vice President, Chief Financial Officer and Treasurer (Principal Financial and Accounting Officer)	May 30, 2008
/s/ Richard F. Pops Richard F. Pops	Director and Chairman of the Board	May 30, 2008
/s/ Floyd E. Bloom Floyd E. Bloom	Director	May 30, 2008
/s/ Robert A. Breyer Robert A. Breyer	Director	May 30, 2008

/s/ Gerri Henwood	Director	May 30, 2008
Gerri Henwood		
/s/ Paul J. Mitchell	Director	May 30, 2008
Paul J. Mitchell		

**Table of Contents**

<b>Signature</b>	<b>Title</b>	<b>Date</b>
/s/ Alexander Rich Alexander Rich	Director	May 30, 2008
/s/ Mark B. Skaletsky Mark B. Skaletsky	Director	May 30, 2008
/s/ Michael A. Wall Michael A. Wall	Director and Chairman Emeritus	May 30, 2008

**Table of Contents**

**Report of Independent Registered Public Accounting Firm**

To the Board of Directors and Shareholders of Alkermes, Inc.

In our opinion, the accompanying consolidated balance sheet and the related consolidated statement of income and comprehensive income, shareholders' equity and cash flows present fairly, in all material respects, the financial position of Alkermes, Inc. and its subsidiaries at March 31, 2008, and the results of their operations and their cash flows for the year ended March 31, 2008 in conformity with accounting principles generally accepted in the United States of America. Also in our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of March 31, 2008, based on criteria established in Internal Control – Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). The Company's management is responsible for these financial statements, for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting, included in the accompanying Management's Annual Report on Internal Control over Financial Reporting under Item 9A. Our responsibility is to express opinions on these financial statements and on the Company's internal control over financial reporting based on our integrated audit. We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement and whether effective internal control over financial reporting was maintained in all material respects. Our audit of the financial statements included examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. Our audit of internal control over financial reporting included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audit also included performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinions.

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

/s/ PricewaterhouseCoopers LLP

Boston, Massachusetts  
May 30, 2008



**Table of Contents**

**Report of Independent Registered Public Accounting Firm**

To the Board of Directors and Shareholders of Alkermes, Inc.  
Cambridge, Massachusetts

We have audited the accompanying consolidated balance sheet of Alkermes, Inc. and subsidiaries (the Company) as of March 31, 2007, and the related consolidated statements of income and comprehensive income, shareholders' equity, and cash flows for each of the two years in the period ended March 31, 2007. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, such consolidated financial statements present fairly, in all material respects, the financial position of Alkermes, Inc. and subsidiaries as of March 31, 2007, and the results of their operations and their cash flows for each of the two years in the period ended March 31, 2007, in conformity with accounting principles generally accepted in the United States of America.

As discussed in Note 2 to the financial statements, the Company changed its method of accounting for share-based payments upon the adoption of Statement of Financial Accounting Standards No. 123(R), *Share-Based Payment*, effective April 1, 2006.

/s/ Deloitte and Touche LLP

Boston, Massachusetts  
June 14, 2007

F-2

---



**Table of Contents****ALKERMES, INC. AND SUBSIDIARIES****CONSOLIDATED BALANCE SHEETS**

March 31, 2008 and 2007

	<b>2008</b>	<b>2007</b>
	<b>(In thousands, except share and per share amounts)</b>	
<b>ASSETS</b>		
<b>CURRENT ASSETS:</b>		
Cash and cash equivalents	\$ 101,241	\$ 80,500
Investments short-term	240,064	271,082
Receivables	47,249	56,049
Inventory, net	18,884	18,190
Prepaid expenses and other current assets	5,720	7,054
<b>Total current assets</b>	<b>413,158</b>	<b>432,875</b>
<b>PROPERTY, PLANT AND EQUIPMENT:</b>		
Land	301	301
Building and improvements	35,003	25,717
Furniture, fixtures and equipment	63,364	64,203
Equipment under capital lease	464	464
Leasehold improvements	33,387	32,345
Construction in progress	42,859	42,442
	175,378	165,472
Less: accumulated depreciation	(62,839)	(41,877)
<b>Property, plant and equipment net</b>	<b>112,539</b>	<b>123,595</b>
<b>INVESTMENTS LONG-TERM</b>	<b>119,056</b>	<b>5,884</b>
<b>OTHER ASSETS</b>	<b>11,558</b>	<b>6,267</b>
<b>TOTAL ASSETS</b>	<b>\$ 656,311</b>	<b>\$ 568,621</b>

**LIABILITIES AND SHAREHOLDERS EQUITY**

<b>CURRENT LIABILITIES:</b>		
Accounts payable and accrued expenses	\$ 29,034	\$ 45,571
Accrued interest	2,975	2,976
Accrued restructuring costs	4,037	284
Unearned milestone revenue current portion	5,927	11,450
Deferred revenue current portion		200
Long-term debt current portion	47	1,579

Total current liabilities	42,020	62,060
ACCRUED RESTRUCTURING COSTS LONG-TERM PORTION	4,041	795
NON-RECOURSE RISPERDAL CONSTA SECURED 7% NOTES	160,324	156,851
UNEARNED MILESTONE REVENUE LONG-TERM PORTION	111,730	117,300
DEFERRED REVENUE LONG-TERM PORTION	27,837	22,153
OTHER LONG-TERM LIABILITIES	5,045	6,001
TOTAL LIABILITIES	350,997	365,160
COMMITMENTS AND CONTINGENCIES (Note 12)		
SHAREHOLDERS EQUITY:		
Capital stock, par value, \$0.01 per share; 4,550,000 shares authorized (includes 3,000,000 shares of preferred stock); none issued		
Common stock, par value, \$0.01 per share; 160,000,000 shares authorized; 102,977,348 and 101,550,673 shares issued; 95,099,166 and 100,726,996 shares outstanding at March 31, 2008 and 2007, respectively	1,030	1,015
Non-voting common stock, par value, \$0.01 per share; 450,000 shares authorized; 382,632 shares issued and outstanding at March 31, 2008 and 2007	4	4
Treasury stock, at cost (7,878,182 shares and 823,677 at March 31, 2008 and 2007, respectively)	(107,322)	(12,492)
Additional paid-in capital	869,695	837,727
Accumulated other comprehensive (loss) income	(1,526)	753
Accumulated deficit	(456,567)	(623,546)
TOTAL SHAREHOLDERS EQUITY	305,314	203,461
TOTAL LIABILITIES AND SHAREHOLDERS EQUITY	\$ 656,311	\$ 568,621

See accompanying notes to the consolidated financial statements.

**Table of Contents****ALKERMES, INC. AND SUBSIDIARIES****CONSOLIDATED STATEMENTS OF INCOME AND COMPREHENSIVE INCOME****Years Ended March 31, 2008, 2007 and 2006**

	<b>2008</b>	<b>2007</b>	<b>2006</b>
	<b>(In thousands, except per share amounts)</b>		
<b>REVENUES:</b>			
Manufacturing revenues	\$ 101,700	\$ 105,416	\$ 64,901
Royalty revenues	29,457	23,151	16,532
Research and development revenue under collaborative arrangements	89,510	74,483	45,883
Net collaborative profit	20,050	36,915	39,285
<b>Total revenues</b>	<b>240,717</b>	<b>239,965</b>	<b>166,601</b>
<b>EXPENSES:</b>			
Cost of goods manufactured	40,677	45,209	23,489
Research and development	125,268	117,315	89,068
Selling, general and administrative	59,508	66,399	40,383
Impairment of long-lived assets	11,630		
Restructuring	6,423		
<b>Total expenses</b>	<b>243,506</b>	<b>228,923</b>	<b>152,940</b>
<b>OPERATING (LOSS) INCOME</b>	<b>(2,789)</b>	<b>11,042</b>	<b>13,661</b>
<b>OTHER INCOME (EXPENSE):</b>			
Gain on sale of investment in Reliant Pharmaceuticals, Inc.	174,631		
Interest income	17,834	17,707	11,569
Interest expense	(16,370)	(17,725)	(20,661)
Derivative loss related to convertible subordinated notes			(1,084)
Other income (expense), net	(476)	(481)	333
<b>Total other income (expense)</b>	<b>175,619</b>	<b>(499)</b>	<b>(9,843)</b>
<b>INCOME BEFORE INCOME TAXES</b>	<b>172,830</b>	<b>10,543</b>	<b>3,818</b>
<b>INCOME TAXES</b>	<b>5,851</b>	<b>1,098</b>	
<b>NET INCOME</b>	<b>\$ 166,979</b>	<b>\$ 9,445</b>	<b>\$ 3,818</b>
<b>EARNINGS PER COMMON SHARE:</b>			
<b>BASIC</b>	<b>\$ 1.66</b>	<b>\$ 0.10</b>	<b>\$ 0.04</b>
<b>DILUTED</b>	<b>\$ 1.62</b>	<b>\$ 0.09</b>	<b>\$ 0.04</b>

WEIGHTED AVERAGE NUMBER OF COMMON SHARES  
OUTSTANDING:

BASIC	100,742	99,242	91,022
DILUTED	102,923	103,351	97,377
COMPREHENSIVE INCOME:			
Net income	\$ 166,979	\$ 9,445	\$ 3,818
Unrealized (losses) gains on marketable securities:			
Holding (losses) gains	(3,849)	(1,054)	2,046
Less: Reclassification adjustment for losses (gains) included in net income	1,570	743	(761)
Unrealized (losses) gains on marketable securities	(2,279)	(311)	1,285
COMPREHENSIVE INCOME	\$ 164,700	\$ 9,134	\$ 5,103

See accompanying notes to the consolidated financial statements.

F-4

---

Table of Contents

## ALKERMES, INC. AND SUBSIDIARIES

**CONSOLIDATED STATEMENTS OF SHAREHOLDERS' EQUITY**  
**Years Ended March 31, 2008, 2007 and 2006**

Common Stock Shares	Amount	Non-voting Common Stock		Additional Paid-In Capital	Deferred Compensation	Translation Adjustments	Accumulated Other Comprehensive (Loss) Income Foreign Currency	Unrealized (Loss) Gain on Marketable Securities	Accumulated Deficit	Treasury Stock Shares	Amount
		Shares	Amount								
89,999,526	\$ 900	382,632	\$ 4	\$ 640,238	\$	\$ (142)	\$ (79)	\$ (636,809)			\$
921,477	9			8,550							
823,677	8			14,992							
				(89)	89						
				905	(664)						
					201						
								1,285			
									3,818		
91,744,680	\$ 917	382,632	\$ 4	\$ 664,596	\$ (374)	\$ (142)	\$ 1,206	\$ (632,991)			\$
780,722	8			7,539							
9,025,271	90			(374)	374						
				124,312							

				(1,751)							
				15,000							
				28,249						(823,677)	
				156							
								(311)			
									9,445		
101,550,673	\$ 1,015	382,632	\$ 4	\$ 837,727	\$	\$ (142)	\$	895	\$ (623,546)	(823,677)	\$
1,426,675	15			11,144							
				1,480						(85,769)	
				19,222						(6,968,736)	
				122							
								(2,279)			
									166,979		
102,977,348	\$ 1,030	382,632	\$ 4	\$ 869,695	\$	\$ (142)	\$	(1,384)	\$ (456,567)	(7,878,182)	\$

See accompanying notes to the consolidated financial statements.



**Table of Contents****ALKERMES, INC. AND SUBSIDIARIES****CONSOLIDATED STATEMENTS OF CASH FLOWS**  
**Years Ended March 31, 2008, 2007 and 2006**

	<b>2008</b>	<b>2007</b>	<b>2006</b>
	<b>(In thousands)</b>		
<b>CASH FLOWS FROM OPERATING ACTIVITIES:</b>			
Net income	\$ 166,979	\$ 9,445	\$ 3,818
Adjustments to reconcile net income to cash flows from operating activities:			
Share-based compensation expense	19,445	27,687	442
Depreciation	12,138	11,991	10,879
Impairment of long-lived assets	11,630		
Other non-cash charges	3,732	3,783	5,251
Derivative loss related to convertible subordinated notes			1,084
Gain on sale of investment in Reliant Pharmaceuticals, Inc.	(174,631)		
Realized losses (gains) on investments	1,570	743	(761)
Gain on sale of equipment		(530)	(70)
Changes in assets and liabilities:			
Receivables	15,041	(13,537)	(20,987)
Inventory, prepaid expenses and other assets	(1,450)	(12,240)	(3,601)
Accounts payable, accrued expenses and accrued interest	(13,988)	8,070	18,329
Accrued restructuring costs	5,955	(496)	(995)
Unearned milestone revenue	(11,093)	29,214	99,536
Deferred revenue	6,961	18,694	950
Other long-term liabilities	135	649	2,831
Cash flows from operating activities	42,424	83,473	116,706
<b>CASH FLOWS FROM INVESTING ACTIVITIES:</b>			
Additions to property, plant and equipment	(21,890)	(36,305)	(28,660)
Proceeds from sales of equipment		12,571	122
Proceeds from the sale of investment in Reliant Pharmaceuticals, Inc.	166,865		
Purchases of short and long-term investments	(639,582)	(329,234)	(661,671)
Sales and maturities of short and long-term investments	556,572	322,989	552,161
Cash flows from investing activities	61,965	(29,979)	(138,048)
<b>CASH FLOWS FROM FINANCING ACTIVITIES:</b>			
Proceeds from issuance of common stock for share-based compensation arrangements	11,159	7,547	8,559
Excess tax benefit from share-based compensation	122	156	
Payment of debt and capital leases	(1,579)	(1,783)	(1,124)
Purchase of common stock for treasury	(93,350)	(12,492)	



Edgar Filing: ALKERMES INC - Form 10-K

Cash flows from financing activities	(83,648)	(6,572)	7,435
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	20,741	46,922	(13,907)
CASH AND CASH EQUIVALENTS Beginning of period	80,500	33,578	47,485
CASH AND CASH EQUIVALENTS End of period	\$ 101,241	\$ 80,500	\$ 33,578
SUPPLEMENTAL CASH FLOW DISCLOSURE:			
Cash paid for interest	\$ 12,002	\$ 13,647	\$ 14,319
Cash paid for taxes	\$ 5,300	\$ 1,051	\$
Non-cash investing and financing 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	\$
Purchased capital expenditures included in accounts payable and accrued expenses	\$ (663)	\$ (1,321)	\$
Sales of property, plant and equipment included in receivables	\$ 7,717	\$	\$
Net share exercise of warrants into common stock of the issuer	\$ 2,994	\$	\$
Receipt of Alkermes shares for the purchase of stock options or to satisfy minimum withholding tax obligations related to stock based awards	\$ 1,480	\$	\$
Funds held in escrow for the sale of investment in Reliant Pharmaceuticals, Inc.	\$ 7,766	\$	\$

See accompanying notes to the consolidated financial statements.

