

ALKERMES INC  
Form 10-K  
May 21, 2010

**Table of Contents**

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

**Form 10-K**

- þ ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934  
For the fiscal year ended March 31, 2010**
- OR**
- o TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934  
For the transition period from to**

**Commission file number: 1-14131**

**ALKERMES, INC.**

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

**Pennsylvania**  
*State or other jurisdiction of  
incorporation or organization*

**23-2472830**  
*(I.R.S. Employer  
Identification No.)*

**852 Winter Street, Waltham Massachusetts**  
*(Address of principal executive offices)*

**02451-1420**  
*(Zip Code)*

**(781) 609-6000**  
**(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 whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). 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 30, 2009 (the last business day of the second fiscal quarter) the aggregate market value of the 92,809,788 outstanding shares of voting and non-voting common equity held by non-affiliates of the registrant was \$852,921,952. Such aggregate value was computed by reference to the closing price of the common stock reported on the NASDAQ Stock Market on September 30, 2009.

As of May 13, 2010, 94,875,127 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, 2010 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, 2010**

**INDEX**

<b><u>PART I</u></b>		5
<u>Item 1.</u>	<u>Business</u>	5
<u>Item 1A.</u>	<u>Risk Factors</u>	23
<u>Item 1B.</u>	<u>Unresolved Staff Comments</u>	41
<u>Item 2.</u>	<u>Properties</u>	42
<u>Item 3.</u>	<u>Legal Proceedings</u>	42
<u>Item 4.</u>	<u>[Removed and Reserved]</u>	42
 <b><u>PART II</u></b>		 43
<u>Item 5.</u>	<u>Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities</u>	43
<u>Item 6.</u>	<u>Selected Financial Data</u>	45
<u>Item 7.</u>	<u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	47
<u>Item 7A.</u>	<u>Quantitative and Qualitative Disclosures about Market Risk</u>	64
<u>Item 8.</u>	<u>Financial Statements and Supplementary Data</u>	65
<u>Item 9.</u>	<u>Changes in and Disagreements With Accountants on Accounting and Financial Disclosures</u>	66
<u>Item 9A.</u>	<u>Controls and Procedures</u>	66
 <b><u>PART III</u></b>		 67
<u>Item 10.</u>	<u>Directors, Executive Officers and Corporate Governance</u>	67
<u>Item 11.</u>	<u>Executive Compensation</u>	67
<u>Item 12.</u>	<u>Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters</u>	67
<u>Item 13.</u>	<u>Certain Relationships and Related Transactions, and Director Independence</u>	67
<u>Item 14.</u>	<u>Principal Accounting Fees and Services</u>	67
 <b><u>PART IV</u></b>		 67
<u>Item 15.</u>	<u>Exhibits and Financial Statement Schedules</u>	67
<b><u>SIGNATURES</u></b>		73
<u>EX-10.27(A)</u>		
<u>EX-10.27(B)</u>		
<u>EX-10.28</u>		
<u>EX-21.1</u>		
<u>EX-23.1</u>		
<u>EX-31.1</u>		
<u>EX-31.2</u>		
<u>EX-32.1</u>		



**Table of Contents**

**FORWARD-LOOKING STATEMENTS**

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

our expectations regarding our financial performance, including revenues, expenses, gross margins, liquidity, capital expenditures and income taxes;

our expectations regarding the commercialization of RISPERDAL® CONSTA® [(risperidone) long-acting injection] and VIVITROL® (naltrexone for extended-release injectable suspension) including the sales and marketing efforts of our partners Ortho-McNeil-Janssen Pharmaceuticals, Inc. and Janssen Pharmaceutica International, a division of Cilag International AG, which we refer to as Janssen, and our ability to establish and maintain successful sales and marketing, reimbursement and distribution arrangements for VIVITROL;

the recognition of milestone payments from Cilag GmbH International, or Cilag, a subsidiary of Johnson & Johnson, related to the future sales of VIVITROL;

our efforts and ability to evaluate and license product candidates and build our pipeline;

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

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

our expectation and timeline for regulatory approval of the NDA submission for VIVITROL for the treatment of opioid dependence and, if approved, our ability to commercialize VIVITROL in this new indication;

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

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

our expectations regarding the financial impact of recently enacted health care reform legislation and foreign currency exchange rate fluctuations and valuations;

the impact of new accounting pronouncements;

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

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

You are cautioned that forward-looking statements are based on current expectations and are inherently uncertain. Actual performance and results of operations may differ materially from those projected or suggested in the forward-looking statements due to various risks and uncertainties, including the risks and uncertainties described or discussed in the section entitled **Risk Factors** in this Annual Report. The forward-looking statements contained and incorporated herein represent our judgment as of the date of this Annual

**Table of Contents**

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

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



**Table of Contents**

**PART I**

**Item 1. Business**

*The following discussion contains forward-looking statements. Actual results may differ significantly from those projected in the forward-looking statements. Factors that might cause future results to differ materially from those projected in the forward-looking statements include, but are not limited to, those discussed in Risk Factors and elsewhere in this Annual Report. See also Forward-Looking Statements.*

**General**

Alkermes, Inc. (as used in this section, together with our subsidiaries, us, we, our or the Company) is a fully integrated biotechnology company committed to developing innovative medicines to improve patients' lives. We developed, manufacture and commercialize VIVITROL for alcohol dependence and manufacture RISPERDAL CONSTA for schizophrenia and bipolar I disorder. Our robust pipeline includes extended-release injectable and oral products for the treatment of prevalent, chronic diseases, such as central nervous system, or CNS, disorders, reward disorders, addiction, diabetes and autoimmune disorders. We have a research facility in Massachusetts and a commercial manufacturing facility in Ohio. In January 2010, we relocated our corporate headquarters from Cambridge, Massachusetts, to Waltham, Massachusetts.

**Our Strategy**

We leverage our formulation expertise and proprietary product platforms to develop, both with partners and on our own, innovative and competitively advantaged medications that can enhance patient outcomes in major therapeutic areas. We enter into select collaborations with pharmaceutical and biotechnology companies to develop significant new product candidates, based on existing drugs and incorporating our proprietary product platforms. In addition, we apply our innovative formulation expertise and drug development capabilities to create our own new, proprietary pharmaceutical products. 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, and is the first and only long-acting, atypical antipsychotic approved by the Food and Drug Administration, or FDA, for the treatment of schizophrenia and for the treatment of bipolar I disorder. The medication uses our proprietary MEDISORB® injectable extended-release technology to deliver and maintain therapeutic medication levels in the body through just one injection every two weeks. RISPERDAL CONSTA is marketed by Janssen and is exclusively manufactured by us. RISPERDAL CONSTA was first approved for the treatment of schizophrenia by regulatory authorities in the United Kingdom and Germany in August 2002 and by the FDA in October 2003. The Pharmaceuticals and Medical Devices Agency in Japan approved RISPERDAL CONSTA for the treatment of schizophrenia in April 2009. RISPERDAL CONSTA is the first long-acting atypical antipsychotic to be available in Japan. RISPERDAL CONSTA is approved for the treatment of schizophrenia in approximately 85 countries and marketed in approximately 60 countries, and Janssen continues to launch the product around the world.

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

**Table of Contents**

The FDA approved RISPERDAL CONSTA as both monotherapy and adjunctive therapy to lithium or valproate in the maintenance treatment of bipolar I disorder in May 2009. RISPERDAL CONSTA is also approved for the maintenance treatment of bipolar I disorder in Canada, Australia and Saudi Arabia. The European Union, or EU, regulatory authorities did not approve RISPERDAL CONSTA for the treatment of bipolar I disorder.

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

Revenues from Janssen relating to the manufacture and sale of RISPERDAL CONSTA accounted for approximately 83%, 46% and 52% of total net revenues for the years ended March 31, 2010, 2009 and 2008, respectively. See Collaborative Arrangements below for information about our relationship with Janssen.

***VIVITROL***

We developed VIVITROL, an extended-release MEDISORB formulation of naltrexone, as the first and only once-monthly injectable medication for the treatment of alcohol dependence. Alcohol dependence is a serious and chronic brain disease characterized by cravings for alcohol, loss of control over drinking, withdrawal symptoms and an increased tolerance for alcohol. According to the National Institute on Alcohol Abuse and Alcoholism's 2001-2002 National Epidemiologic Survey on Alcohol and Related Conditions, it is estimated that more than 18 million Americans suffer from alcohol dependence. Adherence to medication is particularly challenging with this patient population. In clinical trials, when used in combination with psychosocial support, VIVITROL was shown to reduce the number of drinking days and heavy drinking days and to prolong abstinence in patients who abstained from alcohol the week prior to starting treatment. VIVITROL was approved by the FDA in April 2006 and was launched in the U.S. in June 2006 with our partner, Cephalon, Inc., or Cephalon. In December 2008, we assumed responsibility for the commercialization of VIVITROL in the U.S. from Cephalon. In December 2007, we exclusively licensed the right to commercialize VIVITROL for the treatment of alcohol dependence and opioid dependence in Russia and other countries in the Commonwealth of Independent States, or CIS, to Cilag. In August 2008, the Russian regulatory authorities approved VIVITROL for the treatment of alcohol dependence. Cilag launched VIVITROL in Russia in March 2009. In March 2010, the FDA approved a Risk Evaluation and Mitigation Strategy, or REMS, for VIVITROL that consists of a Medication Guide and other customary REMS assessment requirements.

We are also developing VIVITROL for the treatment of opioid dependence, a serious and chronic brain disease characterized by compulsive, prolonged self-administration of opioid substances that are not used for a medical purpose. According to the 2008 U.S. National Survey on Drug Use and Health, an estimated 1.3 million people aged 18 or older were dependent on pain relievers or heroin. In November 2009, we announced positive preliminary results from a phase 3 clinical trial of VIVITROL for the treatment of opioid dependence. The six-month phase 3 study met its primary efficacy endpoint and all secondary endpoints. Data from the intent-to-treat, or ITT, analysis showed that patients treated once-monthly with VIVITROL demonstrated statistically significant higher rates of opioid-free urine screens, compared to patients treated with placebo. In addition, patients treated with VIVITROL demonstrated a significant reduction in opioid craving compared to patients treated with placebo as measured by a visual analog scale. VIVITROL was generally well tolerated in the study and no patients on VIVITROL discontinued the study due to adverse events. The most common adverse events experienced by patients receiving VIVITROL during the study were nasopharyngitis and insomnia. Based on these positive results, in April 2010, we submitted a supplemental NDA, or sNDA, for VIVITROL to the FDA for approval as a treatment for opioid dependence. We requested a priority review

of our sNDA submission which, if granted, should result in a six month review timeline.

**Table of Contents**

***BYDUREON***

We are collaborating with Amylin on the development of a once weekly formulation of exenatide, called BYDUREON, for the treatment of type 2 diabetes. BYDUREON is an injectable formulation of Amylin's BYETTA® (exenatide) and is being developed with the goal of providing patients with an effective and more patient-friendly treatment option. BYETTA is an injection administered twice daily. Diabetes is a disease in which the body does not produce or properly use insulin. Diabetes can result in serious health complications, including cardiovascular, kidney and nerve disease. Diabetes is believed to affect more than 24 million people in the U.S. and an estimated 285 million adults worldwide. Approximately 90-95% of those affected have type 2 diabetes. According to the Centers for Disease Control and Prevention's National Health and Nutrition Examination Survey, approximately 60% of people with diabetes do not achieve their target blood sugar levels with their current treatment regimen. In addition, 85% of type 2 diabetes patients are overweight and 55% are considered obese. BYETTA was approved by the FDA in April 2005 as adjunctive therapy to improve blood sugar control in patients with type 2 diabetes who have not achieved adequate control on metformin and/or a sulfonylurea, which are commonly used oral diabetes medications. In December 2006, the FDA approved BYETTA as an add-on therapy for people with type 2 diabetes unable to achieve adequate glucose control on thiazolidinediones, a class of diabetes medications. In October 2009, the FDA approved BYETTA as a stand-alone medication (monotherapy) along with diet and exercise to improve glycemic control in adults with type 2 diabetes. Amylin has an agreement with Lilly for the development and commercialization of exenatide, including BYDUREON.

In May 2009, Amylin submitted a NDA for BYDUREON to the FDA for the treatment of type 2 diabetes. The FDA accepted the submission in July 2009.

In July 2009, Amylin, Lilly and we announced positive results from the DURATION-3 study, which was designed to compare BYDUREON to LANTUS® (insulin glargine) in 467 patients with type 2 diabetes taking stable doses of metformin alone or in combination with a sulfonylurea. Patients randomized to BYDUREON experienced a statistically superior reduction in A1C, a measure of average blood sugar over three months, of 1.5 percentage points from baseline, compared to a reduction of 1.3 percentage points for LANTUS after completing 26 weeks of treatment. At the end of the study, patients treated with BYDUREON achieved a mean A1C of 6.8% compared with a mean A1C of 7.0% in those treated with LANTUS. Treatment with BYDUREON also produced a statistically significant difference in weight, with a mean weight loss of 5.8 pounds at 26 weeks, compared with a mean weight gain of 3.1 pounds for LANTUS, a difference of 8.9 pounds between the treatments. In addition, patients treated with BYDUREON reported significantly fewer episodes of confirmed hypoglycemia than those patients treated with LANTUS.

In December 2009, Amylin, Lilly and we announced positive results from the DURATION-5 study, which was designed to compare BYDUREON to BYETTA in patients with type 2 diabetes who were not achieving adequate glucose control using background therapies that included diet and exercise, metformin, sulfonylurea, thiazolidinediones or a combination of the agents. Patients randomized to BYDUREON experienced a statistically superior reduction in A1C, of 1.6 percentage points from baseline, compared to a reduction of 0.9 percentage points for BYETTA after completing 24 weeks of treatment. At the end of the study, patients treated with BYDUREON achieved a mean A1C of 7.1% compared with a mean A1C of 7.7% in those treated with BYETTA. Both treatment groups achieved statistically significant weight loss by the end of the study, with an average loss of 5.1 pounds for patients taking BYDUREON and 3.0 pounds for patients taking BYETTA. Additional studies designed to demonstrate the superiority of BYDUREON compared to commonly prescribed diabetes medications are ongoing.

In March 2010, the FDA issued a complete response letter in reference to the NDA for BYDUREON. The complete response letter did not include requests for new pre-clinical or clinical trials. Requests raised in the letter primarily related to the finalization of the product labeling with accompanying REMS and clarification of existing

manufacturing processes.

In April 2010, Amylin announced that it had submitted a response to the FDA complete response letter and Lilly announced that the European Medicines Agency, or EMA, had accepted the Marketing Authorization Application filing for BYDUREON for the treatment of type 2 diabetes.

## **Table of Contents**

In addition, Amylin announced that it intended to initiate a Phase 2 study of a monthly dose suspension formulation of exenatide in the second calendar quarter of 2010. Such study is expected to evaluate the safety, efficacy and tolerability of this novel formulation that leverages our MEDISORB technology discussed below, but does not require reconstitution.

### ***ALKS 33***

ALKS 33 is an oral opioid modulator that we are developing for the potential treatment of addiction and other CNS disorders. In October 2009, we announced positive topline data from two clinical trials of ALKS 33. Data from the studies, ALK33-003 and ALK33-004, showed that ALKS 33 was generally well tolerated and successfully blocked the effects of an opioid with a duration of action that supports once daily dosing. ALK33-003 was a phase 1 randomized, double-blind, placebo-controlled, multi-dose study designed to assess the steady-state pharmacokinetics, safety and tolerability of ALKS 33 in 30 healthy subjects. ALK33-004 was a phase 1, randomized, single-blind, placebo-controlled, single-dose study designed to test the ability of ALKS 33 to block the subjective and objective effects of a potent opioid agonist, remifentanyl (a commercially available analgesic) in 24 healthy, non-dependent, opioid-experienced subjects.

In November 2009, we initiated a phase 2 clinical study to assess the safety and efficacy of multiple doses of ALKS 33 in patients with alcohol dependence and to further define the clinical profile of ALKS 33.

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

### ***ALKS 37***

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

In February 2010, we announced positive topline data from a randomized, double-blind, placebo-controlled phase 1 clinical study designed to assess the safety, tolerability and pharmacokinetics of a single oral administration of five ascending doses of ALKS 37, from 1 mg to 100 mg, in 40 healthy volunteers. Data from the study showed that ALKS 37 was generally well tolerated and demonstrated low systemic exposure across a wide range of doses. These data were consistent with prior preclinical results indicating that ALKS 37 targets the gastrointestinal tract with limited systemic exposure and little to no CNS penetration. Based on these positive phase 1 clinical results, we initiated a phase 1 multi-dose study of ALKS 37 in March 2010. The study, ALK37-002, is a randomized, double-blind, placebo-controlled repeat dose study designed to assess the safety, tolerability and pharmacokinetics of daily oral administration of two dose levels of ALKS 37 for a seven day period in 24 healthy volunteers.

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

***ALKS 36***

In October 2009, we announced our intention to develop ALKS 36, which is expected to consist of a co-formulation of an opioid analgesic and ALKS 37, for the treatment of pain without the side effects of



## **Table of Contents**

constipation. Research indicates that a high percentage of patients receiving opioids are likely to experience side effects affecting gastrointestinal motility. A pain medication that does not inhibit gastrointestinal motility, such as ALKS 36, could provide an advantage over current therapies. The Phase 2 clinical trial results of ALKS 37 will inform further development of ALKS 36.

### ***ALKS 9070***

ALKS 9070 is a once-monthly, injectable, sustained-release version of aripiprazole for the treatment of schizophrenia. ALKS 9070 is our first candidate to leverage our proprietary LinkeRx™ product platform discussed below. Aripiprazole is commercially available under the name ABILIFY® for the treatment of a number of CNS disorders. Based on encouraging preclinical results, ALKS 9070 is expected to enter the clinic in the second half of calendar 2010.

### ***ALKS 6931***

ALKS 6931 is a long-acting form of a TNF receptor-FC fusion protein for the treatment of rheumatoid arthritis and related autoimmune diseases. ALKS 6931 is our first candidate being developed using the MEDIFUSION™ technology licensed from Acceleron Pharma, Inc., or Acceleron. ALKS 6931 is structurally similar to etanercept, commercially available under the name ENBREL®.

### ***ALKS 7921***

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

## ***Our Research and Development Expenditures***

We devote significant resources to research and development programs. We focus our research and development efforts on finding novel therapeutics in areas of high unmet medical need. Please see *Item 6. Selected Financial Data* below for our research and development expenditures for our prior three fiscal years.

## **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.

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 receive royalty payments equal to 2.5% of Janssen's net sales of RISPERDAL CONSTA in each country where the license is in effect based on the quarter when

the product is sold by Janssen. This royalty may be reduced in any country based on lack of patent coverage and significant competition from generic versions of the product. Janssen can terminate the license agreements upon 30 days prior written notice to us. The licenses granted to Janssen expire on a country by country basis upon the later of (i) the expiration of the last patent claiming the product in such country, or (ii) fifteen years after the date of the first commercial sale of the product in such country, provided that in no event will the license granted to Janssen expire later than the twentieth anniversary of the

## **Table of Contents**

first commercial sale of the product in such country, with the exception of certain countries where the fifteen year limitation shall pertain regardless, as set forth in greater detail in the license agreements filed with our Annual Report on Form 10-K for the fiscal year ended March 31, 1996. We exclusively manufacture RISPERDAL CONSTA for commercial sale. 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 after receipt of a written notice specifying the material breach 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% to 5.0%.

### ***Amylin***

In May 2000, we entered into a development and license agreement with Amylin for the development of BYDUREON, 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 product platform 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 BYDUREON. 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 future product sales, if any. In October 2005 and in July 2006, we amended the development and license agreement. Under the amended agreement, we are responsible for formulation and are principally responsible for non-clinical development of any products that may be developed pursuant to the agreement and for manufacturing these products for use in early phase clinical trials. 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 conjunction with the 2005 amendment of the development and license agreement with Amylin, we reached an agreement regarding the construction of a manufacturing facility for BYDUREON and certain technology transfer related thereto. In December 2005, Amylin purchased a facility for the manufacture of BYDUREON 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 would transfer our technology for the manufacture of BYDUREON to Amylin. Amylin agreed to reimburse us for the time, at an agreed-upon full-time equivalent, or FTE, rate, and materials we incurred with respect to the transfer of technology. In January 2009, the parties agreed that the technology transfer was complete. Amylin will be responsible for the manufacture of BYDUREON and will operate the facility. For a period of time commencing upon the first commercial sale of BYDUREON, we will receive royalties equal to 8% of net sales from the first 40 million units of BYDUREON sold in any particular year and 5.5% of net sales from units sold beyond the first 40 million for that year. In addition, we will receive a \$7.0 million milestone payment upon the first commercial sale of BYDUREON in the U.S. and an additional \$7.0 million milestone payment upon the first commercial sale in a major European market country. For additional information regarding royalty payment terms, please see the development and license agreement, as amended, filed with this Annual Report on Form 10-K.

Amylin may terminate the development and license agreement for any reason upon 180 days written notice to us. 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.

**Table of Contents**

***Cilag***

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 has primary responsibility for securing all necessary regulatory approvals for VIVITROL, and Janssen-Cilag, an affiliate of Cilag, commercializes the product. We are responsible for the manufacture of VIVITROL and receive manufacturing and royalty revenues based upon product sales.

Cilag has paid us \$6.0 million to date in nonrefundable payments and our agreement provides that we could be eligible for up to an additional \$33.0 million in milestone payments upon the receipt of regulatory approvals for the product, the occurrence of certain agreed-upon events and the achievement of certain VIVITROL sales levels.

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 after receipt of written notice specifying the material breach or, in certain circumstances, a 30 day extension of that period.

***Rensselaer Polytechnic Institute***

In September 2006, we and the Rensselaer Polytechnic Institute, or 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 CNS 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. In July 2008, the parties amended the agreement to expand the license to include certain additional patent applications. We paid RPI an additional nonrefundable payment of \$0.1 million and slightly increased the annual fees in consideration of this amendment. In May 2009, the parties further amended the agreement to expand the license to include a patent application covering a joint invention made by the parties.

***Acceleron***

In December 2009, we entered into a collaboration and license agreement with Acceleron. In exchange for a nonrefundable upfront payment of \$2.0 million, an equity investment in Acceleron of \$8.0 million and certain potential milestone payments and royalties, we obtained an exclusive license to Acceleron's proprietary long-acting Fc fusion technology platform, called the MEDIFUSION technology, which is designed to extend the circulating half-life of proteins and peptides. The first drug candidate being developed with this technology, ALKS 6931, is a long-acting form of a TNF receptor-Fc fusion protein for the treatment of rheumatoid arthritis and related autoimmune diseases. We and Acceleron have agreed to collaborate on the development of product candidates from the MEDIFUSION technology. Pursuant to the terms of the agreement, Acceleron will perform research on a number of candidate

compounds and develop up to two selected drug compounds using the MEDIFUSION technology through preclinical studies, at which point we will assume responsibility for all clinical development and commercialization of these two compounds and any other compounds we

## **Table of Contents**

elect to develop resulting from the platform. Acceleron will retain all rights to the technology for products derived from the TGF-beta superfamily.

Our \$8.0 million equity investment in Acceleron consists of shares of Series D-1 convertible, redeemable preferred stock. Our Chief Executive Officer is one of nine members of Acceleron's board of directors.

In addition to the upfront payment and equity investment, we will reimburse Acceleron for any time, at an agreed-upon FTE rate, and materials Acceleron incurs during development. We are obligated to make development and sales milestone payments in the aggregate of up to \$110.0 million per product in the event that certain development and sales goals are achieved. We are also obligated to make tiered royalty payments in the mid-single digits on annual net sales in the event any products developed under the agreement are commercialized.

## **Proprietary Product Platforms**

Our proprietary product platforms, which include technologies owned and exclusively licensed to us, address several important development opportunities, including injectable extended-release of proteins, peptides and small molecule pharmaceutical compounds. We have used these technologies as platforms to establish drug development, clinical development and regulatory expertise.

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

The MEDISORB technology encapsulates medication into polymer-based microspheres that are injected into the body, where they degrade slowly, gradually releasing the drug at a controlled rate. This allows patients to receive the benefit of medication for weeks or potentially months at a time with just one extended-release injection, thereby eliminating the need for daily dosing.

### ***MEDIFUSION Technology***

Our proprietary long-acting Fc fusion technology platform is designed to extend the circulating half-life of proteins and peptides in order to create an effective, long-acting injectable medication. The MEDIFUSION technology is able to extend the half-life of proteins and peptides through the combined action of Fc fusion and hyperglycosylation. The resulting extended systemic half-life of the therapeutic compound could allow for reduced dosing frequency.

### ***LINKERx Technology***

The long-acting LinkeRx technology platform is designed to enable the creation of extended-release injectable versions of antipsychotic therapies and may also be useful in other disease areas in which long action may provide therapeutic benefits. The technology uses proprietary linker-tail chemistry to create New Molecular Entities, or NMEs, derived from known agents. These NMEs are designed to have improved clinical utility, manufacturing and ease-of-use compared to other long-acting medications.

## **Manufacturing and Product Supply**

We own and occupy a manufacturing, office and laboratory facility in Wilmington, 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, or cGMP, and other regulatory agency regulations. We have been producing commercial product since 1999.

Although some materials for our drug products are currently available from a single-source or a limited number of qualified sources, we attempt to acquire an adequate inventory of such materials, establish alternative sources and/or negotiate long-term supply arrangements. We believe we do not have any significant issues obtaining suppliers. However, we cannot be certain that we will continue to be able to obtain long-term supplies of our manufacturing materials.



## **Table of Contents**

Our third party service providers involved in the manufacture of our products are subject to inspection by the FDA or comparable agencies in other jurisdictions. Any delay, interruption or other issues that arise in the acquisition of active pharmaceutical ingredients, or API, manufacture, fill-finish, packaging, or storage of our products or product candidates, including 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 sell our products or advance our development efforts, as the case may be. For information about risks relating to the manufacture of our products and product candidates, see Item 1A Risk Factors and specifically those sections entitled RISPERDAL CONSTA, VIVITROL, BYDUREON and our product candidates may not generate significant revenues . We are subject to risks related to the manufacture of our products . We rely on third parties to provide services in connection with the manufacture and distribution of our products . If we fail to meet the stringent requirements of governmental regulation in the manufacture of our products, we could incur substantial remedial costs and a reduction in sales , and We rely heavily on collaborative partners.

### ***Commercial Products***

We manufacture RISPERDAL CONSTA and VIVITROL in our Wilmington, Ohio facility. The facility has been inspected by U.S., European, Japanese, Brazilian and Saudi Arabian regulatory authorities for compliance with required cGMP standards for continued commercial manufacturing. See Item 2. Properties .

We source our packaging operations for VIVITROL to a third party contractor. Janssen is responsible for packaging operations for RISPERDAL CONSTA.

### ***Clinical Products***

We have established and are operating clinical facilities with the capability to produce clinical supplies of our injectable extended-release products at our Wilmington, Ohio facility. We have also contracted with third party manufacturers to formulate certain products for clinical use. We require that our contract manufacturers adhere to cGMP in the manufacture of products for clinical use.