**Table of Contents**

**ALKERMES, INC. AND SUBSIDIARIES**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**1. THE COMPANY**

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

**2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES**

***Principles of Consolidation***

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

***Use of Estimates***

The preparation of the Company's consolidated financial statements in conformity with accounting principles generally accepted in the United States (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 consolidated financial statements; and (3) the reported amounts of revenues and expenses during the reporting period. Actual results could differ from these estimates.

***Cash and Cash Equivalents***

The Company values its cash and cash equivalents at cost plus accrued interest, which the Company believes approximates their market value. The Company's cash equivalents consist principally of money market funds, mutual funds and an overnight repurchase agreement, which is fully collateralized by U.S. government securities.

***Fair Value of Financial Instruments***

The carrying amounts reflected in the consolidated balance sheets for cash and cash equivalents, accounts receivable, other current assets, accounts payable and accrued expenses approximate fair value due to their short-term nature. The Company's investments in marketable securities and its strategic investments, substantially all of which are available-for-sale, are carried at fair value and generally based on quoted market prices. When quoted market prices are not available, fair values are estimated based on dealer quotes or quoted prices for instruments with similar characteristics or a discounted cash flow model. The following table sets forth the carrying values and estimated fair values of the Company's debt instruments at March 31:

**2008**

**2007**

Edgar Filing: ALKERMES INC - Form 10-K

	<b>Carrying Value</b>	<b>Fair Value</b>	<b>Carrying Value</b>	<b>Fair Value</b>
			<b>(In thousands)</b>	
7% Notes	\$ 160,324	\$ 153,000	\$ 156,851	\$ 156,400
Obligation under capital lease	47	47	152	152
Term loan			1,474	1,474

F-7

---

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

The estimated fair value of the 7% Notes was based on quoted market price indications. The estimated fair values of the obligation under capital lease and the term loan were based on prevailing interest rates or rates of return on similar instruments.

***Investments***

The Company invests its excess cash balances in short-term and long-term investments consisting of U.S. government obligations, investment grade corporate notes, commercial paper and student loan backed auction rate securities. The Company places substantially all of its interest-bearing investments with major financial institutions, and in accordance with documented corporate policies the Company limits the amount of credit exposure to any one financial institution or corporate issuer. At March 31, 2008, substantially all these investments are classified as available-for-sale and recorded at fair value and include any unrealized holding gains and losses (the adjustment to fair value) in shareholders' equity. Realized gains and losses are reported in other income (expense) net. Valuation of available-for-sale securities for purposes of determining the amount of gains and losses is based on the specific identification method. The Company's held-to-maturity investments are restricted investments held as collateral under certain letters of credit related to the Company's lease agreements and are recorded at amortized cost as Investments Long-Term in the consolidated balance sheets.

Declines in value judged to be other-than-temporary on available-for-sale securities are reported in other income (expense) net. The Company reviews its investments for impairment in accordance with the Financial Accounting Standard Board's (FASB) Statement of Financial Accounting Standards (SFAS) No. 115, *Accounting for Certain Investments in Debt and Equity Securities*, the SEC's Staff Accounting Bulletin (SAB) Topic 5, *Miscellaneous Accounting* and FASB Staff Position (FSP) SFAS No. 115-1 and FSP SFAS No. 124-1, *The Meaning of Other-Than-Temporary Impairment and Its Application to Certain Investments*, to determine if a decline in the fair value of an investment is temporary or other-than-temporary. In making this determination, the Company reviews several factors to determine whether losses are other-than-temporary, including but not limited to: i) the length of time each security was in an unrealized loss position; ii) the extent to which fair value was less than cost; iii) the financial condition and near term prospects of the issuer or insurer and; iv) the Company's intent and ability to hold each security for a period of time sufficient to allow for any anticipated recovery in fair value. If the Company determines that the decline in the fair value of an investment is other-than-temporary, the accumulated unrealized loss on the investment is recognized as a charge to the statement of income.

***Inventory, net***

Inventory, net is stated at the lower of cost or market value. Cost is determined using the first-in, first-out method. Included in inventory, net are raw materials used in production of pre-clinical and clinical products, which have alternative future use and are charged to research and development expense when consumed. Inventory, net consisted of the following at March 31:

	2008	2007
	(In thousands)	
Raw materials	\$ 8,373	\$ 7,238

Edgar Filing: ALKERMES INC - Form 10-K

Work in process	3,060	4,291
Finished goods	7,451	6,661
Total	\$ 18,884	\$ 18,190

F-8

---

**Table of Contents****ALKERMES, INC. AND SUBSIDIARIES****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)*****Property, Plant and Equipment***

Property, plant and equipment are recorded at cost, subject to review for impairment whenever events or changes in circumstances indicate that the carrying amount of the assets may not be recoverable. Depreciation is generally calculated using the straight-line method over the following estimated useful lives of the assets:

<b>Asset group</b>	<b>Term</b>
Buildings	25 years
Furniture, fixtures and equipment	3 - 7 years
Leasehold improvements	Shorter of useful life or lease term (1 - 20 years)

Expenditures for repairs and maintenance are charged to expense as incurred and major renewals and improvements are capitalized. During the years ended March 31, 2008 and 2007, the Company wrote off approximately \$1.6 million and \$5.6 million, respectively, of fully depreciated furniture, fixtures and equipment in accordance with its capital assets accounting policy. Also, during the year ended March 31, 2008, the Company wrote off furniture, fixtures and equipment that had a carrying value of \$0.8 million at the time of disposition.

Amounts recorded as construction in progress in the consolidated balance sheets consist primarily of costs incurred for the expansion of the Company's manufacturing facility in Ohio.

Property, plant and equipment acquired under capital leases totaled \$0.5 million as of March 31, 2008 and 2007, and accumulated depreciation of such assets totaled \$0.4 million and \$0.3 million as of March 31, 2008 and 2007, respectively.

***Impairment of Long-Lived Assets***

In accordance with SFAS No. 144, *Accounting for the Impairment or Disposal of Long-Lived Assets* ( SFAS No. 144 ), long-lived assets to be held and used, including property, plant and equipment, are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of the assets may not be recoverable. Conditions that would necessitate an impairment assessment include a significant decline in the observable market value of an asset, a significant change in the extent or manner in which an asset is used, or a significant adverse change that would indicate that the carrying amount of an asset or group of assets is not recoverable. Determination of recoverability is based on an estimate of undiscounted future cash flows resulting from the use of the asset and its eventual disposition. In the event that such cash flows are not expected to be sufficient to recover the carrying amount of the assets, the assets are written-down to their estimated fair values. Long-lived assets to be disposed of are carried at fair value less costs to sell.

***Asset Retirement Obligations***

In accordance with SFAS No. 143, *Accounting for Asset Retirement Obligations* ( SFAS No. 143 ), as interpreted by FASB Interpretation No. 47, *Accounting for Conditional Asset Retirement Obligations* ( FIN No. 47 ), the Company

has recognized an asset retirement obligation for an obligation to remove leasehold improvements and other related activities at the conclusion of the Company's lease for its AIR<sup>®</sup> manufacturing facility located in Chelsea, Massachusetts.

The carrying amount of the asset retirement obligation at March 31, 2008 and 2007 was \$1.3 million and \$0.9 million, respectively and is included within Other Long-Term Liabilities in the accompanying

F-9

---

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

consolidated balance sheets. The following table shows changes in the carrying amount of the Company's asset retirement obligation for the years ended March 31, 2008 and 2007 (in thousands):

Balance, March 31, 2006	\$ 785
Accretion expense	79
Balance, March 31, 2007	864
Accretion expense	87
Revisions in estimated cash flows	316
Balance, March 31, 2008	\$ 1,267

***Other Assets***

Other assets consist primarily of unamortized debt offering costs which are being amortized over the lives of the expected principal repayment periods of the related notes, funds held in escrow subject to the terms of an escrow agreement between GlaxoSmithKline ( GSK ) and Reliant Pharmaceuticals, Inc. ( Reliant ), and warrants to purchase stock of certain publicly traded companies.

***Unearned Milestone Revenue***

Unearned milestone revenue, current and long-term, consists of nonrefundable payments the Company received from Cephalon, Inc. ( Cephalon ) under the terms of its collaboration agreements. Unearned milestone revenue is recognized as revenue when earned and is recorded within Net collaborative profit and Manufacturing revenues.

***Deferred Revenue***

Deferred revenue, current and long-term, consists primarily of proceeds from the sale of the two VIVITROL manufacturing lines to Cephalon. Deferred revenue related to the sale of the two VIVITROL manufacturing lines will be recognized as revenue over the depreciable life of the assets in amounts equal to the related asset depreciation, beginning when the assets are placed in service. Future sales of assets to Cephalon related to the two VIVITROL manufacturing lines, if any, will be accounted for in a consistent way.

The Company has also received up-front payments for research and development costs and license payments under collaborative arrangements with collaborative partners that are being recognized over the estimated term of the agreements based upon the proportional performance to date.

***Revenue Recognition***

***Manufacturing revenue*** The Company recognizes revenue from manufacturing sales under certain manufacturing and supply arrangements when the product has been shipped, title and risk of loss have passed to the customer and collection from the customer is reasonably assured. Manufacturing revenues recognized by the Company for



RISPERDAL CONSTA are based on information supplied to the Company by Janssen Pharmaceutica, Inc., a division of Ortho-McNeil-Janssen Pharmaceuticals, Inc. and Janssen Pharmaceutica International, a division of Cilag International (together, Janssen ) and requires estimates to be made. Differences between the actual manufacturing revenue and estimated manufacturing revenue are reconciled and adjusted for in the period in which they become known. Historically, adjustments have not been material based on actual amounts paid by Janssen.

*Royalty revenue* The Company receives royalties related to the sale of RISPERDAL CONSTA under certain license arrangements with Janssen. Royalty revenues are earned on sales of RISPERDAL CONSTA made by Janssen and are recorded in the period the product is sold by Janssen.

**Table of Contents**

**ALKERMES, INC. AND SUBSIDIARIES**

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

*Research and development revenue under collaborative arrangements* Research and development revenue under collaborative arrangements consists of nonrefundable research and development funding under collaborative arrangements with various collaborative partners. Research and development funding generally compensates the Company for formulation, preclinical and clinical testing related to the collaborative research programs. The Company generally bills its partners under collaborative arrangements using a single full-time equivalent ( FTE ) or hourly rate. This rate is established by the Company based on its annual budget of employee compensation, employee benefits and billable non-project-specific costs and is generally increased annually based on increases in the consumer price index. Each collaborative partner is billed using a FTE or hourly rate for the hours worked by the Company s employees on a particular project, plus any direct external costs, if any.

The Company recognizes research and development revenue under collaborative arrangements over the term of the applicable agreements through the application of a proportional performance model where revenue is recognized equal to the lesser of the amount due under the agreements or the amount based on the proportional performance to date. The Company recognizes nonrefundable payments and fees for the licensing of technology or intellectual property rights over the related performance period or when there is no remaining performance obligations. Nonrefundable payments and fees are recorded as deferred revenue upon receipt and may require deferral of revenue recognition to future periods.

*Multiple Element Arrangements* The Company evaluates revenue from arrangements that have multiple elements to determine whether the components of the arrangement represent separate units of accounting as defined in the FASB s Emerging Issues Task Force ( EITF ) Issue No. 00-21, *Revenue Arrangements with Multiple Deliverables* ( EITF No. 00-21 ). To recognize a delivered item in a multiple element arrangement, EITF No. 00-21 requires that the delivered items have value to the customer on a stand-alone basis, that there is objective and reliable evidence of fair value of the undelivered items and that it is within the Company s control for any delivered items that have a right of return.

*Revenue Recognition Related to the License and Collaboration Agreement and Supply Agreement (together, the Agreements ) with Cephalon*

The Company s revenue recognition policy related to the Agreements complies with the SEC s Staff Accounting Bulletin No. 101, *Revenue Recognition in Financial Statements*, and EITF No. 00-21 for multiple element revenue arrangements entered into or materially amended after June 30, 2003. For purposes of revenue recognition, the deliverables under these Agreements are generally separated into three units of accounting: (i) net losses on the products; (ii) manufacturing of the products; and (iii) the product license.

Under the terms of the Agreements, the Company was responsible for the first \$120.0 million of net product losses through December 31, 2007, which increased pursuant to the Amendments (see below) to \$124.6 million (the cumulative net loss cap ). The net product losses excluded development costs incurred by the Company to obtain U.S. Food and Drug Administration ( FDA ) approval of VIVITROL and costs incurred by the Company to complete the first VIVITROL manufacturing line, both of which were the Company s sole responsibility. Cephalon was responsible to pay all net product losses in excess of the cumulative net loss cap through December 31, 2007. After December 31, 2007, all net profits and losses earned on the product are divided between the Company and Cephalon in approximately equal shares. Cumulative net product losses since inception of the Agreements through March 31, 2008 were \$174.8 million.

Cephalon records net sales from the products in the United States ( U.S. ). The Company and Cephalon reconcile the costs incurred in the period by each party to develop, commercialize and manufacture the products against revenues earned on the products in the period, to determine net profits or losses on the products in the period. To the extent that the cash earned or expended by either of the parties exceeds or is less than its proportional share of net profit or loss for the period, the parties settle by delivering cash such

F-11

---

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

that the net cash earned or expended equals each party's proportional share. The cash flow between the companies related to the Company's share of net profits or losses is recorded in the period in which it was made as Net collaborative profit in the consolidated statements of income and comprehensive income.

The costs incurred by the Company and Cephalon with respect to the development and commercialization of the products, and which are charged into the collaboration, include employee time, which is billed to the collaboration at negotiated FTE rates, and external expenses incurred by the parties with respect to the products. FTE rates vary depending on the nature of the activity performed (such as development and sales) and are intended to approximate the Company's actual costs. Cost of goods manufactured related to the products is based on a fully burdened manufacturing cost, determined in accordance with U.S. GAAP.

The nonrefundable payments of \$160.0 million and \$110.0 million the Company received from Cephalon in June 2005 and April 2006, respectively, and the \$4.6 million payment the Company received from Cephalon in December 2006, pursuant to the Amendments (see below), have been deemed to be arrangement consideration in accordance with EITF No. 00-21. This arrangement consideration is recognized as milestone revenue across the three accounting units referred to above. The allocation of the arrangement consideration to each of the accounting units was based initially on the fair value of each unit as determined at the date the consideration was received. Of the initial \$160.0 million nonrefundable payment received from Cephalon upon signing the Agreements, the Company has allocated \$144.4 million to the accounting unit net losses on the products, comprising the \$124.6 million of net product losses for which the Company was responsible and the \$19.8 million of expenses the Company incurred in obtaining FDA approval of VIVITROL and completing the first manufacturing line. The remaining \$20.2 million of the \$160.0 million payment was allocated to the accounting unit product license. Of the \$110.0 million nonrefundable payment received from Cephalon upon VIVITROL approval, the Company allocated \$77.8 million to the accounting unit manufacturing of the products and applied the remaining \$32.2 million to the accounting unit product license. The \$4.6 million payment received from Cephalon pursuant to the Amendments has been allocated to the accounting unit net losses on the products. The fair values of the accounting units are reviewed periodically and adjusted, as appropriate. The above payments were recorded in the consolidated balance sheets as Unearned milestone revenue current portion and Unearned milestone revenue long-term portion prior to being earned. The classification between the current and long-term portions is based on the Company's best estimate of whether the milestone revenue will be recognized during or after the 12-month period following the reporting period, respectively.