### **Marketing, Sales and Distribution**

We focus our sales and marketing efforts on specialist physicians in private practice and in public treatment systems. We use customary pharmaceutical company practices to market our products and to educate physicians, such as sales representatives calling on individual physicians, advertisements, professional symposia, selling initiatives, public relations and other methods. We provide customer service and other related programs for our products, such as product-specific websites, insurance research services and order, delivery and fulfillment services. In December 2008, in connection with the termination of the VIVITROL collaboration with Cephalon, we assumed responsibility for the marketing and sale of VIVITROL in the U.S. Our sales force to market VIVITROL in the U.S. consists of approximately 55 individuals. VIVITROL is sold directly to pharmaceutical wholesalers, specialty pharmacies and a specialty distributor. Product sales of VIVITROL by us during the year ended March 31, 2010, to McKesson Corporation, AmerisourceBergen Drug Corporation, Cardinal Health and Caremark L.L.C. represented approximately 25%, 22%, 21% and 12%, respectively, of total VIVITROL sales. No other customer accounted for more than 10% of VIVITROL product sales in fiscal 2010.

Effective April 1, 2009, we entered into an agreement with Cardinal Health Specialty Pharmaceutical Services or Cardinal SPS, a division of Cardinal, to provide warehouse, shipping and administrative services for VIVITROL. Our expectation for fiscal 2011 is to continue to distribute VIVITROL through Cardinal SPS.

Under our collaboration agreements with Janssen, Cilag, and Amylin, these companies are responsible for the commercialization of any products developed thereunder if and when regulatory approval is obtained.

## **Table of Contents**

### **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, price and reimbursement coverage, 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 sales 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, in obtaining FDA and other regulatory approvals, and in commercializing products. There can be no assurance that developments by our competitors will not render our 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 proprietary injectable product platform, 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 including INVEGA® SUSTENNA™ (paliperidone palmitate), which is marketed and sold in the U.S. by Janssen, ZYPREXA® RELPREVV™ [(Olanzapine) For Extended Release Injectable Suspension] which is marketed and sold by Lilly in the U.S., EU and Australia/New Zealand, and other products currently in development. RISPERDAL CONSTA may also compete with new oral compounds being developed for the treatment of schizophrenia.

VIVITROL competes with CAMPRAL® sold by Forest Laboratories, Inc. and ANTABUSE® sold 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 Pharmaceuticals Ltd. and DEPADE® 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. If approved for the treatment of opioid dependence, VIVITROL would compete with SUBOXONE® (buprenorphine HCl/naloxone HCl dehydrate) CIII sublingual tablets and SUBUTEX® (buprenorphine oral) which are marketed and sold by Reckitt Benckiser Pharmaceuticals, Inc. in the U.S., methadone and oral naltrexone.

If approved, BYDUREON would compete with established therapies for market share. Such competitive products include sulfonylureas, metformin, insulins, thiazolidinediones, glinides, dipeptidyl peptidase type IV inhibitors, insulin sensitizers, alpha-glucosidase inhibitors and sodium-glucose transporter-2 inhibitors. BYDUREON would also compete with other GLP-1 agonists, including VICTOZA® (liraglutide (rDNA origin) injection), which is marketed and sold by Novo Nordisk A/S, and other products currently in development.

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.

**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.

**Table of Contents**

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 140 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 2014. In the future, we plan to file additional 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 43 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, 2010, 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 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.

## **Table of Contents**

### **Government Regulation**

#### ***Overview***

Our current and contemplated activities and the products and processes that result from such activities are subject to substantial government regulation.

#### ***United States: FDA Process***

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 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, manufacturing 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.

*Pre-Clinical Testing:* Before testing of any compounds with potential therapeutic value in human subjects may begin in the U.S., stringent government requirements for pre-clinical data must be satisfied. Pre-clinical testing includes both *in vitro*, or in an artificial environment outside of a living organism, and *in vivo*, or within a living organism, laboratory evaluation and characterization of the safety and efficacy of a drug and its formulation.

*Investigational New Drug Application (IND):* Pre-clinical testing results obtained from studies in several animal species, as well as from *in vitro* studies, are submitted to the FDA as part of an IND application and are reviewed by the FDA prior to the commencement of human clinical trials. These pre-clinical data must provide an adequate basis for evaluating both the safety and the scientific rationale for the initial clinical studies in human volunteers. Unless the FDA objects to an IND, the IND becomes effective 30 days following its receipt by the FDA. Once trials have commenced, the FDA may stop the trials by placing them on clinical hold because of concerns about, for example, the safety of the product being tested. Studies supporting approval of products in the U.S. are typically accomplished under an IND.

*Clinical Trials:* Clinical trials involve the administration of the drug to healthy human volunteers or to patients under the supervision of a qualified investigator pursuant to an FDA-reviewed protocol. Human clinical trials are typically conducted in three sequential phases, although the phases may overlap with one another. Clinical trials must be conducted under protocols that detail the objectives of the study, the parameters to be used to monitor safety, and the efficacy criteria, if any, to be evaluated. Each protocol must be submitted to the FDA as part of the IND. Each clinical trial must be conducted under the auspices of an Institutional Review Board, or IRB, at the institution that is conducting the trial that considers, among other things, ethical factors, the safety of human subjects, the possible liability of the institution and the informed consent disclosure, which must be made to participants in the clinical trial.

*Phase 1 Clinical Trials:* Phase 1 clinical trials represent the initial administration of the investigational drug to a small group of healthy human subjects or, more rarely, to a group of select patients with the targeted disease or disorder. The goal of Phase 1 clinical trials is typically to test for safety, dose tolerance, absorption, bio-distribution, metabolism, excretion and clinical pharmacology and, if possible, to gain early evidence regarding efficacy.

*Phase 2 Clinical Trials:* Phase 2 clinical trials involve a small sample of the actual intended patient population and seek to assess the efficacy of the drug for specific targeted indications, to determine dose response and the optimal dose range and to gather additional information relating to safety and potential adverse effects.



**Table of Contents**

*Phase 3 Clinical Trials:* Once an investigational drug is found to have some efficacy and an acceptable safety profile in the targeted patient population, Phase 3 clinical trials are initiated to establish further clinical safety and efficacy of the investigational drug in a broader sample of the general patient population at geographically dispersed study sites in order to determine the overall risk-benefit ratio of the drug and to provide an adequate basis for product labeling. Phase 3 clinical development programs consist of expanded, large-scale studies of patients with the target disease or disorder to obtain *definitive* statistical evidence of the efficacy and safety of the proposed product and dosing regimen.

All of the phases of clinical studies must be conducted in conformance with the FDA's bioresearch monitoring regulations and Good Clinical Practices, which are ethical and scientific quality standards for conducting, recording, and reporting clinical trials to assure that the rights, safety, and well-being of trial participants are protected.

*New Drug Application (NDA) or Biologics License Application (BLA):* All data obtained from a comprehensive development program including research and product development, manufacturing, pre-clinical and clinical trials and related information are submitted in an NDA to the FDA and in similar regulatory filings with the corresponding agencies in other countries for review and approval. In certain circumstances, this information is submitted in a Biologics License Application, or BLA. In addition to reports of the trials conducted under the IND, the NDA includes information pertaining to the preparation of the new drug, analytical methods, details of the manufacture of finished products and proposed product packaging and labeling. The submission of an application is no guarantee that the FDA will find the application complete and accept it for filing. The FDA may refuse to file the application and request additional information rather than accept the application for filing, in which case, the application must be resubmitted with the supplemental information. Once an application is accepted for filing, an FDA review team medical doctors, chemists, statisticians, microbiologists, pharmacologists, and other experts evaluates whether the studies the sponsor submitted show that the drug is safe and effective for its proposed use. The FDA review process may be extended by FDA requests for additional information or clarification. In fact, FDA performance goals generally provide for action on an application within 10 months, but even that deadline gets extended in certain circumstances. In some cases, the FDA may decide to expedite the review of new drugs that are intended to treat serious or life threatening conditions and demonstrate the potential to address unmet medical needs.

As part of its review, the FDA may refer the application to an advisory committee for evaluation and a recommendation as to whether the application should be approved. The FDA is not bound by the recommendation of an advisory committee, but it generally follows such recommendations. Under legislation enacted in 2007, the FDA may determine that a REMS is necessary to ensure that the benefits of a new product outweigh its risks. If required, a REMS may include various elements, such as publication of a medication guide, patient package insert, a communication plan to educate healthcare providers of the drug's risks, limitations on who may prescribe or dispense the drug, or other measures that the FDA deems necessary to assure the safe use of the drug.

In reviewing a BLA or NDA, the FDA may grant marketing approval, request additional information or deny the application if it determines the application does not provide an adequate basis for approval. The FDA may require larger or additional clinical trials, leading to unanticipated delay or expense. Even if such additional information and data are submitted, the FDA may ultimately decide that the BLA or NDA does not satisfy the criteria for approval. Data from clinical trials may be subject to different interpretation, and the FDA may interpret data differently than the applicant. 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. The FDA may require, as a condition of approval, restricted distribution and use, enhanced labeling, special packaging or labeling, expedited reporting of certain adverse events, pre-approval of promotional materials, or restrictions on direct-to-consumer advertising. 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.



## **Table of Contents**

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 requires review and approval of the FDA.

*Phase 4 Clinical Trials:* Phase 4 clinical trials are studies that are conducted after a product has been approved. These trials can be conducted for a number of purposes, including to collect long-term safety information or to collect additional data about a specific population. As part of a product approval, the FDA may require that certain Phase 4 studies be conducted post-approval, and in these cases these Phase 4 studies are called post-marketing commitments.

*Adverse Event Reporting:* 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, including the development and implementation of a REMS.

*Hatch-Waxman Act:* Under the Drug Price Competition and Patent Term Restoration Act of 1984, also known as the Hatch-Waxman Act, Congress created an abbreviated FDA review process for generic versions of pioneer (brand name) drug products. The law also provides incentives by awarding, in certain circumstances, non-patent marketing exclusivities to pioneer drug manufacturers. Newly approved drug products and changes to the conditions of use of approved products may benefit from periods of non-patent marketing exclusivity in addition to any patent protection the drug product may have. The Hatch-Waxman Act provides five years of new chemical entity, or NCE, marketing exclusivity to the first applicant to gain approval of an NDA for a product that contains an active ingredient, not found in any other approved product. The FDA is prohibited from accepting any abbreviated NDA, or ANDA, for a generic drug for five years from the date of approval of the NCE, or four years in the case of an ANDA containing a patent challenge (see below). The FDA is similarly prohibited from accepting any NDA where the applicant does not own or have a legal right of reference to all of the data required for approval, otherwise known as a 505(b)(2) application. The five-year exclusivity protects the entire new chemical entity franchise, including all products containing the active ingredient for any use and in any strength or dosage form. This exclusivity will not prevent the submission or approval of a full NDA, as opposed to an ANDA or 505(b)(2) application, for any drug, including, for example, a drug with the same active ingredient, dosage form, route of administration, strength and conditions of use.

The Hatch-Waxman Act also provides three years of exclusivity for applications containing the results of new clinical investigations (other than bioavailability studies) essential to the FDA's approval of new uses of approved products, such as new indications, dosage forms, strengths, or conditions of use. However, this exclusivity only protects against the approval of ANDAs and 505(b)(2) applications for the protected use and will not prohibit the FDA from accepting or approving ANDAs or 505(b)(2) applications for other products containing the same active ingredient.

The Hatch-Waxman Act requires NDA applicants and NDA holders to provide certain information about patents related to the drug for listing in the Orange Book. ANDA and 505(b)(2) applicants must then certify regarding each of the patents listed with the FDA for the reference product. A certification that a listed patent is invalid or will not be infringed by the marketing of the applicant's product is called a Paragraph IV certification. If the ANDA or 505(b)(2) applicant provides such a notification of patent invalidity or noninfringement, then the FDA may accept the ANDA or 505(b)(2) application four years after approval of the NDA. If a Paragraph IV certification is filed and the ANDA or 505(b)(2) application has been accepted as a reviewable filing by the FDA, the ANDA or 505(b)(2) applicant must then within 30 days provide notice to



## **Table of Contents**

the NDA holder and patent owner stating that the application has been submitted and providing the factual and legal basis for the applicant's opinion that the patent is invalid or not infringed. The NDA holder or patent owner may file suit against the ANDA or 505(b)(2) applicant for patent infringement. If this is done within 45 days of receiving notice of the Paragraph IV certification, a one-time 30-month stay of the FDA's ability to approve the ANDA or 505(b)(2) application is triggered. The 30-month stay begins at the end of the NDA holder's data exclusivity period, or, if data exclusivity has expired, on the date that the patent holder is notified. The FDA may approve the proposed product before the expiration of the 30-month stay if a court finds the patent invalid or not infringed, or if the court shortens the period because the parties have failed to cooperate in expediting the litigation.

*Pediatric Exclusivity:* Section 505(a) of the Federal Food, Drug, and Cosmetics Act provides for six months of exclusivity based on the submission of pediatric data subsequent to a written request from the FDA. This period of exclusivity is added to whatever statutory or regulatory periods of exclusivity cover a drug (e.g. NCE exclusivity or patents). This is not a patent term extension, rather, it extends the period during which the FDA cannot approve an ANDA or 505(b)(2) application.

### ***European Union    EMA Process***

In the EU, medicinal products must be authorized either through the decentralized procedure by the competent authorities of the EU Member States, or through the centralized procedure by the European Commission following an opinion by the EMA. In many EU countries, pricing negotiations also must take place between the Marketing Authorization Holder and the competent national authorities before the product is sold in their market.

### ***Other International Markets    Drug Approval Process***

In some international markets (e.g. China, Japan), additional clinical trials may be required prior to the filing or approval of marketing applications within the country.

### ***Good Manufacturing Processes***

The FDA, the EMA, the competent authorities of the EU Member States and other regulatory agencies regulate and inspect equipment, facilities, and processes used in the manufacturing of pharmaceutical and biologic products prior to approving a product. Among the conditions for a NDA or BLA approval is the requirement that the prospective manufacturer's quality control and manufacturing procedures adhere to 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 EMA 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 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.



## **Table of Contents**

### ***Good Clinical Practices***

The FDA, the EMA and other regulatory agencies promulgate regulations and standards, commonly referred to as current Good Clinical Practices, or cGCP, for designing, conducting, monitoring, auditing and reporting the results of clinical trials to ensure that the data and results are accurate and that the trial participants are adequately protected. The FDA, the EMA and other regulatory agencies enforce cGCP through periodic inspections of trial sponsors, principal investigators and trial sites. If our study sites fail to comply with applicable cGCP, the clinical data generated in our clinical trials may be deemed unreliable and relevant regulatory agencies may require us to perform additional clinical trials before approving our marketing applications.

### ***Sales and Marketing***

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 or her 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.

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. In addition, several states require that companies implement compliance programs or comply with industry ethics codes, adopt spending limits, and report to state governments any gifts, compensation, and other remuneration provided to physicians. The recently enacted health care reform legislation will require disclosure to the federal government of payments to physicians commencing in 2012. 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 Item 1A Risk Factors and specifically those sections entitled "If we fail to comply with the extensive legal and regulatory requirements affecting the health care industry, we could face increased costs, penalties and a loss of business" and "Revenues generated by sales of our products depend on the availability of reimbursement from third party payors and a reduction in payment rate or reimbursement or an increase in our financial obligation to governmental payors could result in decreased sales of our products and revenue" and "We may be exposed to product liability claims and recalls."

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**

***Pricing and Reimbursement***

In the U.S. and internationally, sales of our products, including those sold by our collaborators, and our ability to generate revenues on such sales are dependent, in significant part, on the availability and level of reimbursement from third party payors such as state and federal governments, including Medicare and Medicaid, managed care providers, and private insurance plans. The significant governmental reimbursement and cost programs are described below. Private insurers, such as health maintenance organizations and managed care providers, have also implemented cost-cutting and reimbursement initiatives and will likely continue to do so in the future. These include establishing formularies that govern the drugs and biologics that will be offered and the out-of-pocket obligations for such products. In addition, in the U.S. in particular, we are required to provide discounts and pay rebates to state and federal governments and agencies in connection with purchases of our products that are reimbursed by such entities.

Medicare pays physicians and suppliers that furnish our products under a payment methodology using average sales price, or ASP, information. Manufacturers, including us, are required to provide ASP information to the Centers for Medicare and Medicaid Services, or CMS, on a quarterly basis. This information is used to compute Medicare payment rates, which are generally set at ASP plus six percent and are updated quarterly. Medicare also uses the ASP payment methodology to determine Medicare rates paid for most drugs and biologics furnished by hospital outpatient departments. As of January 1, 2010, the reimbursement rate in the hospital outpatient setting was ASP plus four percent. There is a mechanism for comparison of such payment rates to widely available market prices, which could cause further decreases in Medicare payment rates, although this mechanism has yet to be utilized. If a manufacturer is found to have made a misrepresentation in the reporting of ASP, the statute provides for civil monetary penalties for each misrepresentation for each day in which the misrepresentation was applied.

Medicare also provides for an expanded prescription drug benefit for all Medicare beneficiaries known as Medicare Part D. This is a voluntary benefit that is implemented through private plans under contractual arrangements with the federal government. Similar to pharmaceutical coverage through private health insurance, Part D plans are expected to negotiate discounts from drug manufacturers and pass on some of those savings to Medicare beneficiaries.

We also participate in the Medicaid rebate program established by the Omnibus Budget Reconciliation Act of 1990, and under multiple subsequent amendments of that law. Under the Medicaid rebate program, we pay a rebate for each unit of product reimbursed by Medicaid, including pursuant to the health care reform legislation signed into law in March 2010 a rebate for those drugs supplied to enrollees of Medicaid managed care organizations. This recently enacted health care reform legislation is also likely to increase the amount of the unit rebate payable by us in two ways by increasing the percentage of average manufacture price, or AMP, that forms part of the unit rebate calculation and by altering the definition of AMP in a manner that may result in a higher AMP for our products. Effective January 1, 2010, the unit rebate amount is now equal to the greater of 23.1% of AMP, or the difference between AMP and the best price available from us to any commercial or non-federal governmental customer, which we are obligated to report on a monthly basis. Effective October 1, 2010, AMP is believed to include only sales to wholesalers for drugs distributed to retail community pharmacies and direct sales to retail community pharmacies. The rebate amount must be adjusted upward where the AMP for a product's first full quarter of sales, when adjusted for increases in the Consumer Price Index - Urban, or CPI-U, exceeds the AMP for the current quarter with the upward adjustment equal to the excess amount. In addition, the health care reform legislation contains a provision relating to line extensions of certain innovator drugs that may, depending on the content of interpretive guidance to be issued by CMS, have an impact on the calculation of AMP for certain drugs. The rebate amount is required to be recomputed each quarter based on our report of current AMP and best price for each of our products to CMS. The terms of our participation in the rebate program imposes a requirement for us to report revisions to AMP or best price within a period not to exceed 12 quarters from the quarter in which the data was originally due. Any such revisions could have the impact of increasing or decreasing our rebate liability for prior quarters, depending on the direction of the revision. In addition, if we were found to have knowingly submitted false information to the government, the statute provides

for civil monetary penalties per item of false information in addition to other penalties available to the government.

**Table of Contents**

The availability of federal funds to pay for our products under the Medicaid and Medicare Part B programs requires that we extend discounts under the 340B/PHS drug pricing program. The 340B/PHS drug pricing program extends discounts to a variety of community health clinics and other entities that receive health services grants from the Public Health Service, or PHS, as well as hospitals that serve a disproportionate share of poor Medicare beneficiaries. The recently enacted health care reform legislation enables certain children's hospitals, cancer hospitals, critical access and sole community hospitals, and rural referral centers to also participate in the 340B drug pricing program.

We also make our products available for purchase by authorized users of the Federal Supply Schedule, or FSS, of the General Services Administration pursuant to our FSS contract with the Department of Veterans Affairs. Under the Veterans Health Care Act of 1992, or the VHC Act, we are required to offer deeply discounted FSS contract pricing to four federal agencies—the Department of Veterans Affairs, the Department of Defense, the Coast Guard and the PHS (including the Indian Health Service)—for federal funding to be made available for reimbursement of any of our products under the Medicaid program and for our products to be eligible to be purchased by those four federal agencies and certain federal grantees. FSS pricing to those four federal agencies must be equal to or less than the Federal Ceiling Price, which is, at a minimum, 24% off the Non-Federal Average Manufacturer Price, or Non-FAMP, for the prior fiscal year. In addition, if we are found to have knowingly submitted false information to the government, the VHC Act provides for civil monetary penalties per false item of information in addition to other penalties available to the government.

In addition to that set forth above, the recently enacted health care reform legislation may have an adverse impact on our revenues by, among other things, mandating that brand name drug manufacturers provide a 50% discount for drugs in the Medicare Part D coverage gap starting in 2011 and assessing a pharmaceutical manufacturer fee. Many provisions of the recently enacted health care reform legislation, including but not limited to those set forth above, are subject to further interpretation and guidance from CMS to determine their applicability to us.

***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.

*Environmental Laws.* We are subject to federal, state, local and foreign environmental laws and regulations. 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. We do not anticipate any significant expenditures in order to comply with existing environmental laws and regulations that would have a material impact on our earnings or competitive position. We are not aware of any pending litigation or significant financial obligations arising from current or past environmental practices that are likely to have a material adverse effect on our financial position. We cannot assure you, however, that environmental problems relating to facilities owned or operated by us will not develop in the future, and we cannot predict whether any such problems, if they were to develop, could require significant expenditures on our part. In addition, we are unable to predict what legislation or regulations may be adopted or enacted in the future with respect to environmental protection and waste disposal.

*Other Laws.* We are subject to a variety of financial disclosure and securities trading regulations as a public company in the U.S., including laws relating to the oversight activities of the Securities and Exchange Commission, or SEC, and the regulations of the NASDAQ Global Select Market, on which our shares are traded. We are also subject to 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.



**Table of Contents**

**Employees**

As of May 13, 2010, we had approximately 570 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 is 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 852 Winter Street, Waltham, Massachusetts 02451-1420. Our telephone number is (781) 609-6000 and our website address is [www.alkermes.com](http://www.alkermes.com). We make available free of charge through the Investors section of our website our Annual Reports on Form 10-K, 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 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**

*Investing in our company involves a high degree of risk. You should consider carefully the risks described below, together with the other information in and incorporated by reference into this Annual Report. If any of the following risks actually occur, they could materially adversely affect our business, financial condition or operating results. This could cause the market price of our common stock to decline, and could cause you to lose all or a part of your investment.*

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

Even if our product candidates, including BYDUREON, receive regulatory approval for commercial sale, the revenues received or to be received from the sale of any such 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 or our partner's expectations.

***VIVITROL***

In December 2008, we assumed responsibility for the marketing and sale of VIVITROL in the U.S. from Cephalon. To facilitate this transfer of commercialization of VIVITROL, Cephalon provided certain transition services to us until May 2009. VIVITROL is our first commercial product for which we have had sole responsibility for marketing and sales operations. 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

**Table of Contents**

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 are responsible for the manufacture of VIVITROL and receive manufacturing revenues and royalty revenues based upon product sales. The revenues received or to be received from the sale of VIVITROL under the agreement with Cilag 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.

Based on the positive results of our phase 3 clinical trial of VIVITROL for the treatment of opioid dependence, we submitted a sNDA to the FDA for approval as a treatment for opioid dependence. We requested a priority review of our sNDA submission which, if granted, would mean a six month review timeline. 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 for the treatment of opioid dependence in the U.S. and for the treatment of alcohol and opioid dependence elsewhere in the world.

*BYDUREON*

We are not involved in, or responsible for, the clinical development of BYDUREON, including interactions with the FDA and other regulatory agencies. There can be no assurance that the phase 3 clinical trial results and other clinical and preclinical data will be sufficient to obtain regulatory approval for BYDUREON in the U.S. or elsewhere in the world. If BYDUREON receives approval for commercial sale, the revenues received or to be received from the sale of the product may not be significant. We are not involved in the manufacture, marketing or sales efforts for BYDUREON. Our revenues will depend on royalties we receive from our partner for BYDUREON, which relates directly to sales of BYDUREON by our partner. For reasons outside of our control, including those mentioned below, sales of BYDUREON may not meet our or our partner's expectations.

We cannot be assured that RISPERDAL CONSTA, VIVITROL and BYDUREON, if approved for commercial sale, 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 revenues from RISPERDAL CONSTA, VIVITROL, BYDUREON, if approved, 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 as to our products' safety and efficacy relative to that of competing products;
- the cost-effectiveness of our products;
- patient and physician satisfaction with our products;
- the ability to manufacture our commercial products successfully and on a timely basis;
- the cost and availability of raw materials necessary for the manufacture of our products;
- the size of the markets for our products;
- reimbursement policies of government and third party payors;
- unfavorable publicity concerning our products, similar classes of drugs, or the industry generally;

the introduction, availability and acceptance of competing treatments, including treatments marketed and sold by our collaborators;

the reaction of companies that market competitive products;

adverse event information relating to our products or to similar classes of drugs;

changes to the product labels of our products or of those within the same drug class to add significant warnings or restrictions on use;

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



**Table of Contents**

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

regulatory developments related to the manufacture or continued use of our products, including the issuance of a REMS by the FDA;

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

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

foreign exchange rate valuations and fluctuations; and

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

Our revenues will fluctuate from quarter to quarter based on a number of factors, including the acceptance of our products in the marketplace, our partners' orders, the timing of shipments, our ability to manufacture successfully, our yield and our production schedule. The unit 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 or at all.

***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, including those marketed and sold by our collaborator, 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.***

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 failure, equipment failure, vendor error 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. We may not be able to resolve any such problems in a timely fashion, if at all.

We rely solely on our manufacturing facility in Wilmington, Ohio for the manufacture of RISPERDAL CONSTA, VIVITROL, polymer for BYDUREON and some of our product candidates. We contract with third party manufacturers to manufacture or formulate other of our product candidates for use in clinical trials. Supply of these products depends on the uninterrupted and efficient operation of our facility, which could be adversely affected by equipment failure, labor shortages (whether as a result of pandemic flu or otherwise), natural disasters, power failures and many other factors. 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 and may not be

successful.

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.

**Table of Contents**

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

In December 2008, we assumed responsibility for the marketing and sale of VIVITROL in the U.S. from Cephalon. To facilitate this transfer of commercialization of VIVITROL, Cephalon provided certain transition services to us until May 2009. VIVITROL is our first commercial product for which we have had sole responsibility for marketing and sales operations.

We have little experience with the commercialization of pharmaceutical products, including the marketing and sale of prescription drugs. We must build an infrastructure to support the sales and marketing of VIVITROL, including building a distribution and expanded commercial infrastructure and providing various support services for the sales force. If we are unable to successfully market and sell VIVITROL, our revenues could be materially diminished.

Our ability to realize significant revenues from the marketing and sales activities associated with VIVITROL also depends on our ability to retain qualified sales personnel. We must also be able to attract new qualified sales personnel as needed to support potential sales growth and competition for qualified sales personnel is intense. Any failure to attract and retain qualified sales personnel now and in the future, could impair our ability to maintain sales levels and/or support potential future sales growth.