In October 2006, the Company and Cephalon entered into binding amendments to the license and collaboration agreement and the supply agreement (the Amendments). Under the Amendments, the parties agreed that Cephalon would purchase from the Company two VIVITROL manufacturing lines (and related equipment) under construction. Amounts the Company received from Cephalon for the sale of the two VIVITROL manufacturing lines were recorded as Deferred revenue long-term portion in the consolidated balance sheets and will be recorded as revenue over the depreciable life of the assets in amounts equal to the related asset depreciation once the assets are placed in service. Future purchases of physical assets by Cephalon will be accounted for in a consistent way. Beginning October 2006, all FTE-related costs the Company incurs that are reimbursable by Cephalon related to the construction and validation of the two additional VIVITROL manufacturing lines are recorded as research and development revenue as incurred. In December 2006, the Company received a \$4.6 million payment from Cephalon as reimbursement for certain costs incurred by the Company prior to October 2006, which the Company had charged to the collaboration and that were related to the construction of the VIVITROL manufacturing lines. These costs consisted primarily of internal or temporary employee time, billed at negotiated FTE rates. The Company and Cephalon agreed to increase the

cumulative net loss cap from \$120.0 million to \$124.6 million to account for this reimbursement.

F-12

---

**Table of Contents**

**ALKERMES, INC. AND SUBSIDIARIES**

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

*Manufacturing Revenues Related to the Agreements with Cephalon*

Under the terms of the Agreements, the Company is responsible for the manufacture of clinical and commercial supplies of the products for sale in the U.S. Under the terms of the Agreements, the Company bills Cephalon at cost for finished product shipped to them. The Company records this manufacturing revenue as Manufacturing revenues in the consolidated statements of income and comprehensive income. An amount equal to this manufacturing revenue is recorded as cost of goods manufactured in the consolidated statements of income and comprehensive income. Manufacturing revenue and cost of goods manufactured related to VIVITROL were recorded for the first time in the year ended March 31, 2007, as the Company began shipping VIVITROL to Cephalon.

The amount of the arrangement consideration allocated to the accounting unit manufacturing of the products is based on the estimated fair value of manufacturing profit to be earned over the expected ten year life of VIVITROL.

Manufacturing profit is estimated at 10% of the forecasted cost of goods manufactured over the expected life of VIVITROL. This profit margin was determined by reference to margins on other products the Company produces for partners, an analysis of margins enjoyed by other pharmaceutical contract manufacturers and other available data. The forecast of units to be manufactured was negotiated between the Company and Cephalon. The Company's obligation to manufacture VIVITROL is limited to volumes that the Company is capable of supplying at its manufacturing facility, and the units to be manufactured in the forecast are in line with, and do not exceed, this maximum anticipated capacity. The Company estimates the fair value of this accounting unit to be \$77.8 million and this amount was allocated out of the \$110.0 million in consideration received from Cephalon upon FDA approval of VIVITROL. The Company records the earned portion of the arrangement consideration allocated to this accounting unit to revenue in proportion to the units of finished VIVITROL shipped during the reporting period, to the total expected units of finished VIVITROL to be shipped over the expected life of VIVITROL. This milestone revenue is recorded as Manufacturing revenues in the consolidated statements of income and comprehensive income. During the years ended March 31, 2008, 2007 and 2006, the Company recorded \$0.6 million, \$1.5 million and \$0 of milestone revenue, respectively, related to this accounting unit.

*Net Collaborative Profit Related to the Agreements with Cephalon*

The amount of the arrangement consideration allocated to the accounting unit net losses on the products represents the Company's best estimate of the net product losses that the Company was responsible for through December 31, 2007, plus those development costs incurred by the Company to obtain FDA approval of VIVITROL and to complete the first manufacturing line, both of which were the Company's sole responsibility. The Company estimates the fair value of this accounting unit to be approximately \$144.4 million and this amount was allocated out of the \$160.0 million in consideration the Company received from Cephalon upon signing the Agreements. The Company records the earned portion of the arrangement consideration allocated to this accounting unit to revenue in the period that the Company was responsible for product losses, being the period ending December 31, 2007. This milestone revenue directly offsets the Company's expenses incurred on VIVITROL and Cephalon's net losses on VIVITROL and is recorded as Net collaborative profit in the consolidated statements of income and comprehensive income. During the years ended March 31, 2008, 2007 and 2006, the Company recorded \$5.3 million \$78.8 million and \$60.5 million, respectively, of milestone revenue related to this accounting unit. In the years ended March 31, 2008, 2007 and 2006, because a portion of these amounts related to cash returned to Cephalon as reimbursement for its net losses up to the cumulative net loss cap, those net payments, which totaled \$5.2 million, \$47.0 million and \$21.2 million, respectively, were

netted against the milestone revenue. In addition, in the year ended March 31, 2008, the Company received cash of \$14.8 million from Cephalon as reimbursement for the Company's net product losses that exceeded the cumulative net loss cap through

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

December 31, 2007 and to reimburse the Company for expenses that exceeded the Company's share of net product losses after December 31, 2007

Under the terms of the Agreements, the Company granted Cephalon a co-exclusive license to the Company's patents and know-how necessary to use, sell, offer for sale and import the products for all current and future indications in the U.S. The arrangement consideration allocated to the product license is based on the residual method of allocation as outlined in EITF No. 00-21, because fair value evidence exists separately for the undelivered obligations under the Agreements. The arrangement consideration allocated to this accounting unit equals the total arrangement consideration received from Cephalon less the fair value of the manufacturing obligations and the net losses on VIVITROL. The Company estimates the fair value of this accounting unit to be approximately \$52.4 million of the \$274.6 million in total consideration the Company has received to date. The Company records the earned portion of the arrangement consideration allocated to the product license to revenue on a straight-line basis over the expected life of VIVITROL, being ten years. This revenue is recorded as "Net collaborative profit" in the consolidated statements of income and comprehensive income. The Company began to recognize milestone revenue related to this accounting unit upon FDA approval of VIVITROL in April 2006. During the years ended March 31, 2008, 2007 and 2006, the Company recorded \$5.2 million, \$5.1 million and \$0 of milestone revenue, respectively, related to the product license.

If there are significant changes in the Company's estimates of the fair value of an accounting unit, the Company would reallocate the arrangement consideration to the accounting units based on the revised fair values. This revision would be recognized prospectively in the consolidated statements of income and comprehensive income over the remaining terms of the affected accounting units.

Under the terms of the Agreements, Cephalon will pay the Company up to \$220.0 million in nonrefundable milestone payments if calendar year net sales of the products exceed certain agreed-upon sales levels. Under current accounting guidance, the Company expects to recognize these milestone payments in the period earned as "Net collaborative profit" in the consolidated statement of income and comprehensive income.

***Concentrations***

Financial instruments that potentially subject the Company to concentrations of credit risk are accounts receivable and marketable securities. Large pharmaceutical companies account for the majority of the Company's accounts receivable and collateral is generally not required from these customers. To mitigate credit risk, the Company monitors the financial performance and credit worthiness of its customers.

The following represents revenue and receivables from the Company's customers exceeding 10% of the total in each category as of and for the year ended March 31:

Customer	2008		2007		2006	
	Revenue	Receivables	Revenue	Receivables	Revenue	Receivables
Janssen	52%	33%	47%	35%	49%	69%
Eli Lilly & Company	23%	30%	20%	33%	21%	21%
Amylin Pharmaceuticals, Inc.	14%	31%		18%		



Cephalon	11%	5%	24%	14%	24%
----------	-----	----	-----	-----	-----

***Research and Development Expenses***

The Company's research and development expenses include employee compensation, including share-based compensation expense, and related benefits, laboratory supplies, temporary help costs, external research costs, consulting costs, occupancy costs, depreciation expense and other allocable costs directly related to the

F-14

---

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

Company's research and development activities. Research and development expenses are incurred in conjunction with the development of the Company's technologies, proprietary product candidates, collaborators' product candidates and in-licensing arrangements. External research costs relate to toxicology studies, pharmacokinetic studies and clinical trials that are performed for the Company under contract by external companies, hospitals or medical centers. A significant portion of the Company's 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 the Company's technologies in general. Expenses incurred to purchase specific services from third parties to support the Company's collaborative research and development activities are tracked by project and are reimbursed to the Company by its partners. The Company accounts for its research and development expenses on a departmental and functional basis in accordance with its budget and management practices. All such costs are expensed as incurred.

***Share-Based Compensation***

The Company's share-based compensation programs consist of share-based awards granted to employees and members of the Company's board of directors, including stock options and restricted stock. Until March 31, 2006, the Company applied Accounting Principles Board (APB) Opinion No. 25, *Accounting for Stock Issued to Employees* (APB No. 25), in accounting for the Company's plans and applied SFAS No. 123, *Accounting for Stock Issued to Employees* (SFAS No. 123), as amended by SFAS No. 148, *Accounting for Stock-Based Compensation: Transition and Disclosure* (SFAS No. 148), for disclosure purposes only. The SFAS No. 123 disclosures included pro forma net income and earnings per share as if the fair value-based method of accounting had been used. Stock-based compensation issued to non-employees was accounted for in accordance with SFAS No. 123 and related interpretations.

Effective April 1, 2006, the Company adopted SFAS No. 123 (revised 2004), *Share-Based Payments* (SFAS No. 123(R)), which replaced SFAS No. 123 and superseded APB No. 25. SFAS No. 123(R) requires compensation cost relating to share-based payment transactions to be recognized in the financial statements using a fair-value measurement method. Under the fair value method, the estimated fair value of awards is charged against income over the requisite service period, which is generally the vesting period. The Company selected the modified prospective transition method upon adoption of SFAS No. 123(R). 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 fair value of the stock option grants is based on estimates as of the date of grant using a Black-Scholes option valuation model. The fair value of restricted stock is based on the market value of the Company's common stock on the date of grant. Compensation expense for stock options and restricted stock, including the effect of forfeitures, is recognized over the applicable service period. Certain of the Company's employees are retirement eligible under the terms of the Company's stock option plans (the Plans), and awards to these employees generally vest in full upon retirement; since there are no effective future service requirements for these employees, the fair value of these awards is expensed in full on the grant date.

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

The following table illustrates the effects on net income and earnings per common share, basic and diluted, for the year ended March 31, 2006 as if the Company had applied the fair value recognition provisions of SFAS No. 123 to share-based awards.

	<b>Year Ended March 31, 2006 (In thousands, except per share amounts)</b>
Net income as reported	\$ 3,818
Add: share-based compensation expense as reported in the consolidated statement of income and comprehensive income	442
Deduct: share-based compensation expense determined under the fair-value method for all options and awards	(22,472)
Net loss pro-forma	\$ (18,212)
Reported earnings per common share:	
Basic	\$ 0.04
Diluted	\$ 0.04
Pro-forma loss per common share:	
Basic	\$ (0.20)
Diluted	\$ (0.20)

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

	<b>Year Ended March 31, 2006</b>
Expected option term	4.8 years
Expected stock volatility	50%
Risk-free interest rate	4.27%
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 consolidated statement of income and comprehensive income for the year ended March 31, 2007 and was included in operating income in the quarter

ended June 30, 2006.

***Income Taxes***

The Company recognizes income taxes under the asset and liability method. Deferred income taxes are recognized for differences between the financial reporting and tax bases of assets and liabilities at enacted statutory tax rates in effect for the years in which differences are expected to reverse. The effect on deferred taxes of a change in tax rates is recognized in income in the period that includes the enactment date.

Effective April 1, 2007, the Company accounts for uncertain tax positions in accordance with FASB Interpretation No. 48, *Accounting for Uncertainty in Income Taxes – an Interpretation of FASB Statement No. 109* ( FIN No. 48 ). FIN No. 48 prescribes a recognition threshold and measurement attribute for financial statement recognition and measurement of a tax position taken or expected to be taken in a tax

F-16

---

**Table of Contents**

**ALKERMES, INC. AND SUBSIDIARIES**

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

return and also provides guidance on various related matters such as derecognition, interest and penalties, and disclosure. The Company also recognizes interest and penalties, if any, related to unrecognized tax benefits in income tax expense.

***Comprehensive Income***

SFAS No. 130, *Reporting Comprehensive Income*, ( SFAS No. 130 ) requires the Company to display comprehensive income and its components as part of the Company's consolidated financial statements. Comprehensive income consists of net income and other comprehensive income. Other comprehensive income includes changes in equity that are excluded from net income, such as unrealized holding gains and losses on available-for-sale marketable securities.

***Earnings per Share***

The Company calculates earnings per share in accordance with SFAS No. 128, *Earnings per Share* ( SFAS No. 128 ). SFAS No. 128 requires the presentation of basic earnings per share and diluted earnings per share. Basic earnings per share is calculated based upon net income available to holders of common shares divided by the weighted average number of shares outstanding. For the calculation of diluted earnings per 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 and redeemable convertible preferred stock.

***Segment Information***

SFAS No. 131, *Disclosures about Segments of and Enterprise and Related Information*, ( SFAS No. 131 ) establishes standards for reporting information on operating segments in interim and annual financial statements. The Company operates one segment, which is the business of developing, manufacturing and commercialization of innovative medicines for the treatment of prevalent, chronic diseases. The Company's chief decision maker, the Chief Executive Officer, reviews the Company's operating results on an aggregate basis and manages the Company's operations as a single operating unit.

***401(k) Plan***

The Company's 401(k) retirement savings plan (the 401(k) Plan ) covers substantially all of its employees. Eligible employees may contribute up to 100% of their eligible compensation, subject to certain Internal Revenue Service limitations. The Company matches a portion of employee contributions. The match is equal to 50% of the first 6% of employee pay and is fully vested when made. During the years ended March 31, 2008, 2007 and 2006, the Company contributed approximately \$1.6 million, \$1.5 million and \$1.1 million, respectively, to match employee deferrals under the 401(k) Plan.

***Reclassifications***

Long-term investments of \$0.7 million that were classified as Other Assets at March 31, 2007, were reclassified to Investments Long-Term in the accompanying consolidated balance sheet to conform to the current year presentation.

***New Accounting Pronouncements***

In September 2006, the FASB issued 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

F-17

---

**Table of Contents**

**ALKERMES, INC. AND SUBSIDIARIES**

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

those definitions in GAAP. SFAS No. 157 is effective for the Company on a prospective basis for the reporting period beginning April 1, 2008 for its financial assets and liabilities. In February 2008, the FASB issued FASB Staff Position ( FSP ) SFAS No. 157-2, which delayed the effective date of SFAS No. 157 for all nonrecurring fair value measurements of nonfinancial assets and nonfinancial liabilities until the period beginning April 1, 2009. The Company does not expect the adoption of SFAS No. 157 to have a significant impact on its consolidated financial statements.