***Revenues generated by sales of our products depend on the availability of reimbursement from third party payors and a reduction in payment rate or reimbursement or an increase in our financial obligation to governmental payors could result in decreased sales of our products and revenue.***

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, including Medicare and Medicaid, managed care providers, and private insurance plans. Our future revenues and profitability will be adversely affected if these third party payors do not sufficiently cover and reimburse the cost of our products, or related procedures or services, or any other future drug product we may market. If these entities do not provide coverage and reimbursement for our products or if they provide an insufficient level of coverage and reimbursement, our products may be too costly for use, and physicians may not prescribe them or may prescribe them less frequently. In this manner, levels of reimbursement for drug products by government authorities, private health insurers, and other organizations, such as Health Maintenance Organizations, or HMOs, may have a material adverse effect on our business, financial condition, cash flows and results of operations.

In both the U.S. and in foreign jurisdictions, legislative and regulatory actions, including but not limited to the following, may reduce the revenues that we derive from our products:

the U.S. health care reform legislation signed into law in March 2010 may reduce revenues that we derive from sales of our products, including those of our products marketed and sold by our collaborators, by, among other things:

increasing the amount of the Medicaid rebate payable to states by increasing the formula for determination of the unit rebate amount and by altering the definition of AMP;

expanding the scope of our rebate obligation by mandating that rebates also be paid on products used by Medicaid managed care organizations;

expanding the number of entities eligible to purchase our products at a discounted basis under the 340B/PHS drug pricing program;

assessing a pharmaceutical manufacturer fee;

mandating that brand name drug manufacturers provide a 50% discount for drugs in the Medicare Part D coverage gap starting in 2011; and

redefining the impact to AMP of line extensions of certain innovator drugs.

**Table of Contents**

some states are also considering legislation that would control the prices of drugs, and state Medicaid programs are increasingly requesting manufacturers to pay supplemental rebates and requiring prior authorization by the state program for use of any drug for which supplemental rebates are not being paid; and

U.S. government efforts to reduce Medicaid expenses may lead to increased use of managed care organizations by Medicaid programs. This may result in managed care organizations influencing prescription decisions for a larger segment of the population and a corresponding constraint on prices and reimbursement for our products.

Third party payors, including the U.S. government, are increasingly challenging the prices charged for and the cost-effectiveness of medical products, which is sometimes referred to as comparative effectiveness research, and they are increasingly limiting both coverage and the level of reimbursement for prescription drugs. Also, the trend toward managed health care in the U.S. and the concurrent growth of organizations such as HMOs may result in lower prices for pharmaceutical products, including any products that may be offered by us in the future. These actions could materially adversely affect our ability to sell any drug products that are successfully developed by us and approved by regulators. We are unable to predict what additional legislation or regulation, if any, relating to the health care industry or third party coverage and reimbursement may be enacted in the future or what effect such legislation or regulation would have on our business, financial condition, cash flows and results of operations.

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 product candidates, and current reimbursement policies for our marketed products may change at any time.

If reimbursement for our products changes adversely or if we fail to obtain adequate reimbursement for our current or future products, healthcare providers may limit how much, or under what circumstances, they will prescribe or administer them, or patients may be unwilling to pay any required co-payments, which could reduce the use of, and revenues generated from, our products and which could have a material adverse effect on our business, financial condition, cash flows and results of operations.

***Our customer base that purchase VIVITROL directly from us is highly concentrated.***

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

We have entered into wholesaler distribution service agreements, or DSAs, with our three largest wholesale drug distributors. Under the DSAs, we will obtain more precise information as to the level of our product inventory available throughout the product distribution channel. We cannot be certain that the DSAs will be effective in limiting speculative purchasing activity, that there will not be a future drawdown of inventory as a result of declining minimum inventory requirements, or otherwise, or that the inventory level data provided through our DSAs are accurate. If speculative purchasing does occur, if the wholesalers significantly decrease their inventory levels, or if inventory level data provided through DSAs is inaccurate, our business, financial condition, cash flows and results of operations may be adversely affected.



**Table of Contents**

***We rely on third parties to provide services in connection with the manufacture and distribution of our products.***

We are responsible for the entire supply chain for VIVITROL, up to sale of final product and 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 product distribution network and issues with our third party providers may have a material adverse effect on our business, financial condition, cash flows and results of operations. 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 us 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 product platforms can be commercialized as a stand-alone product but must be combined with a drug. To develop any new proprietary product candidate using one of these platforms, 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.

We rely on third parties for the timely supply of specified raw materials, equipment, contract manufacturing, formulation or packaging services, product distribution services, customer service activities and product returns processing. Although we actively manage these third party relationships to ensure continuity and quality, some events beyond our control could result in the complete or partial failure of these goods and services. Any such failure could materially adversely affect our business, financial condition, cash flows and results of operations.

***If we fail to meet the stringent requirements of governmental regulation in the manufacture of our products, we could incur substantial remedial costs and a reduction in sales.***

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 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, European, Japanese, Brazilian and Saudi Arabian 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 any other facility we or our suppliers may operate 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, financial condition, cash flows and results of operations could be materially adversely affected.



**Table of Contents**

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

Our business involves the controlled use of hazardous materials and chemicals and is therefore subject to numerous environmental and safety laws and regulations and to periodic inspections for possible violations of these laws and regulations. The costs of compliance with environmental and safety laws and regulations are significant. Any violations, even if inadvertent or accidental, of current or future environmental, safety laws or regulations and the cost of compliance with any resulting order or fine could adversely affect our operations.

***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, financial condition, cash flows and results of operations.

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 and/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. For example, Janssen, which markets and sells RISPERDAL CONSTA, recently launched a competing long-acting injectable product, INVEGA SUSTENNA.

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, financial condition, cash flows and results of operations.

***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 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 RISPERDAL CONSTA, and will rely upon Lilly and Amylin to market and distribute BYDUREON. In these instances, our future revenues will be materially dependent upon the success of the efforts of these third parties.

We are responsible for the marketing and sale of VIVITROL in the U.S. We have limited experience in the commercialization of pharmaceutical products. We may not be able to attract and retain qualified personnel to serve in our sales and marketing organization, to develop an effective distribution network or to otherwise effectively support our commercialization activities. 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 sales efforts are not effective or if costs of developing sales and marketing capabilities exceed

**Table of Contents**

their cost effectiveness, our business, results of operations and financial condition could be materially adversely affected.

***Our product platforms 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, financial condition, cash flows and results of operations 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.

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; and

unforeseen governmental or regulatory delays.

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 early clinical trials, but subsequently failed to establish sufficient safety and efficacy data to obtain necessary regulatory approvals. Clinical trials

**Table of Contents**

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.

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 then be unable to find additional collaborative partners or to obtain additional financing. Our business, financial condition, cash flows and results of operations may be materially adversely affected by any delays in, or termination of, our clinical trials.

***We often depend on third parties in the conduct of our clinical trials 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 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.***

At March 31, 2010, our accumulated deficit was \$365.7 million, which is primarily the result of net losses incurred from 1987, the year we were founded, to date, partially offset by net income over previous fiscal years. There can be no assurance we will achieve sustained profitability.

A major component of our revenue is dependent on our partners and our 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.

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, and for our partnered products, including BYDUREON, both 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;

successfully commercialize VIVITROL in the U.S.;

support the marketing and sale of VIVITROL in Russia and the countries of the CIS by our partner Cilag;

enter into agreements to develop and commercialize our products and product candidates;

develop, have manufactured or 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; and

achieve certain product development milestones.

**Table of Contents**

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 cost of third party manufacture;

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;

the costs of potential litigation; and

the costs associated with recruiting and compensating a highly skilled workforce in an environment where competition for such employees may be intense.

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 or sustained 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 we may seek funds through various sources, including debt and equity offerings, corporate collaborations, bank borrowings, arrangements relating to assets, sale of royalty streams we receive on our products 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 or give up some of our rights to our product platforms, product candidates or licensed products. If we issue additional equity securities or securities convertible into equity 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 or may impose limitations upon any product approval.***

We must obtain government approvals before marketing or selling our drug candidates in the U.S. and in foreign jurisdictions. The FDA and comparable regulatory agencies in foreign countries impose substantial and rigorous requirements for the development, production and commercial introduction of drug products. These include pre-clinical, laboratory and clinical testing procedures, sampling activities, clinical trials and other costly and time-consuming procedures. In addition, regulation is not static and regulatory authorities, including the FDA, evolve in their staff, interpretations and practices and may impose more stringent requirements than currently in effect, which may adversely affect our planned drug development and/or our sales and marketing efforts. Satisfaction of the requirements of the FDA and of foreign regulators typically takes a significant number of years and can vary substantially based upon the type, complexity and novelty of the drug candidate. The approval procedure and the time required to obtain approval also varies among countries. Regulatory agencies may have varying interpretations of the same data, and approval by one regulatory authority does not



**Table of Contents**

ensure approval by regulatory authorities in other jurisdictions. In addition, 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, BYDUREON and our product candidates may not generate significant revenues.

This product development 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 demonstrate safety and efficacy for each target indication in accordance with FDA standards or standards of foreign regulatory agencies;

- poor rate of patient enrollment, including limited availability of patients who meet the criteria for certain clinical trials;

- 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 or our partners' manufacturing processes or facilities;

- the FDA may not approve accelerated development timelines for our product candidates;

- the failure of third party clinical research organizations and other third party service providers and independent clinical investigators to manage and conduct the trials, to perform their oversight of the trials, or to meet expected deadlines;

- the failure of our clinical investigational sites and the records kept at such sites, including the clinical trial data, to be in compliance with the FDA's Good Clinical Practices, or EU legislation governing good clinical practice, including the failure to pass FDA, EMA, or EU Member State inspections of clinical trials;

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

- adverse medical events during the trials could lead to requirements that trials be repeated or extended, or that a program be terminated or placed on clinical hold, even if other studies or trials relating to the program are successful; and

- 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.

In addition, our product development timelines may be impacted by third party patent litigation. Moreover, recent events, including complications experienced by patients taking FDA-approved drugs, have raised questions about the safety of marketed drugs and may result in new legislation by the U.S. Congress and increased caution by the FDA and comparable foreign regulatory authorities in reviewing new drugs. In summary, we cannot be sure that regulatory approval will be granted for drug candidates that we submit for regulatory review. Our ability to generate revenues from the commercialization and sale of additional drug products will be limited by any failure to obtain these approvals. In addition, stock prices have declined significantly in certain instances where companies have failed to obtain FDA approval of a drug candidate or if the timing of FDA approval is delayed. If the FDA's or any foreign regulatory authority's response to any application for approval is delayed or not favorable for any of our product

candidates, our stock price could decline significantly.

Even if regulatory approval to market a drug product is granted, the approval may impose limitations on the indicated use for which the drug product may be marketed as well as additional post-approval requirements. Even if our drug products are approved for marketing and commercialization, we will need to comply with post-approval clinical study commitments in order to maintain the approval of such products. Our business could be seriously harmed if we do not complete these studies and the FDA, as a result, requires us to change related sections of the marketing label for our products.

## **Table of Contents**

In addition, adverse medical events that occur during clinical trials or during commercial marketing of our products could result in legal claims against us and the temporary or permanent withdrawal of our products from commercial marketing, which could seriously harm our business and cause our stock price to decline.

### ***Changes in laws affecting the health care industry 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:

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;

changes in FDA and foreign regulations that may require additional safety monitoring, labeling changes, restrictions on product distribution or use, or other measures, which could increase our costs of doing business, adversely affect the future permitted uses of approved products, or otherwise adversely affect the market for our products;

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

changes in the tax laws relating to our operations.

For example, the recently enacted health care reform legislation in the U.S. could have an adverse impact on our revenues by, among other things, increasing the amount of the Medicaid rebate and drugs for which this rebate is payable; changing the definition of AMP; mandating that brand name drug manufacturers provide a 50% discount for drugs in the Medicare Part D coverage gap starting in 2011; and assessing a pharmaceutical manufacturer fee. 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.

### ***If we fail to comply with the extensive legal and regulatory requirements affecting the health care industry, we could face increased costs, penalties and a loss of business.***

Our activities, and the activities of our collaborators and third party providers, are subject to extensive and complex government regulation and oversight, including regulation under the federal Food, Drug and Cosmetic Act, the federal False Claims Act, the federal Anti-Kickback Statute, and other state and federal laws and regulations. The FDA and comparable agencies in other jurisdictions directly regulate many of our most critical business activities, including the conduct of preclinical and clinical studies, product manufacturing, advertising and promotion, product distribution, adverse event reporting and product risk management. States increasingly have been placing greater restrictions on the marketing practices of health care companies. In addition, pharmaceutical and biotechnology companies have been the target of lawsuits and investigations alleging violations of government regulation, including claims asserting submission of incorrect pricing information, impermissible off-label promotion of pharmaceutical products, payments intended to influence the referral of federal or state health care business, submission of false claims for government reimbursement, antitrust violations, or violations related to environmental matters. Violations of governmental regulation may be punishable by criminal and civil sanctions, including fines and civil monetary penalties and

exclusion from participation in government programs, including Medicare and Medicaid. In addition to penalties for violation of laws and regulations, we could be required to repay amounts we received from government payors, or pay additional rebates and interest if we are found to have miscalculated the pricing information we have submitted to the government. 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

**Table of Contents**

are instituted against us or our 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.

***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 product platforms, 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 or regulations. 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.

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.

**Table of Contents**

As more products are commercialized using our proprietary product platforms, 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 non-infringement 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.

***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 will produce undesirable or unintended side effects that have not been evident in the use of, or in clinical trials conducted for, such products 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 (including additional regulatory scrutiny and requirements for additional labeling), all of which could have a material adverse effect on our business, results of operations and financial condition. In addition, the reporting of adverse safety events involving our products and public rumors about such events could cause our stock price to decline or experience periods of volatility.

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

We may be exposed to product liability claims arising from the testing, manufacture and commercial sale of RISPERDAL CONSTA, VIVITROL and, if approved, BYDUREON, as well as from 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 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



**Table of Contents**

materially adversely affected by a product liability claim. Uncertainties resulting from the initiation and continuation of products liability litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace. Products liability litigation and other related proceedings may also absorb significant management time.