In February 2007, the FASB issued SFAS No. 159, *The Fair Value Option for Financial Assets and Financial Liabilities Including an Amendment of FASB Statement No. 115* ( SFAS No. 159 ). SFAS No. 159 permits entities to elect to measure selected financial instruments and certain other items at fair value. Unrealized gains and losses on items for which the fair value option has been elected are recognized in earnings at each reporting period. SFAS No. 159 is effective for the Company's fiscal year beginning April 1, 2008. The Company does not expect the adoption of SFAS No. 159 to have a significant impact on its consolidated financial statements.

In June 2007, the EITF reached a final consensus on EITF Issue No. 07-3, *Accounting for Nonrefundable Advance Payments for Goods or Services to Be Used in Future Research and Development Activities* ( EITF No. 07-3 ). EITF No. 07-3 is effective for the Company's fiscal year beginning April 1, 2008. EITF No. 07-3 requires nonrefundable advance payments for future research and development activities to be capitalized until the goods have been delivered or related services have been performed. Adoption is on a prospective basis and could impact the timing of expense recognition for agreements entered into after March 31, 2008. The Company does not expect the adoption of EITF No. 07-3 to have a significant impact its consolidated financial statements.

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

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

In May 2008, the FASB issued FASB Staff Position ( FSP ) No. APB 14-1, *Accounting for Convertible Debt Instruments That May Be Settled in Cash upon Conversion (Including Partial Cash Settlement)* ( FSP No. APB 14-1 ), which is effective for the Company's fiscal year beginning on April 1, 2009. FSP No. APB 14-1 requires that proceeds from the issuance of such instruments be allocated between a liability and equity component in a manner that will reflect the Company's nonconvertible debt borrowing rate when interest cost is recognized in subsequent periods. Adoption is on a retrospective basis to all prior periods presented for all convertible debt instruments within the scope of the FSP existing as of the effective date. The Company does not expect the adoption of FSP No. APB 14-1 to have a significant impact on its consolidated financial statements.





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

Basic and diluted earnings per share for the years ended March 31 were calculated as follows:

	<b>2008</b>	<b>2007</b>	<b>2006</b>
	<b>(In thousands)</b>		
Numerator:			
Net income	\$ 166,979	\$ 9,445	\$ 3,818
Denominator:			
Weighted average number of common shares outstanding, basic	100,742	99,242	91,022
Effect of dilutive securities:			
Stock options	2,101	3,411	4,132
Restricted stock awards	80	254	84
Redeemable convertible preferred stock		444	2,139
Dilutive potential common share equivalents	2,181	4,109	6,355
Shares used in calculating diluted earnings per share	102,923	103,351	97,377

The following amounts were not included in the calculation of earnings per share because their effects were anti-dilutive for the years ended March 31:

	<b>2008</b>	<b>2007</b>	<b>2006</b>
	<b>(In thousands)</b>		
Numerator:			
Adjustment for interest, net of tax	\$	\$ 1,246	\$ 3,150
Adjustment for derivative loss			1,084
Total	\$	\$ 1,246	\$ 4,234
Denominator:			
Stock options	12,300	6,985	4,912
2.5% convertible subordinated notes		1,879	9,025
3.75% convertible subordinated notes		9	10
Total	12,300	8,873	13,947

#### **4. RESTRUCTURING**

In March 2008, the Company's collaborative partner Eli Lilly and Company (Lilly) announced the decision to discontinue the AIR Insulin development program and gave notice of termination under the collaborative development and license agreement. In connection with the program termination, in March 2008, the Company's board of directors approved a plan (the 2008 Restructuring) to reduce the Company's workforce by approximately 150 employees and to cease operations at the Company's AIR commercial manufacturing facility located in Chelsea, Massachusetts. The Company notified employees affected by the 2008 Restructuring in March 2008.

F-19

---

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

In connection with the 2008 Restructuring, the Company recorded restructuring charges consisting of the following (in thousands):

Severance, continuation of benefits and outplacement services	\$ 2,881
Leasehold costs	3,886
Other contract losses	146
Total restructuring charges	\$ 6,913

As of March 31, 2008, the Company had paid approximately \$0.1 million in connection with the 2008 Restructuring. The Company expects to incur and pay an additional \$0.4 million in the year ended March 31, 2009 related to costs for severance, continuation of benefits and costs to decommission the AIR commercial manufacturing facility associated with the 2008 Restructuring. The amounts remaining in the restructuring accrual as of March 31, 2008 are expected to be paid out through fiscal 2016 and relate primarily to estimates of lease costs associated with the exited facility, and may require adjustment in the future.

In connection with the termination of the AIR Insulin development program, the Company performed an impairment analysis on the assets that supported the production of AIR Insulin, which consisted of equipment and leasehold improvements at the AIR commercial manufacturing facility. The Company determined that the carrying value of these assets exceeded their fair value and recorded an impairment charge of \$11.6 million in March 2008. Fair value of the impaired assets was based on internally established estimates and selling prices of similar assets.

In June 2004, the Company and its former collaborative partner Genentech, Inc. ( Genentech ) announced the decision to discontinue commercialization of NUTROPIN DEPOT® (the 2004 Restructuring ). In connection with the 2004 Restructuring, the Company recorded charges of \$11.5 million in the year ended March 31, 2005. In addition to the restructuring, the Company also recorded a one-time write-off of NUTROPIN DEPOT inventory of approximately \$1.3 million, which was recorded as Cost of goods manufactured in the consolidated statement of operations and comprehensive loss in the year ended March 31, 2005. As of March 31, 2008, the Company had paid in cash, written down, recovered and made restructuring charge adjustments that aggregated approximately \$11.3 million in connection with the 2004 Restructuring, and the amounts remaining in the restructuring accrual at March 31, 2008 will be paid out in fiscal 2009.

In August 2002, the Company announced a restructuring program (the 2002 Restructuring ) to reduce its cost structure as a result of the Company's expectations regarding the financial impact of a delay in the U.S. launch of RISPERDAL CONSTA by the Company's collaborative partner, Janssen. In connection with the 2002 Restructuring, the Company recorded charges of approximately \$6.5 million for the year ended March 31, 2003. There are no remaining liabilities associated with the 2002 Restructuring as of March 31, 2008.

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

The following restructuring activity was recorded during the years ended March 31, 2008, 2007 and 2006:

	<b>2002</b>	<b>2004</b>	<b>2008</b>	<b>Total</b>
	<b>Restructuring</b>	<b>Restructuring</b>	<b>Restructuring</b>	<b>Liability</b>
	<b>(In thousands)</b>			
Balance, April 1, 2005	\$ 389	\$ 2,974	\$	\$ 3,363
Adjustments	(34)			(34)
Non-cash writedowns and payments	(355)	(606)		(961)
Balance March 31, 2006	\$	\$ 2,368	\$	\$ 2,368
Adjustments(1)		(518)		(518)
Non-cash writedowns and payments		(771)		(771)
Balance March 31, 2007	\$	\$ 1,079	\$	\$ 1,079
Charges(2)		(490)	6,913	6,423
Reclassification(3)			1,044	1,044
Non-cash writedowns and payments		(359)	(109)	(468)
Balance March 31, 2008	\$	\$ 230	\$ 7,848	\$ 8,078

- (1) Consists of \$0.5 million of income due to the Company under a sublease agreement for a facility that the Company closed in connection with the 2004 Restructuring in the year ended March 31, 2007. This adjustment is included in selling, general and administrative expenses in the accompanying consolidated statements of income and comprehensive income.
- (2) Charges related to the 2008 Restructuring of \$6.9 million are described above. The income of \$0.5 million related to the 2004 Restructuring is due to an adjustment made in expected future lease expense for a facility that the Company closed in connection with the 2004 Restructuring. Both amounts are included in restructuring expense in the accompanying consolidated statements of income and comprehensive income.
- (3) The reclassification of \$1.0 million related to the 2008 Restructuring is related to amounts previously accrued by the Company related to escalating lease payments under the Company's AIR commercial manufacturing facility lease.

Table of Contents**ALKERMES, INC. AND SUBSIDIARIES****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)****5. INVESTMENTS**

Investments consisted of the following at March 31:

	<b>Amortized Cost</b>	<b>Gross Unrealized Gains      Losses (In thousands)</b>		<b>Estimated Fair Value</b>
<b>2008</b>				
Short-term investments:				
Available-for-sale securities:				
U.S. government obligations	\$ 216,479	\$ 1,261	\$	\$ 217,740
Corporate debt securities	22,327		(3)	22,324
Total short-term investments	238,806	1,261	(3)	240,064
Long-term investments:				
Available-for-sale securities:				
Asset backed securities	9,485		(460)	9,025
Auction rate securities	10,000		(682)	9,318
Corporate debt securities	95,627		(1,539)	94,088
	115,112		(2,681)	112,431
Held-to-maturity securities:				
U.S. government obligations	413			413
Corporate debt securities	4,240			4,240
	4,653			4,653
Other strategic investments	1,908	91	(27)	1,972
Total long-term investments	121,673	91	(2,708)	119,056
Total investments	\$ 360,479	\$ 1,352	\$ (2,711)	\$ 359,120
<b>2007</b>				
Short-term investments:				
Available-for-sale securities:				
U.S. government obligations	\$ 89,377	\$ 495	\$	\$ 89,872
Corporate debt securities	181,074	175	(39)	181,210

Edgar Filing: ALKERMES INC - Form 10-K

Total short-term investments	270,451	670	(39)	271,082
Long-term investments:				
Held-to-maturity securities:				
U.S. government obligations	404			404
Corporate debt securities	4,740			4,740
	5,144			5,144
Other strategic investments	510	230		740
Total long-term investments	5,654	230		5,884
Total investments	\$ 276,105	\$ 900	\$ (39)	\$ 276,966

F-22

---

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

The proceeds from the sales and maturities of marketable securities, excluding strategic investments, which were primarily reinvested, and resulting realized gains and losses were as follows:

	<b>Year Ended March 31,</b>		
	<b>2008</b>	<b>2007</b>	<b>2006</b>
	<b>(In thousands)</b>		
Proceeds from sales and maturities of marketable securities	\$ 544,783	\$ 307,050	\$ 541,061
Realized gains	\$ 172	\$ 220	\$ 61
Realized losses	\$ 48	\$ 144	\$ 69

The Company's available-for-sale and held-to-maturity securities at March 31, 2008 have contractual maturities in the following periods:

	<b>Available-for-Sale</b>		<b>Held-to-Maturity</b>	
	<b>Amortized Cost</b>	<b>Estimated Fair Value</b>	<b>Amortized Cost</b>	<b>Estimated Fair Value</b>
	<b>(In thousands)</b>			
Within 1 year	\$ 177,163	\$ 177,428	\$ 4,653	\$ 4,653
After 1 year through 5 years(1)	44,610	44,363		
After 5 years through 10 years(1)	122,145	121,386		
After 10 years	10,000	9,318		
Total	\$ 353,918	\$ 352,495	\$ 4,653	\$ 4,653

(1) Certain of the Company's investments in available-for-sale securities have call features which may bring the terms to less than maturity.

As of March 31, 2008, the Company had available-for-sale, long-term investments with maturities in excess of one year that had gross unrealized losses of \$2.7 million. These investments were in a continuous unrealized loss position for less than twelve months, and the Company believes these losses are temporary and has the intent and ability to hold these securities to recovery, which may be at maturity. The investments generally consist of investment grade corporate debt securities, auction rate debt securities and asset backed debt securities.

As of March 31, 2008, the Company's investments in auction rate securities had an unrealized loss of \$0.7 million. The securities represent the Company's investment in taxable student loan revenue bonds issued by state higher education authorities which service student loans under the Federal Family Education Loan Program (FFELP). The bonds were AAA rated at the date of purchase and are collateralized by student loans purchased by the authorities which are guaranteed by state sponsored agencies and reinsured by the U.S. Department of Education.

Liquidity for these securities is typically provided by an auction process that resets the applicable interest rate at pre-determined intervals. Each of these securities had been subject to auction processes for which there had been insufficient bidders on the scheduled auction dates and the auctions subsequently failed. The Company is not able to liquidate its investments in auction rate securities until future auctions are successful, a buyer is found outside of the auction process or the notes are redeemed by the issuer. The securities continue to pay interest at predetermined interest rates during the periods in which the auctions have failed at interest rates that exceed the interest rate established at the last successful auction.

Typically, auction rate securities trade at their par value due to the short interest rate reset period and the availability of buyers of sellers of the securities at recurring auctions. However, since the security auctions have failed and fair value cannot be derived from quoted prices, the Company used a discounted cash flow model to determine the estimated fair value of the securities as of March 31, 2008. The assumptions used in



**Table of Contents**

**ALKERMES, INC. AND SUBSIDIARIES**

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

the discounted cash flow model include estimates for interest rates, timing of cash flows, expected holding periods and a risk adjusted discount rate, which includes a provision for default and liquidity risk. As of March 31, 2008, the Company determined that the securities were temporarily impaired due to the length of time each security was in an unrealized loss position, the extent to which fair value was less than cost, financial condition and near term prospects of the issuers and the Company's intent and ability to hold each security for a period of time sufficient to allow for any anticipated recovery in fair value.

At March 31, 2008, the Company's investment in asset backed securities had an unrealized loss of \$0.5 million. The securities represent the Company's investment in AAA rated medium term floating rate notes ( MTN ) of Aleutian Investments, LLC ( Aleutian ) and Meridian Funding Company, LLC ( Meridian ), which are qualified special purpose entities ( QSPE s ) of Ambac Financial Group, Inc. ( Ambac ) and MBIA, Inc. ( MBIA ), respectively. Ambac and MBIA are guarantors of financial obligations and are referred to as monoline financial guarantee insurance companies. The QSPE s, which purchase pools of assets or securities and fund the purchase through the issuance of MTN s, have been established to provide a vehicle to access the capital markets for asset backed securities and corporate borrowers. The MTN s include a sinking fund redemption feature which match-fund the terms of redemptions to the maturity dates of the underlying pools of assets or securities in order to mitigate potential liquidity risk to the QSPE s. At March 31, 2008, a substantial portion of the Company's initial investment in the Meridian MTN s had been redeemed by MBIA through scheduled sinking fund redemptions at par value, and the first sinking fund redemption on the Aleutian MTN is scheduled for June 2009.

The liquidity and fair value of these securities has been negatively impacted by the uncertainty in the credit markets, and the exposure of these securities to the financial condition of monoline financial guarantee insurance companies, including Ambac and MBIA. The Company may not be able to liquidate its investment in the securities before the scheduled redemptions or until trading in the securities resumes in the credit markets, which may not occur. Because the MTN s are not trading in the credit markets and fair value cannot be derived from quoted prices, the Company has used a discounted cash flow model to determine the estimated fair value of the securities as of March 31, 2008. The assumptions used in the discounted cash flow model include estimates for interest rates, timing of cash flows, expected redemptions and a risk adjusted discount rate, which includes a provision for default risk on Ambac and MBIA issued debt. As of March 31, 2008, the Company determined that the securities had been temporarily impaired due to the length of time each security was in an unrealized loss position, the extent to which fair value was less than cost, financial condition and near term prospects of the issuers and the Company's intent and ability to hold each security for a period of time sufficient to allow for any anticipated recovery in fair value or until scheduled redemption.

The Company's strategic investments include equity securities in certain publicly held companies in connection with the Company's collaboration and licensing activities. For the years ended March 31, 2008, 2007 and 2006, the Company recognized \$1.6 million, \$0 and \$0.6 million, respectively, in charges for other-than-temporary losses on its strategic investments.

The Company also holds warrants to purchase securities of certain publicly held companies in connection with its collaboration and licensing activities that are considered to be derivative instruments. As of March 31, 2008 and 2007, the warrants had carrying values of less than \$0.1 million and \$1.6 million, respectively. In the year ended March 31, 2008, the Company exercised certain of its warrants to purchase the common stock of a collaborator, which had a fair value of \$3.0 million on the date of exercise. The warrants are valued using an established option pricing model, and

changes in value are recorded in the consolidated statement of income and comprehensive income as Other income (expense), net. During the year ended March 31, 2008, 2007 and 2006, the Company recorded income of \$1.4 million, a charge of \$0.7 million, and income of \$1.4 million, respectively, related to changes in the value of warrants. The recorded value of the warrants can fluctuate significantly based on fluctuations in the market value of the underlying securities of the issuer of the warrants. These warrants are included in Other Assets in the accompanying consolidated balance sheets.

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

In November 2007, Reliant Pharmaceuticals, Inc. ( Reliant ) was acquired by GlaxoSmithKline ( GSK ). Under the terms of the acquisition, the Company received \$166.9 million upon the closing of the transaction in December 2007 in exchange for the Company's investment in Series C convertible, redeemable preferred stock of Reliant. The Company purchased the Series C convertible, redeemable preferred stock of Reliant for \$100.0 million in December 2001. The Company's investment in Reliant had a carrying value of \$0 at the time of the sale. This transaction was recorded as a non-operating gain on sale of investment in Reliant Pharmaceuticals, Inc. of \$174.6 million in the three months ended December 31, 2007. The Company is entitled to receive up to an additional \$7.7 million of funds held in escrow subject to the terms of an escrow agreement between GSK and Reliant. The \$7.7 million of funds held in escrow is included within Other Assets in the consolidated balance sheet as of March 31, 2008. See Note 12 for further discussion regarding the funds held in escrow.

**6. ACCOUNTS PAYABLE AND ACCRUED EXPENSES**

Accounts payable and accrued expenses consisted of the following at March 31:

	<b>2008</b>	<b>2007</b>
	<b>(In thousands)</b>	
Accounts payable	\$ 7,042	\$ 12,097
Accrued expenses related to collaborative arrangements	859	16,155
Accrued compensation	11,245	10,917
Accrued other	9,888	6,402
Total	\$ 29,034	\$ 45,571

**7. LONG-TERM DEBT**

Long-term debt consisted of the following at March 31:

	<b>2008</b>	<b>2007</b>
	<b>(In thousands)</b>	
Non-recourse RISPERDAL CONSTA secured 7% notes	\$ 160,324	\$ 156,851
Term loan and equipment financing arrangement		1,474
Obligation under capital lease	47	152
Total	160,371	158,477
Less: current portion	(47)	(1,579)
Long-term debt	\$ 160,324	\$ 156,898

***Non-Recourse RISPERDAL CONSTA Secured 7% Notes***

On February 1, 2005, the Company, pursuant to the terms of a purchase and sale agreement, sold, assigned and contributed to Royalty Sub the rights of the Company to collect certain royalty payments and manufacturing fees (the Royalty Payments ) earned under the Janssen Agreements (defined below) and certain agreements that may arise in the future, in exchange for approximately \$144.2 million in cash. The Royalty Payments arise under: (i) the license agreements dated February 13, 1996 for the U.S. and its territories and February 21, 1996 for all countries other than the U.S. and its territories, by and between the Company, and its successors, and Janssen Pharmaceutical, Inc. and certain of its affiliated entities ( JP ); and (ii) the manufacturing and supply agreement dated August 6, 1997 by and between JPI Pharmaceutica International ( JPI and together with JP, Janssen ), JP and the Company (collectively, the Janssen

F-25

---

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

Agreements ). The assets of Royalty Sub consist principally of the rights to the Royalty Payments described above.

Concurrently with the purchase and sale agreement, on February 1, 2005, Royalty Sub issued an aggregate principal amount of \$170.0 million of its 7% Notes to certain institutional investors in a private placement, for net proceeds of approximately \$144.2 million, after the original issue discount and offering costs of approximately \$19.7 million and \$6.1 million, respectively. The yield to maturity at the time of the offer was 9.75%. The annual cash coupon rate is 7% and is payable quarterly, beginning on April 1, 2005, however, portions of the principal amount that are not paid off in accordance with the expected principal repayment profile will accrue interest at 9.75%. Through January 1, 2009, the holders will receive only the quarterly cash interest payments. Beginning on April 1, 2009, principal payments will be made to the holders, subject to certain conditions. Timing of the principal repayment will be based on the revenues received by Royalty Sub but will occur no earlier than equally over the twelve quarters between April 1, 2009 and January 1, 2012, subject to certain conditions. Non-payment of principal will not be an event of default prior to the legal maturity date of January 1, 2018. The 7% Notes, however, may be redeemed at Royalty Sub's option, subject, in certain circumstances, to the payment of a redemption premium. The 7% Notes are secured by: (i) all of Royalty Sub's property and rights, including the royalty rights; and (ii) the Company's ownership interests in Royalty Sub. Accordingly, the assets of Royalty Sub will not be available to satisfy other obligations of Alkermes.

The Royalty Payments received by Royalty Sub under the Janssen Agreements are the sole source of payment of the interest, principal and redemption premium, if any, for the 7% Notes. The Company will receive all of the RISPERDAL CONSTA revenues in excess of interest, principal and redemption premium, if any. The Company's rights to receive such excess revenues will be subject to certain restrictions while the 7% Notes remain outstanding. The Company is also subject to comply with certain other customary affirmative covenants and event of default provisions. At March 31, 2008, the Company was in compliance with all such covenants.

Scheduled maturities with respect to the 7% notes for the next four fiscal years are as follows:

	<b>2009</b>	<b>2010</b>	<b>2011</b>	<b>2012</b>
	<b>(In thousands)</b>			
7% Notes(1)	\$	\$ 56,667	\$ 56,667	\$ 56,666

(1) The 7% Notes were issued by Royalty Sub. The 7% Notes are non-recourse to Alkermes.

The offering costs are recorded as Other Assets in the consolidated balance sheets as of March 31, 2008 and 2007. The Company amortizes the original issue discount and the offering costs over the expected principal repayment period ending January 1, 2012 as additional interest expense. During the years ended March 31, 2008, 2007 and 2006, amortization of the original issue discount and the offering costs on the 7% Notes totaled \$4.4 million, \$4.1 million, and \$3.8 million, respectively.

**2.5% Subordinated Notes**

In August and September 2003, the Company issued an aggregate of \$100.0 million and \$25.0 million, respectively, principal amount of the 2.5% convertible subordinated notes due 2023 (the 2.5% Subordinated Notes ). As a part of the sale of the 2.5% Subordinated Notes, the Company incurred approximately \$4.0 million of offering costs which were recorded under the caption Other assets in the consolidated balance sheets and were being amortized to interest expense over the estimated term of the 2.5% Subordinated Notes. The 2.5% Subordinated Notes were convertible into shares of the Company s common stock at a conversion price of \$13.85 per share, subject to adjustment in certain events. Prior to the conversion, the 2.5% Subordinated Notes bore interest at 2.5% per year, payable semiannually on March 1 and September 1,

**Table of Contents**

**ALKERMES, INC. AND SUBSIDIARIES**

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

commencing on March 1, 2004 and were subordinated to existing and future senior indebtedness of the Company.

The Company could have elected to automatically convert the notes anytime the closing price of its common stock had exceeded 150% of the conversion price (\$20.78) for as least 20 trading days during any 30-day trading period. However, if an automatic conversion occurred on or prior to September 1, 2006, the Company would have been required to pay additional interest in cash or, at the Company's option, in common stock, equal to three full years of interest in the converted notes (the three-year interest make-whole), less any interest actually paid or provided for on the notes prior to automatic conversion. The three-year interest make-whole was considered a derivative, and the Company adopted the provisions of the FASB's Derivative Implementation Group (DIG) Issue B39 in the reporting period beginning January 1, 2006, at which time the carrying value of the embedded derivative, of \$1.3 million, contained in the 2.5% Subordinated Notes was combined with the carrying value of the host contracts and no longer required separate recognition or accounting.

On June 15, 2006, the Company converted all of the outstanding \$125.0 million principal amount of 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 the 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 March 31, 2008 or 2007, 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.

***3.75% Subordinated Notes***

On February 15, 2007, the 3.75% convertible subordinated notes due 2007 (the 3.75% Subordinated Notes) matured. The Company repaid the \$0.7 million principal amount of the 3.75% Subordinated Notes on the maturity date. None of the 3.75% Subordinated Notes were outstanding as of March 31, 2008 or 2007.

***Term Loan and Equipment Financing Arrangement***

In December 2004, the Company entered into a term loan in the principal amount of \$3.7 million with General Electric Capital Corporation (GE). The term loan was secured by certain of the Company's equipment pursuant to a security agreement and was subject to an ongoing financial covenant related to the Company's available cash position. The loan was payable in 36 monthly installments and matured in December 2007 and bore a floating interest rate equal to the one-month London Interbank Offered Rate (LIBOR) plus 5.45%.

In addition, in December 2004, the Company entered into a commitment for equipment financing with GE. The equipment financing, in the form of an equipment lease line, provides the Company with the ability to finance up to \$18.3 million in new equipment purchases. The equipment financing would be secured by the purchased equipment and will be subject to a financial covenant. The lease terms provide the Company with the option at the end of the lease to: (a) purchase the equipment from GE at the then prevailing market value; (b) renew the lease at a fair market rental value, subject to remaining economic useful life requirements; or (c) return the equipment to GE, subject to certain conditions. As of March 31, 2008 and 2007, there were no amounts outstanding under this commitment.





**Table of Contents****ALKERMES, INC. AND SUBSIDIARIES****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)*****Obligation Under Capital Lease***

In September 2003, the Company and Johnson & Johnson Finance Corporation ( J&J Finance ) entered into a 60-month sale-leaseback agreement to provide the Company with equipment financing under which the Company received approximately \$0.5 million in proceeds from J&J Finance.

Total annual future minimum lease payments under the capital lease are as follows (in thousands):

Fiscal Year Ending March 31, 2009 :	\$ 48
Less: amount representing interest	(1)
Present value of future lease payments	47
Less: current portion	(47)
Long-term obligation under capital lease	\$

**8. SHAREHOLDERS EQUITY*****Share Repurchase Programs***

In November 2007, the board of directors authorized a share repurchase program to repurchase up to \$175.0 million of the Company's common stock at the discretion of management from time to time in the open market or through privately negotiated transactions (the 2007 repurchase program ). The objective of the 2007 repurchase program is to improve shareholders' returns. As of March 31, 2008, approximately \$81.6 million was available to repurchase common stock pursuant to the 2007 repurchase program. All shares repurchased are recorded as treasury stock. The repurchase program has no set expiration date and may be suspended or discontinued at any time. During the year ended March 31, 2008, the Company expended approximately \$33.4 million on open market purchases and repurchased 2,278,194 shares of outstanding common stock at an average price of \$14.64 under the 2007 repurchase program. Under the 2007 repurchase program, in February 2008, the Company entered into a structured stock repurchase arrangement (the 2008 structured stock repurchase program ) with a large financial institution in order to lower the average cost to acquire shares. The program included terms that required the Company to make an up-front payment of \$60.0 million to the counterparty financial institution and resulted in the receipt of stock at the outset of the arrangement and at the end of the term of the arrangement in March 2008. The 2008 structured stock repurchase program was completed by the counterparty financial institution on March 11, 2008. The Company took delivery of 3,373,313 shares on February 7, 2008, at the outset of the arrangement, and 1,317,229 shares on March 14, 2008, the settlement date, all at an average price of \$12.79.

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 2005 repurchase program ). During the year ended March 31, 2007, the Company expended approximately \$12.5 million and repurchased 823,677 shares at an average price of \$15.20, respectively, under this program. Upon the adoption of the \$175.0 million share repurchase program in November 2007, the repurchase authorization of \$2.5 million remaining

under this program was superceded, and no repurchase authorization remains outstanding under this program.

***Shareholder Rights Plan***

In February 2003, the board of directors of the Company adopted a shareholder rights plan (the Rights Plan ) under which all common shareholders of record as of February 20, 2003 received rights to purchase shares of a new series of preferred stock. The Rights Plan is designed to enable all Alkermes shareholders to realize the full value of their investment and to provide for fair and equal treatment for all shareholders in the event that an unsolicited attempt is made to acquire the Company. The adoption of the Rights Plan is intended

F-28

---

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

as a means to guard against coercive takeover tactics and is not in response to any particular proposal. The rights will be distributed as a nontaxable dividend and will expire ten years from the record date. Each right will initially entitle common shareholders to purchase a fractional share of the preferred stock for \$80. Subject to certain exceptions, the rights will be exercisable only if a person or group acquires 15% or more of the Company's common stock or announces a tender or exchange offer upon the consummation of which such person or group would own 15% or more of the Company's common stock. Subject to certain exceptions, if any person or group acquires 15% or more of the Company's common stock, all rights holders, except the acquiring person or group, will be entitled to acquire the Company's common stock (and in certain instances, the stock of the acquirer) at a discount. The rights will trade with the Company's common stock, unless and until they are separated upon the occurrence of certain future events. Generally, the Company's board of directors may amend the Rights Plan or redeem the rights prior to ten days (subject to extension) following a public announcement that a person or group has acquired 15% or more of the Company's common stock.

**9. SHARE-BASED COMPENSATION***Share-based compensation expense*

The following table presents share-based compensation expense included in the Company's consolidated statements of income and comprehensive income:

	<b>Year Ended March 31,</b>	
	<b>2008</b>	<b>2007</b>
	<b>(In thousands)</b>	
Cost of goods manufactured	\$ 1,812	\$ 2,713
Research and development	7,010	8,604
Selling, general and administrative	10,623	16,370
Total share-based compensation expense	\$ 19,445	\$ 27,687

As of March 31, 2008 and 2007, \$0.3 million and \$0.6 million, respectively, of share-based compensation cost was capitalized and recorded as Inventory, net in the consolidated balance sheets.