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 proprietary product platforms 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 be certain 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 proprietary product platforms 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.

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

We conduct a large portion of our business in international markets. We derive a majority of our RISPERDAL CONSTA revenues from sales in foreign countries and these sales are denominated in foreign currencies. Such revenues 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 foreign 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.

**Table of Contents**

***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 with or without a drug delivery system.

There are other companies developing extended-release product platforms. 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 proprietary product platforms or product candidates. Our collaborative partners could choose a competing technology to use with their drugs instead of one of our product platforms and could develop products that compete with our products. In addition, 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 product platforms obsolete or noncompetitive.

With respect to our proprietary injectable product platform, 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 including INVEGA SUSTENNA, which is marketed and sold in the U.S. by Janssen, ZYPREXA RELPREVV, which is marketed and sold by Lilly and received marketing authorization for sale in the U.S., EU and Australia/New Zealand, and other products currently in development. RISPERDAL CONSTA may also compete with new oral compounds being developed for the treatment of schizophrenia.

VIVITROL competes with CAMPRAL sold by Forest Laboratories, Inc. and ANTABUSE sold 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 Pharmaceuticals Ltd. and DEPADE 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. If approved for the treatment of opioid dependence, VIVITROL would compete with SUBOXONE and SUBUTEX, which are marketed and sold by Reckitt Benckiser Pharmaceuticals, Inc. in the U.S., methadone and oral naltrexone.

If approved, BYDUREON would compete with established therapies for market share. Such competitive products include sulfonylureas, metformin, insulins, thiazolidinediones, glinides, dipeptidyl peptidase type IV inhibitors, insulin sensitizers, alpha-glucosidase inhibitors and sodium-glucose transporter-2 inhibitors. BYDUREON would also compete with other GLP-1 agonists, including VICTOZA, which is marketed and sold by Novo Nordisk, and other products currently in development.

Physicians, patients, third party payors and the medical community may not accept or utilize our products. If our products 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 products, see the risk factor RISPERSDAL CONSTA, VIVITROL, BYDUREON and our product candidates may not generate significant revenues.

**Table of Contents**

***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, manufacturing, management, regulatory compliance and selling and marketing personnel. The loss of key personnel or our inability to hire and retain personnel who have technical, scientific, manufacturing, regulatory compliance or commercial 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. In addition, 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.

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

If we issue additional equity securities or securities convertible into equity securities to raise funds, the ownership share of the current holders of our common stock will be reduced, which may adversely affect the market price of the common stock. As of March 31, 2010, we were obligated to issue 19,547,170 shares of common stock upon the vesting and exercise of stock options and vesting of stock 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.

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

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

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

**Table of Contents**

***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;

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.

***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.

*Our business could be negatively affected as a result of the actions of activist shareholders.*

Proxy contests have been waged against many companies in the biopharmaceutical industry over the last few years. If faced with a proxy contest, we may not be able to respond successfully to the contest, which



**Table of Contents**

would be disruptive to our business. Even if we are successful, our business could be adversely affected by a proxy contest involving us or our collaborators because:

responding to proxy contests and other actions by activist shareholders can be costly and time-consuming, disrupting operations and diverting the attention of management and employees;

perceived uncertainties as to future direction may result in the loss of potential acquisitions, collaborations or in-licensing opportunities, and may make it more difficult to attract and retain qualified personnel and business partners; and

if individuals are elected to a board of directors with a specific agenda, it may adversely affect our ability to effectively and timely implement our strategic plan and create additional value for our stockholders.

These actions could cause our stock price to experience periods of volatility.

***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 may incur financial risk in connection with the relocation of our corporate headquarters from Cambridge, Massachusetts to Waltham, Massachusetts.***

In January 2010, we relocated our corporate headquarters from Cambridge, Massachusetts to Waltham, Massachusetts. In connection with the relocation, we signed a lease agreement and built out a 115,000 square foot facility. We expect the relocation to result in annual cash savings in fiscal year 2011 and beyond of approximately \$8 million; however, expected savings from relocating a facility can be highly variable and uncertain. In addition, we subleased substantially all of our current headquarters for the balance of that lease term. These sublease transactions substantially offset our ongoing expenses associated with our former headquarters; however, to the extent the sublessees of our Cambridge facility encounter financial or other difficulties, we remain primarily liable as the tenant under the lease. In addition, relocation of our corporate headquarters could adversely affect employee retention and focus.

The risk factors discussed within Item 1A and other similar matters could divert our 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 1B.** *Unresolved Staff Comments*

None.

**Table of Contents**

**Item 2. *Properties***

In January 2010, we relocated our corporate headquarters from Cambridge, Massachusetts to Waltham, Massachusetts. We lease space in Waltham, Massachusetts. The lease expires in 2020, with an option to extend the term for up to two five-year periods. Our corporate headquarters, administration areas and laboratories are located in this space.

We have entered into sublease agreements with various tenants to occupy space that we lease in Cambridge, Massachusetts under two 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. As we are not currently utilizing this space, we have no plans to extend the leases beyond their expiration date.

We own a 15-acre manufacturing, office and laboratory site in Wilmington, Ohio. The site produces RISPERDAL CONSTA and VIVITROL. We are currently operating two RISPERDAL CONSTA lines and one VIVITROL line at commercial scale. An additional line for RISPERDAL CONSTA, which was funded by and is owned by Janssen, was recently completed. Janssen has granted us an option, exercisable upon 30 days advance written notice, to purchase the additional RISPERDAL CONSTA manufacturing line at its then-current net book value. In December 2008, we purchased two partially completed VIVITROL manufacturing lines from Cephalon in connection with the termination of the VIVITROL collaboration.

We lease a commercial manufacturing facility in Chelsea, Massachusetts designed for clinical and commercial manufacturing of inhaled products based on our pulmonary technology that we are not currently utilizing. The lease term is for fifteen years, expiring in 2015, with an option to extend the term for up to two five-year periods. We exited this facility in fiscal 2008 and 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***

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. *[Removed and Reserved]***

**Table of Contents****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 Global Select 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 sales prices for our common stock:

	<b>Fiscal 2010</b>		<b>Fiscal 2009</b>	
	<b>High</b>	<b>Low</b>	<b>High</b>	<b>Low</b>
1st Quarter	\$ 12.33	\$ 7.41	\$ 13.94	\$ 10.81
2nd Quarter	11.77	8.64	17.05	11.79
3rd Quarter	10.08	7.54	13.54	5.55
4th Quarter	14.19	9.47	13.16	8.26

The last reported sale price of our common stock as reported on the NASDAQ Global Select Stock Market on May 13, 2010 was \$12.61.

**(b) *Stockholders***

There were 321 shareholders of record for our common stock and one shareholder of record for our non-voting common stock on May 13, 2010.

**(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***

On November 21, 2007, our board of directors authorized a program to repurchase up to \$175.0 million of our common stock to be repurchased at the discretion of management from time to time in the open market or through privately negotiated transactions. On June 16, 2008, the board of directors authorized the expansion of this repurchase program by an additional \$40.0 million, bringing the total authorization under this program to \$215.0 million. We

purchased 328,404 shares at a cost of approximately \$2.7 million under this program during the year ended March 31, 2010 by means of open market purchases. We did not purchase any shares during the quarter ended March 31, 2010. As of March 31, 2010, we have purchased a total of 8,866,342 shares under this program at a cost of approximately \$114.0 million.

In addition to the stock repurchases above, during the quarter and year ended March 31, 2010, we acquired, by means of net share settlements, 1,042 and 100,449 shares, respectively, of our common stock, at an average price of \$13.12 and \$8.68 per share, respectively, related to the vesting of employee stock awards to satisfy withholding tax obligations. In addition, during the quarter and year ended March 31, 2010, we acquired 7,961 shares of our common stock, at an average price of \$12.56 per share, tendered by a former employee as payment of the exercise price of stock options granted under our equity compensation plans.

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

The information contained in the performance graph shall not be deemed to be soliciting material or to be filed with the SEC, and such information shall not be incorporated by reference into any future filing under the Securities Act or Exchange Act, except to the extent that Alkermes specifically incorporates it by reference into such filing.

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, 2005 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****Comparison of Cumulative Total Returns**

	<b>2005</b>	<b>2006</b>	<b>2007</b>	<b>2008</b>	<b>2009</b>	<b>2010</b>
Alkermes, Inc.	100	212	149	114	117	125
NASDAQ Stock Market Index	100	118	122	114	62	97
NASDAQ Biotechnology Index	100	129	119	120	105	144

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

The selected historical financial data set forth below as of March 31, 2010 and 2009 and for the years ended March 31, 2010, 2009 and 2008 are derived from our audited consolidated financial statements, which are included elsewhere in this Annual Report. The selected historical financial data set forth below as of March 31, 2008, 2007 and 2006 and for the years ended March 31, 2007 and 2006 are derived from audited consolidated financial statements, which are not included in this Annual Report.

The following selected consolidated financial data should be read in conjunction with our consolidated financial statements, the related notes and Management's Discussion and Analysis of Financial Condition and Results of Operations included elsewhere in this Annual Report. The historical results are not necessarily indicative of the results to be expected for any future period.

	2010	Year Ended March 31,			2006
		2009	2008	2007	
		(In thousands, except per share data)			
<b>Consolidated Statements of Operations</b>					
<b>Data:</b>					
<b>REVENUES:</b>					
Manufacturing revenues	\$ 112,938	\$ 116,844	\$ 101,700	\$ 105,416	\$ 64,901
Royalty revenues	36,979	33,247	29,457	23,151	16,532
Product sales, net	20,245	4,467			
Research and development revenue under collaborative arrangements	3,117	42,087	89,510	74,483	45,883
Net collaborative profit(1)	5,002	130,194	20,050	36,915	39,285
<b>Total revenues</b>	<b>178,281</b>	<b>326,839</b>	<b>240,717</b>	<b>239,965</b>	<b>166,601</b>
<b>EXPENSES:</b>					
Cost of goods manufactured and sold(2)	49,438	43,396	40,677	45,209	23,489
Research and development(2)	95,363	89,478	125,268	117,315	89,068
Selling, general and administrative(2)	76,514	59,008	59,508	66,399	40,383
Impairment of long-lived assets(3)			11,630		
Restructuring(3)			6,423		
<b>Total expenses</b>	<b>221,315</b>	<b>191,882</b>	<b>243,506</b>	<b>228,923</b>	<b>152,940</b>
<b>OPERATING (LOSS) INCOME</b>	<b>(43,034)</b>	<b>134,957</b>	<b>(2,789)</b>	<b>11,042</b>	<b>13,661</b>
<b>OTHER (EXPENSE) INCOME:</b>					
Interest income	4,667	11,400	17,834	17,707	11,569
Interest expense	(5,974)	(13,756)	(16,370)	(17,725)	(20,661)
Other (expense) income, net	(360)	(1,589)	(476)	(481)	333
Gain on sale of investment in Reliant Pharmaceuticals, Inc.			174,631		
Derivative loss related to convertible subordinated notes(4)					(1,084)

Edgar Filing: ALKERMES INC - Form 10-K

Total other (expense) income	(1,667)	(3,945)	175,619	(499)	(9,843)
(LOSS) INCOME BEFORE INCOME TAXES	(44,701)	131,012	172,830	10,543	3,818
(BENEFIT) PROVISION FOR INCOME TAXES	(5,075)	507	5,851	1,098	
NET (LOSS) INCOME	\$ (39,626)	\$ 130,505	\$ 166,979	\$ 9,445	\$ 3,818
(LOSS) EARNINGS PER COMMON SHARE:					
BASIC	\$ (0.42)	\$ 1.37	\$ 1.66	\$ 0.10	\$ 0.04
DILUTED	\$ (0.42)	\$ 1.36	\$ 1.62	\$ 0.09	\$ 0.04
WEIGHTED AVERAGE NUMBER OF COMMON SHARES OUTSTANDING:					
BASIC	94,839	95,161	100,742	99,242	91,022
DILUTED	94,839	96,252	102,923	103,351	97,377



**Table of Contents**

	2010	Year Ended March 31,			2006
		2009	2008	2007	
		(In thousands, except per share data)			
<b>Consolidated Balance Sheet Data:</b>					
Cash, cash equivalents and investments	\$ 350,193	\$ 404,482	\$ 460,361	\$ 357,466	\$ 303,112
Total assets	515,600	566,486	656,311	568,621	477,163
Long-term debt(5)		75,888	160,371	156,898	279,518
Unearned milestone revenue current and long-term			117,657	128,750	99,536
Redeemable convertible preferred stock					15,000
Shareholders equity	412,616	434,888	305,314	203,461	33,216

- (1) Includes \$120.7 million recognized as revenue upon the termination of the VIVITROL collaboration with Cephalon during the year ended March 31, 2009.
- (2) Includes share-based compensation expense in the years ended March 31, 2010, 2009, 2008 and 2007.
- (3) Represents charges in connection with the termination of the AIR Insulin development program and our March 2008 restructuring of operations. In connection with the termination of the AIR Insulin development program, we determined that the carrying value of the assets at our AIR commercial manufacturing facility exceeded their fair value and recorded an impairment charge. The March 2008 restructuring program was substantially completed during fiscal 2009. 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.
- (4) Represents a noncash loss in connection with derivative liabilities associated with the two-year interest make-whole payment provision of our 6.52% convertible senior subordinated 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 was recorded at fair value in the consolidated balance sheets.
- (5) Includes the Non-Recourse RISPERDAL CONSTA secured 7% Notes (the non-recourse 7% Notes ), which were issued by the RC Royalty Sub LLC, a wholly-owned subsidiary of Alkermes, Inc. ( 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**

*The following should be read in conjunction with our consolidated financial statements and related notes beginning on page F-1 of this report. The following discussion contains forward-looking statements. Actual results may differ significantly from those projected in the forward-looking statements. Factors that might cause future results to differ materially from those projected in the forward-looking statements include, but are not limited to, those discussed in Risk Factors and elsewhere in this Annual Report. See also Forward-Looking Statements.*

**Overview**

We are a fully integrated biotechnology company committed to developing innovative medicines to improve patients lives. We developed, manufacture and commercialize VIVITROL for alcohol dependence and manufacture RISPERDAL CONSTA for schizophrenia and bipolar disorder. We are collaborating with Amylin on the development of BYDUREON for the treatment of type 2 diabetes. We filed a sNDA for VIVITROL for the treatment of opioid dependence in April 2010. Our pipeline includes extended-release injectable and oral products for the treatment of prevalent, chronic diseases, such as central nervous system, or CNS, disorders, reward disorders, addiction, diabetes and autoimmune disorders.