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 years ended March 31, 2008 and 2007. 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 daily 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 U.S. treasury yield curve in effect at the time of grants. 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

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

average of the high and low of the Company's common stock traded on the NASDAQ Global Market on the date of grants.

The fair value of each stock option grant was estimated on the grant date with the following weighted-average assumptions:

	<b>Year Ended March 31,</b>	
	<b>2008</b>	<b>2007</b>
Expected option term	4 - 7 years	4 - 5 years
Expected stock volatility	38% - 50%	50%
Risk-free interest rate	2.78% - 5.07%	4.45% - 5.07%
Expected annual dividend yield		

***Stock Options and Award Plans***

The Company's Plans provide for issuance of non-qualified 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 of the board of directors 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 of the Securities Exchange Act. The limited compensation sub-committee of the board of directors has generally approved new hire employee stock option grants of up to the limit of its authority. In October 2007, this limit was raised by the compensation committee of the board of directors to 15,000 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 of the board of directors has established procedures for the grant of options to new employees. Within the limits of its authority, the limited compensation sub-committee of the board of directors grants options to new hires that commenced their employment with the Company in 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 of the board of directors will be granted on the New Hire Grant Date by the compensation committee of the board of directors as a whole.

The compensation committee of the board of the directors has also established procedures for regular grants of stock options to Company employees. The compensation committee of the board of directors 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.

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

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 March 31, 2008, there were no LSARs outstanding under the 1990 Plan. No LSARs were granted during the years ended March 31, 2008, 2007 and 2006.

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 1,500,000 shares of common stock. Awards may vest based on cliff vesting or graded vesting and vest over various periods.

As of March 31, 2008, the Company has reserved a total of 21,422,083 shares of common stock for issuance upon exercise of stock options and 736,899 shares of common stock for issuance upon release of restricted stock awards that have been or may be granted under the Plans or Award Plans, respectively. The Company generally issues common stock from previously authorized but unissued shares to satisfy option exercises and restricted stock awards.

The following table sets forth the stock option and restricted stock award activity during the year ended March 31, 2008:

	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, 2007	19,672,606	\$ 16.36	6.13	287,075	\$ 16.16
Granted(1)	1,636,050	15.50		355,500	14.83
Exercised	(1,267,749)	9.97			
Vesting of restricted stock				(127,325)	12.65
Cancelled(1)	(1,463,752)	18.87		(32,750)	16.23
Outstanding at March 31, 2008	18,577,155	\$ 16.53	5.53	482,500	\$ 16.11
Exercisable at March 31, 2008	14,035,802	\$ 16.60	4.64		

- (1) Not included in options granted and options cancelled are 4,543,685 options that were cancelled and reissued on November 15, 2007 and 839,707 options that were cancelled and reissued on March 31, 2008, which were held by seven of the Company's executive officers. During the year ended March 31, 2008, the Company determined that the compensation attributable to certain grants of non-qualified stock options made to certain of its executive officers in the past may not be deductible by the Company as a result of the limitations imposed by Section 162(m) of the Internal Revenue Code ( Section 162(m) ) because such stock options were granted pursuant to a stock option plan that did not contain one of the provisions necessary in order to maintain such deductibility under Section 162(m). As such, the Company cancelled and reissued the grants under the Amended and Restated 1999 Stock Option Plan for the sole purpose of preserving the Company's tax deduction in the future with respect to such stock options. The options that were cancelled were re-issued with the same terms and there was no incremental compensation cost as a result of the modifications.

F-31

---



**Table of Contents**

**ALKERMES, INC. AND SUBSIDIARIES**

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

The weighted average grant date fair value of stock options granted during the years ended March 31, 2008, 2007 and 2006 was \$6.93, \$8.13 and \$8.42, respectively. The aggregate intrinsic value of stock options exercised during the years ended March 31, 2008, 2007 and 2006 was \$7.0 million, \$4.8 million and 10.3 million, respectively.

As of March 31, 2008, there were 18,220,942 stock options vested and expected to vest with a weighted average exercise price of \$16.53 per share, a weighted average contractual remaining life of 5.47 years and an aggregate intrinsic value of \$12.1 million. As of March 31, 2008, the aggregate intrinsic value of stock options exercisable was \$12.0 million. The expected to vest options are determined by applying the pre-vesting forfeiture rate to the total outstanding options. 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 March 31, 2008, there was \$12.1 million and \$3.1 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 2.3 years and 2.6 years for the Company's Plans and Award Plans, respectively.

Cash received from option exercises under the Company's Plans during the years ended March 31, 2008 and 2007 was \$11.1 million and \$7.5 million, respectively. The Company issued new shares upon option exercises during the years ended March 31, 2008 and 2007.

Since its adoption of SFAS No. 123(R) on April 1, 2006, the Company has been subject to the U.S. Alternative Minimum Tax (AMT), due to certain limitations on NOL utilization. As a result, the company has recorded a \$0.3 million benefit to additional paid-in capital for the reduction to the AMT tax related to these excess tax benefits.

**10. COLLABORATIVE ARRANGEMENTS**

The Company's business strategy includes forming collaborations to develop and commercialize its products, and to access technological, financial, marketing, manufacturing and other resources. The Company has entered into several collaborative arrangements, as described below.

***Janssen***

Under a product development agreement, the Company collaborated with Janssen on the development of RISPERDAL CONSTA. Under the development agreement, Janssen provided funding to the Company for the development of RISPERDAL CONSTA, and Janssen is responsible for securing all necessary regulatory approvals for the product. RISPERDAL CONSTA has been approved in approximately 85 countries. RISPERDAL CONSTA has been launched in approximately 60 countries, including the U.S. and several major international markets. The Company exclusively manufactures RISPERDAL CONSTA for commercial sale and receives manufacturing revenues when product is shipped to Janssen and royalty revenues upon the final sale of the product. In addition, the Company and Janssen have recently agreed to begin work to develop a four week formulation of RISPERDAL CONSTA.

Under license agreements, the Company granted Janssen and an affiliate of Janssen exclusive worldwide licenses to use and sell RISPERDAL CONSTA. Under the Company's license agreements with Janssen, the Company also records royalty revenues equal to 2.5% of Janssen's net sales of RISPERDAL CONSTA in the quarter when the product is sold by Janssen. Janssen can terminate the license agreements upon 30 days prior written notice to the Company.

Under the manufacturing and supply agreement with Janssen, the Company records manufacturing revenues when product is shipped to Janssen, based on a percentage of Janssen's net unit sales price for RISPERDAL CONSTA for the calendar year. This percentage is determined based on Janssen's unit demand

**Table of Contents**

**ALKERMES, INC. AND SUBSIDIARIES**

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

for the calendar year and varies based on the volume of units shipped, with a minimum manufacturing fee of 7.5%.

The manufacturing and supply agreement terminates on expiration of the license agreements. In addition, either party may terminate the manufacturing and supply agreement upon a material breach by the other party which is not resolved within 60 days written notice or upon written notice in the event of the other party's insolvency or bankruptcy. Janssen may terminate the agreement upon six months written notice to the Company. In the event that Janssen terminates the manufacturing and supply agreement without terminating the license agreements, the royalty rate payable to the Company on Janssen's net sales of RISPERDAL CONSTA would increase from 2.5% to 5.0%.

During the years ended March 31, 2008, 2007, 2006, the Company recognized \$124.7 million, \$113.6 million and \$82.8 million, respectively, of revenue from its arrangements with Janssen.

***Cephalon***

In June 2005, the Company entered into a license and collaboration agreement and supply agreement with Cephalon (together the Agreements) to jointly develop, manufacture and commercialize extended-release forms of naltrexone, including VIVITROL (the product or products), in the U.S. Under the terms of the Agreements, the Company provided Cephalon with a co-exclusive license to use and sell the product in the U.S. and a non-exclusive license to manufacture the product under certain circumstances, with the ability to sublicense. The Company was responsible for obtaining marketing approval for VIVITROL in the U.S. for the treatment of alcohol dependence, which the Company received from the FDA in April 2006, and for completing the first VIVITROL manufacturing line. The companies share responsibility for additional development of the products, which may include continuation of clinical trials, performance of new clinical trials, the development of new indications for the products and work to improve the manufacturing process and increase manufacturing yields. The Company and Cephalon also share responsibility for developing the commercial strategy for the products. Cephalon has primary responsibility for the commercialization, including distribution and marketing, of the products in the U.S., and the Company supports this effort with a team of managers of market development. The Company has the option to staff its own field sales force in addition to its managers of market development at the time of the first sales force expansion, should one occur. The Company has responsibility for the manufacture of the products.

In June 2005, Cephalon made a nonrefundable payment of \$160.0 million to the Company upon signing the Agreements. In April 2006, Cephalon made a second nonrefundable payment of \$110.0 million to the Company upon FDA approval of VIVITROL. Cephalon will make additional nonrefundable milestone payments to the Company of up to \$220.0 million if calendar year net sales of the products exceed certain agreed-upon sales levels. Under the terms of the Agreements, the Company was responsible for the first \$124.6 million of net losses incurred on VIVITROL through December 31, 2007 (the cumulative net loss cap). These net product losses excluded development costs incurred by the Company to obtain FDA approval of VIVITROL and costs to complete the first manufacturing line, both of which were the Company's sole responsibility. Cephalon was responsible for all net product losses in excess of the cumulative net loss cap through December 31, 2007. After December 31, 2007, all net profits and losses earned on VIVITROL are divided between the Company and Cephalon in approximately equal amounts.

In October 2006, the Company and Cephalon entered into binding amendments to the license and collaboration agreement and the supply agreement (the Amendments). Under the Amendments, the parties agreed that Cephalon would purchase from the Company two VIVITROL manufacturing lines (and related equipment) under construction,

which will continue to be operated at the Company's manufacturing facility. Cephalon also agreed to be responsible for its own losses related to the products during the period August 1, 2006 through December 31, 2006. In December 2006, the Company received a \$4.6 million payment from Cephalon as reimbursement for certain costs incurred by the Company prior to October 2006, which the

**Table of Contents**

**ALKERMES, INC. AND SUBSIDIARIES**

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

Company had charged to the collaboration and that were related to the construction of the VIVITROL manufacturing lines. These costs consisted primarily of internal or temporary employee time, billed at negotiated FTE rates. The Company and Cephalon agreed to increase the cumulative net loss cap from \$120.0 million to \$124.6 million to account for this reimbursement. During the years ended March 31, 2008 and 2007, the Company billed Cephalon \$1.6 million and \$21.6 million, respectively, for the sale of the two VIVITROL manufacturing lines, and the Company will bill Cephalon for future costs the Company incurs related to the construction of the manufacturing lines. Beginning in October 2006, all FTE-related costs the Company incurs that are reimbursable by Cephalon and related to the construction and validation of the two VIVITROL manufacturing lines are recorded as research and development revenue as incurred. Cephalon has granted the Company an option, exercisable after two years, to repurchase the two VIVITROL manufacturing lines at the then-current net book value of the assets. Because the Company continues to operate and maintain the equipment and intends to do so for the foreseeable future, the payments made by Cephalon for the assets have been treated as additional consideration under the Agreements. The assets remain on the Company's books.

The Agreements and Amendments are in effect until the later of: (i) the expiration of certain patent rights; or (ii) 15 years from the date of the first commercial sale of the products in the U.S. Cephalon has the right to terminate the Agreements at any time by providing 180 days prior written notice to the Company, subject to certain continuing rights and obligations between the parties. The supply agreement terminates upon termination or expiration of the license and collaboration agreement or the later expiration of the Company's obligations pursuant to the Agreements to continue to supply products to Cephalon. In addition, either party may terminate the license and collaboration agreement upon a material breach by the other party which is not cured within 90 days written notice of material breach or, in certain circumstances, a 30 day extension of that period, and either party may terminate the supply agreement upon a material breach by the other party which is not cured within 180 days written notice of material breach or, in certain circumstances, a 30 day extension of that period.

During the years ended March 31, 2008, 2007, 2006, the Company recognized \$27.7 million, \$58.3 million and \$39.3 million, respectively, of revenue from its arrangements with Cephalon.

***Cilag GmbH International***

In December 2007, the Company entered into a license and commercialization agreement with Cilag GmbH International (Cilag), an affiliate of Janssen, to commercialize VIVITROL for the treatment of alcohol dependence and opioid dependence in Russia and other countries in the Commonwealth of Independent States (CIS). Under the terms of the agreement, Cilag will have primary responsibility for securing all necessary regulatory approvals for VIVITROL and Janssen-Cilag, an affiliate of Cilag, will commercialize the product. The Company will be responsible for the manufacture of VIVITROL and will receive manufacturing revenues and royalty revenues based upon product sales.

In December 2007, Cilag made a nonrefundable payment of \$5.0 million to the Company upon signing the agreement. Cilag will pay the Company up to an additional \$34.0 million upon the receipt of regulatory approvals for the product, the occurrence of certain agreed-upon events and levels of VIVITROL sales.

Commencing five years after the effective date of the agreement, Cilag will have the right to terminate the agreement at any time by providing 90 days prior written notice to the Company, subject to certain continuing rights and

obligations between the parties. Cilag will also have the right to terminate the agreement upon 90 days advance written notice to the Company if a change in the pricing and/or reimbursement of VIVITROL in Russia and other countries of the CIS has a material adverse effect on the underlying economic value of commercializing the product such that it is no longer reasonably profitable to Cilag. In addition, either party may terminate the agreement upon a material breach by the other party which is not cured within

**Table of Contents**

**ALKERMES, INC. AND SUBSIDIARIES**

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

90 days advance written notice of material breach or, in certain circumstances, a 30 day extension of that period.

***Amylin***

In May 2000, the Company entered into a development and license agreement with Amylin Pharmaceuticals, Inc. ( Amylin ) for the development of exenatide once weekly, an injectable formulation of Amylin's BYETTA (Exenatide), which is under development for the treatment of type 2 diabetes. Pursuant to the development and license agreement, Amylin has an exclusive, worldwide license to the Company's Medisor® technology for the development and commercialization of injectable extended-release formulations of exendins and other related compounds. Amylin has entered into a collaboration agreement with Eli Lilly and Company ( Lilly ) for the development and commercialization of exenatide, including exenatide once weekly. The Company receives funding for research and development and milestone payments consisting of cash and warrants for Amylin common stock upon achieving certain development and commercialization goals and will also receive royalty payments based on future product sales, if any. The Company is responsible for formulation and non-clinical development of any products that may be developed pursuant to the agreement and for manufacturing these products for use in clinical trials and, in certain cases, for commercial sale. Subject to its arrangement with Lilly, Amylin is responsible for conducting clinical trials, securing regulatory approvals and marketing any products resulting from the collaboration on a worldwide basis.

In October 2005, the Company amended its existing development and license agreement with Amylin, and reached agreement regarding the construction of a manufacturing facility for exenatide once weekly and certain technology transfer related thereto. In December 2005, Amylin purchased a facility for the manufacture of exenatide once weekly and began construction in early calendar year 2006. Amylin is responsible for all costs and expenses associated with the design, construction and validation of the facility. The parties have agreed that the Company will transfer its technology for the manufacture of exenatide once weekly to Amylin. Amylin reimburses the Company for any time, at an agreed-upon FTE rate, and materials the Company incurs with respect to the transfer of technology. Following the completion of the technology transfer, Amylin will be responsible for the manufacture of exenatide once weekly and will operate the facility. Amylin will pay the Company royalties for commercial sales of this product, if approved, in accordance with the development and license agreement.

Amylin may terminate the development and license agreement for any reason upon 90 days written notice to the Company if such termination occurs before filing a New Drug Application ( NDA ) with the FDA for a product developed under the development and license agreement or upon 180 days written notice to the Company after such event. In addition, either party may terminate the development and license agreement upon a material default or breach by the other party that is not cured within 60 days after receipt of written notice specifying the default or breach.

During the years ended March 31, 2008, 2007, 2006, the Company recognized \$32.9 million, \$19.3 million and \$7.9 million, respectively, of revenue from its arrangements with Amylin.

***Lilly***

***AIR Insulin***

On March 7, 2008, the Company received a letter from Lilly terminating the development and license agreement between Lilly and the Company dated April 1, 2001, as amended, relating to the development of inhaled formulations of insulin and other compounds potentially useful for the treatment of diabetes, based on the Company's proprietary AIR® pulmonary technology. The termination of the agreement will become effective 90 days from March 7, 2008. Termination of the Company's development and license agreement also results in the termination of the supply agreement with Lilly for AIR Insulin.

F-35

---



**Table of Contents**

**ALKERMES, INC. AND SUBSIDIARIES**

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

Upon the effective date of termination of the development and license agreement and the supply agreement, the license the Company granted to Lilly under the development and license agreement will revert to the Company, and the Company will have the option to purchase Lilly-owned manufacturing equipment at a negotiated purchase price not to exceed Lilly's then-current net book value.

*AIR PTH*

On August 31, 2007, the Company received written notice from Lilly terminating the development and license agreement, dated December 16, 2005, between the Company and Lilly pursuant to which the Company and Lilly were collaborating to develop inhaled formulations of parathyroid hormone ( PTH ). This termination became effective 90 days after the receipt of the written notice.

Upon the effective date of termination of the development and license agreement, the license the Company granted to Lilly under this agreement reverted to the Company.

During the years ended March 31, 2008, 2007, 2006, the Company recognized \$54.6 million, \$48.0 million and \$34.9 million, respectively, of revenue from its arrangements with Lilly.

*Indevus*

On April 18, 2008, the Company terminated its joint collaboration with Indevus on the development of ALKS 27, an inhaled formulation of rospium chloride for the treatment of COPD. The Company owns all patent rights related to ALKS 27 and intends to independently continue the development and commercialization of an inhaled rospium product based on its AIR pulmonary technology. In January 2007, the Company and Indevus announced that they had entered into a joint collaboration for the development of ALKS 27. Prior to the termination, the Company and Indevus shared equally all costs of developing ALKS 27.

*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.

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 of \$0.5 million and is obligated to pay annual fees of up to \$0.2 million, and tiered royalty payments of between 1% and 4% of annual net sales in the event any products developed under the agreement are commercialized. In addition, the Company is obligated to make milestone payments in the aggregate of up to \$9.1 million, upon certain agreed-upon development events. All amounts paid to RPI under this license agreement have been expensed and are included in research and development expenses.



Table of Contents**ALKERMES, INC. AND SUBSIDIARIES****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)****11. INCOME TAXES**

The components of the Company's net deferred tax asset were as follows:

	<b>March 31,</b>	
	<b>2008</b>	<b>2007</b>
	<b>(In thousands)</b>	
Net operating loss ( NOL ) carryforwards – federal and state	\$ 48,270	\$ 160,462
Tax benefit from the exercise of stock options	41,694	43,466
Tax credit carryforwards	18,425	38,272
Capitalized research and development expenses – net of amortization	53	161
Alkermes Europe, Ltd. NOL carryforward	7,764	9,546
Deferred revenue	47,063	5,898
Share-based compensation	10,347	6,483
Other	(4,516)	72
Less: valuation allowance	(169,100)	(264,360)
	\$	\$

As of March 31, 2008, the Company had approximately \$249.0 million of federal domestic NOL carryforwards, \$158.8 million of state NOL carryforwards, and \$27.7 million of foreign net operating loss and foreign capital loss carryforwards, which either expire on various dates through the year 2026 or can be carried forward indefinitely. These loss carryforwards are available to reduce future federal and foreign taxable income, if any. These loss carryforwards are subject to review and possible adjustment by the appropriate taxing authorities. These loss carryforwards that may be utilized in any future period may be subject to limitations based upon changes in the ownership of the Company's stock. The valuation allowance relates to the Company's U.S. NOLs and deferred tax assets and certain other foreign deferred tax assets and is recorded based upon the uncertainty surrounding their realizability, as these assets can only be realized via profitable operations in the respective tax jurisdictions.

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. In evaluating the Company's ability to recover its deferred tax assets, the Company considers all available positive and negative evidence including its past operating results, the existence of cumulative income in the most recent fiscal years, changes in the business in which the Company operates and its forecast of future taxable income. In determining future taxable income, the Company is responsible for assumptions utilized including the amount of state, federal and international pre-tax operating income, the reversal of temporary differences and the implementation of feasible and prudent tax planning strategies. These assumptions require significant judgment about the forecasts of future taxable income and are consistent with the plans and estimates that the Company is using to manage the underlying businesses. As of March 31, 2008, the Company determined that it is more likely than not that the deferred tax assets will not be realized and a full valuation allowance has been recorded.

The tax benefit from stock option exercises included in the table above represents benefits accumulated prior to the adoption of SFAS No. 123(R) that have not been realized. Subsequent to the adoption of SFAS No. 123(R) on April 1, 2006, an additional \$4.2 million of tax benefits from stock option exercises have not been recognized in the financial statements and will be once they are realized. In total, the Company has approximately \$45.9 million related to certain operating loss carryforwards resulting from the exercise of employee stock options, the tax benefit of which, when recognized, will be accounted for as a credit to additional paid-in capital rather than a reduction of income tax.

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

In fiscal 2008, the Company concluded a comprehensive study of its historic research and development credit calculations. The Company determined that certain expenditures originally utilized in the calculations did not qualify as research and development charges for purposes of the credit. As a result, the Company reduced its federal and state research and development credit by \$17.3 million and \$1.6 million, respectively. This reduction did not have an impact on reported net income, as the write off of the asset was offset by the reversal of a valuation allowance which had been set up against the asset. The Company has yet to utilize any of its federal research credits and a full valuation allowance continues to be maintained against all of the Company's deferred tax assets. The reduction in the state credit amount did not result in any additional taxes.

The Company's provision for income taxes was comprised of the following:

	<b>Years Ended March 31,</b>		
	<b>2008</b>	<b>2007</b>	<b>2006</b>
	<b>(In thousands)</b>		
Current income tax expense:			
Federal	\$ 5,770	\$ 1,098	\$
State	81		
Foreign			
Deferred income tax expense:			
Federal			
State			
Foreign			
 Total tax provision	 \$ 5,851	 \$ 1,098	 \$

The Company's current provision for federal income taxes in the amount of \$5.8 million and \$1.1 million for the years ended March 31, 2008 and 2007, respectively, represents alternative minimum tax ( AMT ) due without regard to the cash benefit of excess share-based compensation deductions. The AMT paid creates a credit carryforward and a resulting deferred tax asset, for which the Company has recorded a full valuation allowance.

No amount for U.S. income tax has been provided on undistributed earnings of the Company's foreign subsidiary because the Company considers such earnings to be indefinitely reinvested. In the event of distribution of those earnings in the form of dividends or otherwise, the Company would be subject to both U.S. income taxes, subject to an adjustment, if any, for foreign tax credits, and foreign withholding taxes payable to certain foreign tax authorities. Determination of the amount of U.S. income tax liability that would be incurred is not practicable because of the complexities associated with this hypothetical calculation; however, unrecognized foreign tax credit carryforwards may be available to reduce some portion of the U.S. tax liability, if any.

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

A reconciliation of the Company's federal statutory tax rate to its effective rate is as follows:

	<b>Years Ended March 31,</b>		
	<b>2008</b>	<b>2007</b>	<b>2006</b>
Statutory federal rate	34.0%	34.0%	34.0%
State income taxes, net of federal benefit			4.4%
Research and development benefit		(0.9)%	(67.1)%
Amortization of deferred compensation			3.9%
Share-based compensation	1.5%	33.5%	
Other permanent items	0.4%	0.5%	1.5%
Non-deductible interest		4.2%	33.8%
True-up of prior year AMT liability		1.1%	
Change in FIN No. 48 reserve	0.1%		
Change in valuation allowance	(32.6)%	(62.0)%	(10.5)%
Effective tax rate	3.4%	10.4%	0.0%

The Company adopted FIN No. 48 on April 1, 2007. The Company did not record any liabilities upon the implementation of FIN No. 48 due to historic loss carryovers. A reconciliation of the beginning and ending amount of unrecognized tax benefits is as follows (in thousands):

Balance at April 1, 2007	\$
Additions based on tax positions related to the current period	1,796
Balance at March 31, 2008	\$ 1,796

The Company has an unrecognized tax benefit of \$0.1 million at March 31, 2008 which is recorded as either a reduction of the Company's deferred tax assets if it has not yet been used to reduce the Company's tax liability or as part of Other Long-Term Liabilities in the accompanying consolidated balance sheet. If the unrecognized tax benefit at March 31, 2008 is recognized, there would be no effect on the Company's effective income tax rate in any future period. The Company does not expect a significant increase in unrecognized tax benefits within the next twelve months.

The tax years 1993 through 2007 remain open to examination by major taxing jurisdictions to which the Company is subject, which are primarily in the U.S. as carryforward attributes generated in years past may still be adjusted upon examination by the Internal Revenue Service or state tax authorities if they have or will be used in a future period. The Company has elected to include interest and penalties related to uncertain tax positions as a component of its provision for taxes. For the year ended March 31, 2008, the Company's accrued interest and penalties recorded in its consolidated financial statements was not significant.

## 12. COMMITMENTS AND CONTINGENCIES

### *Lease Commitments*

The Company leases certain of its offices, research laboratories and manufacturing facilities under operating leases with initial terms of one to twenty years, expiring through the year 2016. Certain of the leases contain provisions for extensions of up to ten years. These lease commitments are primarily related to the Company's corporate headquarters and manufacturing facilities in Massachusetts.

F-39

---

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

As of March 31, 2008, the total future annual minimum lease payments under the Company's non-cancelable operating leases are as follows (in thousands):

Fiscal Years:	
2009	\$ 10,136
2010	10,233
2011	10,255
2012	10,323
2013	11,282
Thereafter	99,124
	151,353
Less: estimated sublease income	(889)
Total	\$ 150,464

Rent expense related to operating leases charged to operations was approximately \$11.9 million, \$11.5 million and \$16.3 million for the years ended March 31, 2008, 2007 and 2006, respectively.

***License and Royalty Commitments***

As discussed in Note 10, the Company has entered into license agreements with certain corporations and universities that require the Company to pay annual license fees and royalties based on a percentage of revenues from sales of certain products and royalties from sublicenses granted by the Company. Amounts paid under these agreements were approximately \$0.2 million, \$0.8 million and \$0.3 million for the years ended March 31, 2008, 2007 and 2006, respectively, and were recorded as Research and development expenses in the consolidated statements of income and comprehensive income.

***Guarantees***

As discussed in Note 5, Reliant was acquired by GSK in November 2007. Under the terms of the acquisition, the Company received \$166.9 million upon the closing of the transaction in December 2007 in exchange for the Company's investment in Series C convertible, redeemable preferred stock of Reliant. The Company is entitled to receive up to an additional \$7.7 million of funds held in escrow subject to the terms of an escrow agreement between GSK and Reliant. The escrowed funds represent the maximum potential amount of future payments that may be payable to GSK under the terms of the escrow agreement, which is effective for a period of 15 months following the closing of the transaction. The Company has not recorded a liability related to the indemnification to GSK as the Company currently believes that it is remote that any of the escrowed funds will be needed to indemnify GSK for any losses it might incur related to the representations and warranties made by Reliant in connection with the acquisition.

**13. LITIGATION**



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 alleged, among other things that in connection with certain stock option grants made by the Company, certain of its 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 monetary relief from the Company. The lawsuit sought 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. The defendants moved

F-40

---

**Table of Contents**

**ALKERMES, INC. AND SUBSIDIARIES**

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

to dismiss the lawsuit and, following oral argument, the Massachusetts Superior Court issued a decision dated July 10, 2007 granting the defendants' motion to dismiss the lawsuit in its entirety. The plaintiff did not appeal the Court's decision and the plaintiff's time to appeal has expired.

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 its stock option plans, allegedly violating GAAP 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 take action on its 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. The Company's board of directors appointed a special independent committee of the board of directors 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 Company's board of directors. 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 Company's board of directors 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 Company's best interests or the best interests of the Company's shareholders to commence litigation against its current or former officers or directors as demanded in the letters. The findings and conclusions of the special independent committee of the Company's board of directors have been presented to and adopted by the Company's board of directors.