In May 2009, our collaborative partner, Amylin, filed a NDA for BYDUREON for the treatment of type 2 diabetes and received a complete response letter from the FDA in March 2010. In the complete response letter, there were no requests for new pre-clinical or clinical trials and requests primarily related to the finalization of the product labeling with accompanying REMS and clarification of existing manufacturing processes. Amylin submitted a response to the FDA complete response letter in April 2010. In May 2010, the FDA classified the complete response as a Class 2 resubmission and assigned a new Prescription Drug User Fee Act ( PDUFA ) action date of October 22, 2010. Lilly, who has primary responsibility for developing and commercializing BYDUREON for Amylin outside of the U.S. announced that in April 2010, the EMA had accepted the Marketing Authorization Application filing for BYDUREON for the treatment of type 2 diabetes.

In July 2009, Amylin, Lilly and we announced positive results from the DURATION-3 study for BYDUREON. The DURATION-3 study showed the superiority of BYDUREON as compared to LANTUS in patients with type 2 diabetes taking stable doses of metformin alone or in combination with a sulfonylurea. In December 2009, Amylin, Lilly and we announced positive results from the DURATION-5 study for BYDUREON. The DURATION-5 showed the superiority of BYDUREON as compared to BYETTA in patients with type-2 diabetes who were not achieving adequate glucose control using background therapies that included diet and exercise, metformin, sulfonylurea, thiazolidinediones or a combination of the agents.

In April 2009, our collaborative partner, Janssen, received approval from the Pharmaceuticals and Medical Devices Agency in Japan to market RISPERDAL CONSTA for the treatment of schizophrenia. RISPERDAL CONSTA is the first long-acting atypical antipsychotic to be available in Japan. In May 2009, the FDA approved RISPERDAL CONSTA as both monotherapy and adjunctive therapy to lithium or valproate in the maintenance treatment of bipolar I disorder. In July 2009, the FDA approved INVEGA SUSTENNA, a competing product to RISPERDAL CONSTA for the acute and maintenance treatment of schizophrenia in the U.S. Janssen launched this product in August 2009. INVEGA SUSTENNA may negatively impact sales of RISPERDAL CONSTA in the U.S.

In October 2009, we announced positive results from two phase 1 clinical trials of ALKS 33, an oral opioid modulator for the potential treatment of addiction and other central nervous system disorders. Based upon the results of the phase 1 clinical trials, we initiated a phase 2 clinical study in November 2009 to assess the safety and efficacy of multiple doses of ALKS 33 in patients with alcohol dependence and to further define the clinical profile of ALKS 33.

In February 2010, we announced positive results from a phase 1 study of ALKS 37, an orally active, peripherally-restricted opioid antagonist with the potential to block the effects of opioid agonists on gastrointestinal motility. Based on the results of this study, in March 2010, we initiated a multidose phase 1

**Table of Contents**

clinical study of ALKS 37 to assess the safety, tolerability and pharmacokinetics of daily oral administration of two dose levels of ALKS 37 for a seven day period.

In December 2009, we entered into a license and collaboration agreement with Acceleron in which we exclusively licensed a proprietary long-acting Fc fusion technology platform, called the MEDIFUSION technology, which is designed to extend the circulating half-life of proteins and peptides. The first drug candidate being developed with this technology, ALKS 6931 is a long-acting form of a TNF receptor-Fc fusion protein for the treatment of rheumatoid arthritis and related autoimmune diseases.

In January 2010, we relocated our corporate headquarters from Cambridge, Massachusetts to Waltham, Massachusetts. We incurred \$18.9 million of expense as a result of the move during the year ended March 31, 2010, primarily related to noncash charges for the acceleration of depreciation on laboratory related leasehold improvements located at our Cambridge facility and the write-down of laboratory equipment that is no longer in use and was disposed of.

Net loss for the year ended March 31, 2010 was \$39.6 million, or \$0.42 per common share basic and diluted, as compared to net income of \$130.5 million, or \$1.37 per common share basic and \$1.36 per common share diluted for the year ended March 31, 2009 and net income of \$167.0 million, or \$1.66 per common share basic and \$1.62 per common share diluted, for the year ended March 31, 2008.

**Results of Operations****Manufacturing Revenues**

	Years Ended March 31,			Change	
	2010	2009	2008	Favorable/(Unfavorable) 2010-2009	2009-2008
	(In millions)				
Manufacturing revenues:					
Risperdal Consta	\$ 109.0	\$ 112.4	\$ 95.2	\$ (3.4)	\$ 17.2
Polymer	3.4			3.4	
Vivitrol	0.5	4.4	6.5	(3.9)	(2.1)
Manufacturing revenues	\$ 112.9	\$ 116.8	\$ 101.7	\$ (3.9)	\$ 15.1

The decrease in RISPERDAL CONSTA manufacturing revenues for the year ended March 31, 2010, as compared to the year ended March 31, 2009, was due to a 2% decrease in the number of units shipped to Janssen and a 1% decrease in the net unit sales price. The decrease in the net unit sales price is primarily due to an overall strengthening of the U.S. dollar in relation to foreign currencies of the countries in which the product was sold. The increase in RISPERDAL CONSTA manufacturing revenues for the year ended March 31, 2009, as compared to the year ended March 31, 2008, was primarily due to a 19% increase in the number of units shipped to Janssen due to increased customer demand. See Part II, Item 7A. Quantitative and Qualitative Disclosures about Market Risk for information on foreign currency exchange rate risk related to RISPERDAL CONSTA revenues.

Polymer manufacturing revenues for the year ended March 31, 2010 consisted of polymer sales to Amylin for use in the formulation of BYDUREON. We record manufacturing revenues under our arrangement with Amylin at an agreed

upon price when product is shipped to them. We did not make any shipments of polymer to Amylin during the years ended March 31, 2009 and 2008.

**Table of Contents**

VIVITROL manufacturing revenues consist of the following:

	<b>Years Ended March 31,</b>		
	<b>2010</b>	<b>2009</b>	<b>2008</b>
	<b>(In millions)</b>		
VIVITROL manufacturing revenues:			
VIVITROL sold to Cilag for resale in Russia	\$ 0.5	\$ 0.6	\$
VIVITROL sold to Cephalon		3.8	6.5
VIVITROL manufacturing revenues	\$ 0.5	\$ 4.4	\$ 6.5

VIVITROL was approved for sale in Russia for the treatment of alcohol dependence in August 2008 and was launched by Cilag in March 2009. VIVITROL manufacturing revenues on product sold to Cephalon for the years ended March 31, 2009 and 2008 included \$0.3 million and \$0.6 million, respectively, of milestone revenue related to manufacturing profit we earned on VIVITROL, which equaled a 10% markup on VIVITROL cost of goods manufactured that drew down unearned milestone revenue. The decrease in VIVITROL manufacturing revenues on product sold to Cephalon for the year March 31, 2009 as compared to the year ended March 31, 2008, was primarily due to \$2.2 million of billings for idle capacity costs in the year ended March 31, 2008. In December 2008, in connection with the termination of the VIVITROL collaboration with Cephalon, we assumed full responsibility for the marketing and sale of VIVITROL in the U.S. and now report sales of VIVITROL in the U.S. as Product Sales.

**Royalty Revenues**

	<b>Years Ended March 31,</b>			<b>Change</b>		
	<b>2010</b>	<b>2009</b>	<b>2008</b>	<b>Favorable/(Unfavorable)</b>	<b>2010-2009</b>	<b>2009-2008</b>
	<b>(In millions)</b>					
Royalty revenues	\$ 37.0	\$ 33.2	\$ 29.5	\$ 3.8		\$ 3.7

Substantially all of our royalty revenues for the years ended March 31, 2010, 2009 and 2008 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, 2010, 2009 and 2008 were based on RISPERDAL CONSTA sales of \$1,477.6 million, \$1,324.9 million and \$1,176.5 million, respectively. Units sold in foreign countries by Janssen in the year ended March 31, 2010, 2009 and 2008 accounted for 79%, 77% and 77% of the total units sold, respectively.

**Table of Contents****Product Sales, net**

In December 2008, upon termination of the VIVITROL collaboration with Cephalon, we became responsible for the marketing and sale of VIVITROL in the U.S. The following table presents the adjustments deducted from VIVITROL product sales, gross, to arrive at VIVITROL product sales, net, during the year ended March 31, 2010 and the period from December 1, 2008 through March 31, 2009:

	Year Ended March 31, 2010		December 1, 2008 Through March 31, 2009	
	Amount	% of Sales	Amount	% of Sales
	(In millions)			
Product sales, gross	\$ 24.7	100.0%	\$ 6.3	100.0%
Adjustments to product sales, gross:				
Chargebacks	(1.2)	(4.9)%	(0.1)	(1.6)%
Wholesaler fees	(0.9)	(3.6)%		0.0%
Medicaid rebates	(0.9)	(3.6)%	(0.2)	(3.2)%
Reserve for inventory in the channel(1)	(0.5)	(2.0)%	(1.3)	(20.6)%
Other	(1.0)	(4.1)%	(0.2)	(3.2)%
Total adjustments	(4.5)	(18.2)%	(1.8)	(28.6)%
Product sales, net	\$ 20.2	81.8%	\$ 4.5	71.4%

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

During the year ended March 31, 2009, gross sales of VIVITROL were \$18.9 million, which consisted of \$12.6 million of sales by Cephalon prior to the termination of the VIVITROL collaboration and \$6.3 million of sales made by us after the termination of the collaboration. Gross sales of VIVITROL by Cephalon during the year ended March 31, 2008 were \$18.0 million. The increase in total VIVITROL gross sales during the year ended March 31, 2010 as compared to the year ended March 31, 2009, was primarily due to a 23% increase in price and a 7% increase in the number of units sold.

**Research and Development Revenue Under Collaborative Arrangements**

Years Ended March 31,			Change	
2010	2009	2008	Favorable/(Unfavorable) 2010-2009	2009-2008
(In millions)				

Edgar Filing: ALKERMES INC - Form 10-K

Research and development programs:					
Four-week RISPERDAL CONSTA	\$ 2.0	\$ 4.6	\$	\$ (2.6)	\$ 4.6
BYDUREON	0.7	9.5	32.9	(8.8)	(23.4)
AIR <sup>®</sup> Insulin		26.8	49.5	(26.8)	(22.7)
AIR PTH			5.1		(5.1)
Other	0.4	1.2	2.0	(0.8)	(0.8)
Research and development revenue under collaborative arrangements					
	\$ 3.1	\$ 42.1	\$ 89.5	\$ (39.0)	\$ (47.4)

The decrease in the four-week RISPERDAL CONSTA revenues in the year ended March 31, 2010, as compared to the year ended March 31, 2009, was due to the decision made by Johnson & Johnson Pharmaceutical Research & Development, L.L.C. ( J&JPRD ), in August 2009 not to pursue further



**Table of Contents**

development of this product and, consequently, we do not expect to recognize any future revenue from this program. The decrease in revenues earned under the BYDUREON development program in the years ended March 31, 2010 and 2009, as compared to March 31, 2008, was due to reduced activity as the program neared the submission of the NDA to the FDA, which occurred in May 2009.

The decrease in revenue from the AIR Insulin program in the year ended March 31, 2009, as compared to the year ended March 31, 2008, was due to the termination of the AIR Insulin development program in March 2008. We were collaborating with Lilly to develop inhaled formulations of insulin and other potential products for the treatment of diabetes based on our AIR pulmonary technology. The AIR pulmonary technology enables the delivery of both small molecules and macromolecules to the lungs. In June 2008, we entered into an agreement in connection with the termination of the development and license agreements and supply agreement for the development of AIR Insulin (the AIR Insulin Termination Agreement). Under the AIR Insulin Termination Agreement, we recognized \$25.5 million of R&D revenue in the three months ended June 30, 2008. We do not expect to record any revenue from the AIR Insulin development program in the future. The AIR parathyroid hormone (PTH) program was terminated in August 2007. We do not expect to record any revenue from the AIR PTH development program in the future.