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

\* \* \* \* \*

F-41

---

**Table of Contents****EXHIBIT INDEX****Exhibit  
No.**

- 3.1 Third Amended and Restated Articles of Incorporation as filed with the Pennsylvania Secretary of State on June 7, 2001. (Incorporated by reference to Exhibit 3.1 to the Registrant's Report on Form 10-K for the fiscal year ended March 31, 2001 (File No. 001-14131).)
- 3.1(a) Amendment to Third Amended and Restated Articles of Incorporation as filed with the Pennsylvania Secretary of State on December 16, 2002 (2002 Preferred Stock Terms). (Incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K filed on December 16, 2002 (File No. 001-14131).)
- 3.1(b) Amendment to Third Amended and Restated Articles of Incorporation as filed with the Pennsylvania Secretary of State on May 14, 2003 (Incorporated by reference to Exhibit A to Exhibit 4.1 to the Registrant's Report on Form 8-A filed on May 2, 2003 (File No. 000-19267).)
- 3.2 Second Amended and Restated By-Laws of Alkermes, Inc. (Incorporated by reference to Exhibit 3.2 to the Registrant's Current Report on Form 8-K filed on September 28, 2005.)
- 4.1 Specimen of Common Stock Certificate of Alkermes, Inc. (Incorporated by reference to Exhibit 4 to the Registrant's Registration Statement on Form S-1, as amended (File No. 033-40250).)
- 4.2 Specimen of Non-Voting Common Stock Certificate of Alkermes, Inc. (Incorporated by reference to Exhibit 4.4 to the Registrant's Report on Form 10-K for the fiscal year ended March 31, 1999 (File No. 001-14131).)
- 4.3 Rights Agreement, dated as of February 7, 2003, as amended, between Alkermes, Inc. and EquiServe Trust Co., N.A., as Rights Agent. (Incorporated by reference to Exhibit 4.1 to the Registrant's Report on Form 8-A filed on May 2, 2003 (File No. 000-19267).)
- 4.4 Indenture, dated as of February 1, 2005, between RC Royalty Sub LLC and U.S. Bank National Association, as Trustee. (Incorporated by reference to Exhibit 4.1 to the Registrant's Current Report on Form 8-K filed on February 3, 2005.)
- 4.5 Form of Risperdal Consta<sup>®</sup> PhaRMA<sup>sm</sup> Secured 7% Notes due 2018. (Incorporated by reference to Exhibit 4.1 to the Registrant's Current Report on Form 8-K filed on February 3, 2005.)
- 10.1 Amended and Restated 1990 Omnibus Stock Option Plan, as amended. (Incorporated by reference to Exhibit 10.2 to the Registrant's Report on Form 10-K for the fiscal year ended March 31, 1998 (File No. 001-14131).)+
- 10.2 Stock Option Plan for Non-Employee Directors, as amended. (Incorporated by reference to Exhibit 99.2 to the Registrant's Registration Statement on Form S-8 filed on October 1, 2003 (File No. 333-109376).)+
- 10.3 Lease, dated as of October 26, 2000, between FC88 Sidney, Inc. and Alkermes, Inc. (Incorporated by reference to Exhibit 10.3 to the Registrant's Report on Form 10-Q for the quarter ended December 31, 2000 (File No. 001-14131).)
- 10.4 Lease, dated as of October 26, 2000, between Forest City 64 Sidney Street, Inc. and Alkermes, Inc. (Incorporated by reference to Exhibit 10.4 to the Registrant's Report on Form 10-Q for the quarter ended December 31, 2000 (File No. 001-14131).)
- 10.5 License Agreement, dated as of February 13, 1996, between Medisorb Technologies International L.P. and Janssen Pharmaceutica Inc. (U.S.) (assigned to Alkermes Inc. in July 2006). (Incorporated by reference to Exhibit 10.19 to the Registrant's Report on Form 10-K for the fiscal year ended March 31, 1996 (File No. 000-19267).)\*
- 10.6 License Agreement, dated as of February 21, 1996, between Medisorb Technologies International L.P. and Janssen Pharmaceutica International (worldwide except U.S.) (assigned to Alkermes Inc. in July

Edgar Filing: ALKERMES INC - Form 10-K

2006). (Incorporated by reference to Exhibit 10.20 to the Registrant's Report on Form 10-K for the fiscal year ended March 31, 1996 (File No. 000-19267).)\*

- 10.7 Manufacturing and Supply Agreement, dated August 6, 1997, by and among Alkermes Controlled Therapeutics Inc. II, Janssen Pharmaceutica International and Janssen Pharmaceutica, Inc. (assigned to Alkermes Inc. in July 2006)(Incorporated by reference to Exhibit 10.19 to the Registrant's Report on Form 10-K for the fiscal year ended March 31, 2002 (File No. 001-14131).)\*\*\*
-

**Table of Contents****Exhibit  
No.**

- 10.7(a) Third Amendment To Development Agreement, Second Amendment To Manufacturing and Supply Agreement and First Amendment To License Agreements by and between Janssen Pharmaceutica International Inc. and Alkermes Controlled Therapeutics Inc. II, dated April 1, 2000 (assigned to Alkermes Inc. in July 2006) (with certain confidential information deleted) (Incorporated by reference to Exhibit 10.5 to the Registrant's Report on Form 10-Q for the quarter ended December 31, 2004.)\*\*\*\*
- 10.7(b) Fourth Amendment To Development Agreement and First Amendment To Manufacturing and Supply Agreement by and between Janssen Pharmaceutica International Inc. and Alkermes Controlled Therapeutics Inc. II, dated December 20, 2000 (assigned to Alkermes Inc. in July 2006) (with certain confidential information deleted) (Incorporated by reference to Exhibit 10.4 to the Registrant's Report on Form 10-Q for the quarter ended December 31, 2004.)\*\*\*\*
- 10.7(c) Addendum to Manufacturing and Supply Agreement, dated August 2001, by and among Alkermes Controlled Therapeutics Inc. II, Janssen Pharmaceutica International and Janssen Pharmaceutica, Inc. (assigned to Alkermes Inc. in July 2006) (Incorporated by reference to Exhibit 10.19(b) to the Registrant's Report on Form 10-K for the fiscal year ended March 31, 2002 (File No. 001-14131).)\*\*\*
- 10.7(d) Letter Agreement and Exhibits to Manufacturing and Supply Agreement, dated February 1, 2002, by and among Alkermes Controlled Therapeutics Inc. II, Janssen Pharmaceutica International and Janssen Pharmaceutica, Inc. (assigned to Alkermes Inc. in July 2006)(Incorporated by reference to Exhibit 10.19(a) to the Registrant's Report on Form 10-K for the fiscal year ended March 31, 2002.)\*\*\*
- 10.7(e) Amendment to Manufacturing and Supply Agreement by and between JPI Pharmaceutica International, Janssen Pharmaceutica Inc. and Alkermes Controlled Therapeutics Inc. II, dated December 22, 2003 (assigned to Alkermes Inc. in July 2006) (with certain confidential information deleted) (Incorporated by reference to Exhibit 10.8 to the Registrant's Report on Form 10-Q for the quarter ended December 31, 2004.)\*\*\*\*
- 10.7(f) Fourth Amendment To Manufacturing and Supply Agreement by and between JPI Pharmaceutica International, Janssen Pharmaceutica Inc. and Alkermes Controlled Therapeutics Inc. II, dated January 10, 2005 (assigned to Alkermes Inc. in July 2006) (with certain confidential information deleted) (Incorporated by reference to Exhibit 10.9 to the Registrant's Report on Form 10-Q for the quarter ended December 31, 2004.)\*\*\*\*
- 10.8 Agreement by and between JPI Pharmaceutica International, Janssen Pharmaceutica Inc. and Alkermes Controlled Therapeutics Inc. II, dated December 21, 2002 (assigned to Alkermes Inc. in July 2006) (with certain confidential information deleted) (Incorporated by reference to Exhibit 10.6 to the Registrant's Report on Form 10-Q for the quarter ended December 31, 2004.)\*\*\*\*
- 10.8(a) Amendment to Agreement by and between JPI Pharmaceutica International, Janssen Pharmaceutica Inc. and Alkermes Controlled Therapeutics Inc. II, dated December 16, 2003 (assigned to Alkermes Inc. in July 2006) (with certain confidential information deleted) (Incorporated by reference to Exhibit 10.7 to the Registrant's Report on Form 10-Q for the quarter ended December 31, 2004.)\*\*\*\*
- 10.9 Patent License Agreement, dated as of August 11, 1997, between Massachusetts Institute of Technology and Advanced Inhalation Research, Inc. (assigned to Alkermes, Inc. in March 2007), as amended. (Incorporated by reference to Exhibit 10.25 to the Registrant's Report on Form 10-K for the fiscal year ended March 31, 1999 (File No. 001-14131).)\*\*
- 10.10 Promissory Note by and between Alkermes, Inc. and General Electric Capital Corporation, dated December 22, 2004. (Incorporated by reference to Exhibit 10.1 to the Registrant's Report on

Edgar Filing: ALKERMES INC - Form 10-K

Form 10-Q for the quarter ended December 31, 2004.)

- 10.11 Master Security Agreement by and between Alkermes, Inc. and General Electric Capital Corporation dated December 22, 2004. (Incorporated by reference to Exhibit 10.2 to the Registrant's Report on Form 10-Q for the quarter ended December 31, 2004.)
  - 10.11(a) Addendum No. 001 To Master Security Agreement by and between Alkermes, Inc. and General Electric Capital Corporation, dated December 22, 2004. (Incorporated by reference to Exhibit 10.3 to the Registrant's Report on Form 10-Q for the quarter ended December 31, 2004.)
-

**Table of Contents****Exhibit  
No.**

- 10.12 Employment agreement, dated as of December 12, 2007, by and between Richard F. Pops and the Registrant. (Incorporated by reference to Exhibit 10.1 to the Registrant's Report on Form 10-Q for the quarter ended December 31, 2007.)+
- 10.13 Employment agreement, dated as of December 12, 2007, by and between David A. Broecker and the Registrant. (Incorporated by reference to Exhibit 10.2 to the Registrant's Report on Form 10-Q for the quarter ended December 31, 2007.)+
- 10.14 Form of Employment Agreement, dated as of December 12, 2007, by and between the Registrant and each of Kathryn L. Biberstein, Elliot W. Ehrich, M.D., James M. Frates, Michael J. Landine, Gordon G. Pugh. (Incorporated by reference to Exhibit 10.3 to the Registrant's Report on Form 10-Q for the quarter ended December 31, 2007.)+
- 10.15 Form of Covenant Not to Compete, of various dates, by and between the Registrant and each of Kathryn L. Biberstein and James M. Frates.+#
- 10.15(a) Form of Covenant Not to Compete, of various dates, by and between the Registrant and each of Elliot W. Ehrich, M.D., Michael J. Landine, and Gordon G. Pugh.+#
- 10.16 License and Collaboration Agreement between Alkermes, Inc. and Cephalon, Inc. dated as of June 23, 2005. (Incorporated by reference to Exhibit 10.1 to the Registrant's Report on Form 10-Q for the quarter ended June 30, 2005.)\*\*\*\*\*
- 10.16(a) Supply Agreement between Alkermes, Inc. and Cephalon, Inc. dated as of June 23, 2005. (Incorporated by reference to Exhibit 10.2 to the Registrant's Report on Form 10-Q for the quarter ended June 30, 2005.)\*\*\*\*\*
- 10.16(b) Amendment to the License and Collaboration Agreement between Alkermes, Inc. and Cephalon, Inc. dated as of December 21, 2006. (Incorporated by reference to Exhibit 10.16(b) to the Registrant's Report on Form 10-K for the year ended March 31, 2007.)\*\*\*\*\*
- 10.16(c) Amendment to the Supply Agreement between Alkermes, Inc. and Cephalon, Inc. dated as of December 21, 2006. (Incorporated by reference to Exhibit 10.16(c) to the Registrant's Report on Form 10-K for the year ended March 31, 2007.)\*\*\*\*\*
- 10.17 Accelerated Share Repurchase Agreement, dated as of February 7, 2008, between Morgan Stanley & Co. Incorporated and Alkermes, Inc.#
- 10.18 Alkermes, Inc. 1998 Equity Incentive Plan as Amended and Approved on November 2, 2006. (Incorporated by reference to Exhibit 10.1 to the Registrant's Report on Form 10-Q for the fiscal quarter ended December 31, 2006.)+
- 10.18(a) Form of Stock Option Certificate pursuant to Alkermes, Inc. 1998 Equity Incentive Plan. (Incorporated by reference to Exhibit 10.37 to the Registrant's Report on Form 10-K for the fiscal year ended March 31, 2006.)+
- 10.19 Alkermes, Inc. Amended and Restated 1999 Stock Option Plan. (Incorporated by reference to Appendix A to the Registrant's Definitive Proxy Statement on Form DEF 14/A filed on July 27, 2007.)+
- 10.19(a) Form of Incentive Stock Option Certificate pursuant to the 1999 Stock Option Plan, as amended. (Incorporated by reference to Exhibit 10.35 to the Registrant's Report on Form 10-K for the fiscal year ended March 31, 2006.)+
- 10.19(b) Form of Non-Qualified Stock Option Certificate pursuant to the 1999 Stock Option Plan, as amended. (Incorporated by reference to Exhibit 10.36 to the Registrant's Report on Form 10-K for the fiscal year ended March 31, 2006.)+
- 10.20 Alkermes, Inc. 2002 Restricted Stock Award Plan as Amended and Approved on November 2, 2006. (Incorporated by reference to Exhibit 10.3 to the Registrant's Report on Form 10-Q for the fiscal

Edgar Filing: ALKERMES INC - Form 10-K

- quarter ended December 31, 2006.)+
- 10.20(a) Amendment to Alkermes, Inc. 2002 Restricted Stock Award Plan. (Incorporated by reference to Appendix B to the Registrant's Definitive Proxy Statement on Form DEF 14/A filed on July 27, 2007.)+
- 10.21 2006 Stock Option Plan for Non-Employee Directors. (Incorporated by reference to Exhibit 10.4 to the Registrant's Report on Form 10-Q for the fiscal quarter ended September 30, 2006.)+
-



**Table of Contents**

**Exhibit  
No.**

- 10.21(a) Amendment to 2006 Stock Option Plan for Non-Employee Directors. (Incorporated by reference to Appendix C to the Registrant's Definitive Proxy Statement on Form DEF 14/A filed on July 27, 2007.)+
- 10.22 Alkermes Fiscal 2008 Named-Executive Bonus Plan. (Incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed on April 26, 2007.)+
- 10.23 Alkermes Fiscal Year 2009 Reporting Officer Performance Pay Plan. (Incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed on May 16, 2008.)+
- 21.1 Subsidiaries of the Registrant.#
- 23.1 Consent of Independent Registered Public Accounting Firm PriceWaterhousecoopers LLP.#
- 23.2 Consent of Independent Registered Public Accounting Firm Deloitte & Touche LLP.#
- 24.1 Power of Attorney (included on signature pages).#
- 31.1 Rule 13a-14(a)/15d-14(a) Certification.#
- 31.2 Rule 13a-14(a)/15d-14(a) Certification.#
- 32.1 Certification pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.#

\* Confidential status has been granted for certain portions thereof pursuant to a Commission Order granted September 3, 1996. Such provisions have been filed separately with the Commission.

\*\* Confidential status has been granted for certain portions thereof pursuant to a Commission Order granted August 19, 1999. Such provisions have been filed separately with the Commission.

\*\*\* Confidential status has been granted for certain portions thereof pursuant to a Commission Order granted September 16, 2002. Such provisions have been separately filed with the Commission.

\*\*\*\* Confidential status has been granted for certain portions thereof pursuant to a Commission Order granted September 26, 2005. Such provisions have been filed separately with the Commission.

\*\*\*\*\* Confidential status has been granted for certain portions thereof pursuant to a Commission Order granted July 31, 2006. Such provisions have been filed separately with the Commission.

\*\*\*\*\* Confidential status has been granted for certain portions thereof pursuant to a Commission Order granted April 15, 2008. Such provisions have been filed separately with the Commission.

+ Indicates a management contract or any compensatory plan, contract or arrangement.

# Filed herewith.