**Net Collaborative Profit**

	<b>Years Ended March 31,</b>			<b>Change</b>	
	<b>2010</b>	<b>2009</b>	<b>2008</b>	<b>Favorable/(Unfavorable)</b>	<b>2010-2009</b>
	<b>(In millions)</b>				
Net collaborative profit:					
VIVITROL losses funded by Cephalon, post termination	\$ 5.0	\$ 6.0	\$	\$ (1.0)	\$ 6.0
Milestone revenue – license		3.5	5.2	(3.5)	(1.7)
Milestone revenue – cost recovery			5.3		(5.3)
Net payments from Cephalon			9.6		(9.6)
Recognition of deferred and unearned milestone revenue due to termination of VIVITROL collaboration		120.7		(120.7)	120.7
Net collaborative profit	\$ 5.0	\$ 130.2	\$ 20.1	\$ (125.2)	\$ 110.1

Prior to the termination of the VIVITROL collaboration, Cephalon had paid us an aggregate of \$274.6 million in nonrefundable milestone payments, and we were responsible to fund the first \$124.6 million of cumulative net losses incurred on VIVITROL (the cumulative net loss cap). VIVITROL reached the cumulative net loss cap in April 2007, at which time Cephalon became responsible to fund all net losses incurred on VIVITROL through December 31, 2007. Beginning January 1, 2008, all net losses incurred on VIVITROL within the collaboration were divided between us and Cephalon in approximately equal shares. For the year ended March 31, 2009, we recognized no milestone revenue – cost recovery, as VIVITROL had reached the cumulative loss cap prior to this reporting period. Milestone revenue – license, which related to the license provided to Cephalon to commercialize VIVITROL, was being recognized on a straight-line basis over a 10 year amortization schedule.

Upon the termination of the VIVITROL collaboration with Cephalon, we recognized \$120.7 million of net collaborative profit which consisted of \$113.9 million of unearned milestone revenue that existed at December 1,

2008 (the Termination Date ) and \$6.8 million of deferred revenue. At the Termination Date, we had \$22.8 million of deferred revenue related to the original sale of two partially completed VIVITROL manufacturing lines to Cephalon. We paid Cephalon \$16.0 million to acquire the title to these manufacturing lines and accounted for the payment as a reduction to deferred revenue. The remaining \$6.8 million of deferred revenue and the \$113.9 million of unearned milestone revenue were recognized as revenue in the three months ended December 31, 2008, as we had no remaining performance obligations to Cephalon and the

**Table of Contents**

amounts were nonrefundable. Net payments from Cephalon were received based upon the sharing of VIVITROL costs and losses incurred during the reporting periods.

Upon termination of the VIVITROL collaboration, we received \$11.0 million from Cephalon to fund their share of estimated VIVITROL losses during the one-year period following the Termination Date. We recorded the \$11.0 million as deferred revenue and recognized \$5.0 million and \$6.0 million as revenue through the application of a proportional performance model based on net VIVITROL losses in the years ended March 31, 2010 and 2009, respectively. We do not expect to recognize any net collaborative profit from the Cephalon collaboration in the future.

**Cost of Goods Manufactured and Sold**

	Years Ended March 31,			Change	
	2010	2009	2008	Favorable/(Unfavorable) 2010-2009	2009-2008
	(In millions)				
Cost of goods manufactured and sold:					
Risperdal Consta	\$ 40.2	\$ 31.3	\$ 34.8	\$ (8.9)	\$ 3.5
Vivitrol	6.9	11.8	5.9	4.9	(5.9)
Polymer	2.3	0.3		(2.0)	(0.3)
Cost of goods manufactured and sold	\$ 49.4	\$ 43.4	\$ 40.7	\$ (6.0)	\$ (2.7)

The increase in cost of goods manufactured for RISPERDAL CONSTA in the year ended March 31, 2010, as compared to the year ended March 31, 2009, was primarily due to a \$7.2 million increase in overhead and support costs allocated to cost of goods manufactured and a \$1.8 million increase in the cost for failed batches. These costs were partially offset by a 2% decrease in the number of units of RISPERDAL CONSTA shipped to Janssen. The increase in overhead and support costs allocated to cost of goods manufactured is the result of increasing the focus on manufacturing activities, as compared to development activities, at our Ohio manufacturing facility. The decrease in cost of goods manufactured for RISPERDAL CONSTA in the year ended March 31, 2009, as compared to the year ended March 31, 2008, was due to a 24% decrease in the unit cost of RISPERDAL CONSTA, primarily due to increased operating efficiencies, partially offset by a 19% increase in the number of units of RISPERDAL CONSTA shipped to Janssen to meet customer demand.

The decrease in cost of goods manufactured and sold for VIVITROL in the year ended March 31, 2010, as compared to the year ended March 31, 2009, was primarily due to a \$4.5 million reduction in costs incurred for failed batches and costs related to the restart of the manufacturing line following scheduled shutdowns of the line. Cost of goods manufactured and sold for VIVITROL in the year ended March 31, 2009 consisted of \$7.7 million of cost of goods manufactured for Cephalon incurred prior to the Termination Date, \$3.6 million for product we sold in the U.S. after the Termination Date and \$0.5 million of cost of goods manufactured for Cilag for resale in Russia. VIVITROL cost of goods manufactured for the year ended March 31, 2008 consisted of \$3.2 million of product shipments to Cephalon and \$2.7 million of idle capacity costs, which consisted of manufacturing costs allocated to cost of goods manufactured which were related to underutilized VIVITROL manufacturing capacity.

We also began to manufacture polymer for Amylin for use in the formulation of BYDUREON during the fourth quarter of fiscal year 2009.

***Research and Development Expense***

	<b>Years Ended March 31,</b>			<b>Change</b>		
	<b>2010</b>	<b>2009</b>	<b>2008</b>	<b>Favorable/(Unfavorable)</b>	<b>2010-2009</b>	<b>2009-2008</b>
	<b>(In millions)</b>					
Research and development	\$ 95.4	\$ 89.5	\$ 125.3	\$ (5.9)		\$ 35.8

**Table of Contents**

The increase in research and development ( R&D ) expenses for the year ended March 31, 2010, as compared to the year ended March 31, 2009, was primarily due to \$18.7 million of costs we incurred as a result of the relocation of our corporate headquarters from Cambridge, Massachusetts to Waltham, Massachusetts. These costs consisted primarily of the acceleration of depreciation on laboratory related leasehold improvements located at our Cambridge facility and the write-down of laboratory equipment that is no longer in use and was disposed of. In addition, we had a \$7.7 million increase in clinical and pre-clinical study expense due to an increase in the number of ongoing studies and we incurred \$2.9 million of expense under the collaboration and license agreement we signed with Acceleron. These expenses were partially offset by a \$7.2 million decrease in overhead and support costs allocated to R&D at our Ohio manufacturing facility as discussed above under Cost of Goods Manufactured and Sold, a decrease of \$7.2 million in labor and benefits due to a reduction in R&D headcount and a \$4.5 million decrease in occupancy costs due to the consolidation of space at our Cambridge facility prior to our relocation to Waltham.

The decrease in R&D expenses for the year ended March 31, 2009, as compared to the year ended March 31, 2008, was primarily due to the termination of the AIR Insulin development program in March 2008, the termination of the AIR PTH development program in August 2007 and reductions in costs incurred on the BYDUREON development program as the program neared the submission of the NDA to the FDA, which occurred in May 2009. In connection with the termination of the AIR Insulin development program, we closed our AIR commercial manufacturing facility located in Chelsea, Massachusetts and reduced our workforce by approximately 150 employees (the 2008 Restructuring ). In addition to the workforce reductions, non-cash compensation, occupancy and depreciation expense savings realized from the 2008 Restructuring, there were reductions in laboratory expenses, including clinical raw materials, professional service and third party packaging fees related to the AIR Insulin and AIR PTH programs. These expense reductions were partially offset by increased clinical study costs related to the ALKS 33 and four-week RISPERDAL CONSTA development programs, which began phase 1 clinical trials in December 2008 and January 2009, respectively, and the ALKS 36 program, which began a phase 1 clinical trial in the second half of calendar 2009 and the VIVITROL opioid dependence development program, in which a multi-center registration study was initiated in June 2008.

A significant portion of our R&D 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 R&D 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 R&D expenses on a departmental and functional basis in accordance with our budget and management practices.

***Selling, General and Administrative Expense***

	Years Ended March 31,			Change	
	2010	2009	2008	Favorable/(Unfavorable) 2010-2009	2009-2008
	(In millions)				
Selling, general and administrative	\$ 76.5	\$ 59.0	\$ 59.5	\$ (17.5)	\$ 0.5

The increase in selling, general and administrative costs for the year ended March 31, 2010, as compared to the year ended March 31, 2009, was primarily due to increased sales and marketing costs as we became responsible for the marketing and sale of VIVITROL in the U.S. beginning in December 2008. Our labor costs increased by \$10.0 million and our marketing costs increased by \$3.0 million in the year ended March 31, 2010, as compared to the year ended March 31, 2009, primarily due to our commercialization of VIVITROL. Also included in the labor costs for the year ended March 31, 2010 are \$1.5 million of severance costs and

**Table of Contents**

share-based compensation expense in connection with the resignation of our former President and Chief Executive Officer in September 2009. In fiscal 2011, we expect selling and marketing expenses to increase over fiscal 2010 in preparation for the possible FDA approval of VIVITROL for the treatment of opioid dependence and its potential launch in fiscal 2011.

The decrease in selling, general and administrative costs for the year ended March 31, 2009, as compared to the year ended March 31, 2008, was primarily due to a decrease in share-based compensation expense, professional fees, taxes and depreciation, partially offset by the increased sales and marketing costs related to VIVITROL as we became responsible for the marketing and sale of VIVITROL on December 1, 2008.

***Impairment and Restructuring Expenses***

	Years Ended March 31,			Change	
	2010	2009	2008	2010-2009	2009-2008
	(In millions)				
Impairment of long-lived assets	\$	\$	\$ 11.6	\$	\$ 11.6
Restructuring			6.4		6.4
Total impairment and restructuring expenses	\$	\$	\$ 18.0	\$	\$ 18.0

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 the 2008 Restructuring and as a result we recorded a restructuring charge of \$6.9 million, consisting primarily of lease and severance related costs. As of March 31, 2010, the only costs remaining from the 2008 Restructuring relate to lease costs on the exited facility, which will be paid out through fiscal 2016.

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 and externally established estimates and the selling prices of similar assets.

***Other (Expense) Income***

	Years Ended March 31,			Change	
	2010	2009	2008	2010-2009	2009-2008
	(In millions)				
Interest income	\$ 4.7	\$ 11.4	\$ 17.8	\$ (6.7)	\$ (6.4)
Interest expense	(6.0)	(13.7)	(16.4)	7.7	2.7
Other expense, net	(0.4)	(1.6)	(0.4)	1.2	(1.2)
			174.6		(174.6)

Gain on sale of investment in Reliant  
Pharmaceuticals, Inc.

Total other (expense) income	\$ (1.7)	\$ (3.9)	\$ 175.6	\$ 2.2	\$ (179.5)
------------------------------	----------	----------	----------	--------	------------

The decrease in interest income for the year ended March 31, 2010, as compared to the year ended March 31, 2009, was due to a lower average balance of cash and investments and lower interest rates earned during the year ended March 31, 2010 as compared to March 31, 2009. The decrease in interest income for the year ended March 31, 2009, as compared to the year ended March 31, 2008, was due to lower interest rates earned during the year ended March 31, 2009 as compared to March 31, 2008, partially offset by a higher average balance of cash and investments.

The decrease in interest expense for the year ended March 31, 2010, as compared to the year ended March 31, 2009, was due to the reduction in the outstanding balance of our non-recourse 7% Notes as a result



**Table of Contents**

of quarterly scheduled principal payments on the notes in the year ended March 31, 2010 and repurchases of the notes in the year ended March 31, 2009. The decrease in interest expense for the year ended March 31, 2009, as compared to the year ended March 31, 2008, was the result of our repurchase of an aggregate total of \$93.0 million principal amount of the non-recourse 7% Notes in five separately negotiated transactions during the year ended March 31, 2009. Included in interest expense for the year ended March 31, 2009 is a loss on the extinguishment of the non-recourse 7% Notes of \$2.5 million, consisting of \$0.9 million of transaction fees and a \$1.6 million difference between the carrying value and the purchase price of the non-recourse 7% Notes.

The non-recourse 7% Notes, which have a remaining principal amount of \$51.3 million at March 31, 2010, are scheduled to be paid in full on January 1, 2012. On May 11, 2010, we delivered a notice to the trustee of the non-recourse 7% Notes exercising our option to redeem these notes in full on July 1, 2010 in accordance with the provisions of the purchase and sale agreement. This redemption will result in an additional savings to us of \$2.4 million in interest through the scheduled maturity date in addition to the \$12.9 million we saved as a result of the purchase of \$93.0 million aggregate principal value of the non-recourse 7% Notes we made during the year ended March 31, 2009.

In the years ended March 31, 2010, 2009 and 2008, we recorded other-than-temporary impairments on our investments in the common stock of our collaborators of \$0.1 million, \$1.2 million and \$1.6 million, respectively, in other expense, net. In the year ended March 31, 2008, this impairment charge was offset by income earned on the change in the fair value of our investments in the warrants of our collaborators.

We recorded a gain on sale of our investment in Reliant Pharmaceuticals, Inc. ( 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. In March 2009, we received an additional \$7.7 million of funds, which had been held in escrow subject to the terms of an 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 been written down to zero prior to the time of the sale.

**Provision for Income Taxes**

	Years Ended March 31,		Change	
	2010	2009	2010-2009	2009-2008
	(In millions)			
(Benefit) provision for income taxes	\$ (5.1)	\$ 0.5	\$ 5.9	\$ 5.4

The income tax benefit of \$5.1 million for the year ended March 31, 2010 primarily consists of a current federal income tax benefit of \$3.3 million and a deferred federal and state tax benefit of \$1.8 million. The current federal income tax benefit is the result of a carryback of our 2010 alternative minimum tax ( AMT ) net operating loss ( NOL ) pursuant to the *Worker, Homeownership and Business Act of 2009*. This law increased the carryback period for certain net operating losses from two years to five years. Prior to the adoption of this law, we had recorded a full valuation allowance against the credits that were established in prior periods when we were subject to AMT provisions. The deferred federal and state tax benefit was due to our recognition of a \$1.8 million income tax expense associated with the increase in the value of certain securities that we carried at fair market value during the year ended March 31, 2010. This income tax expense was recorded in other comprehensive income. There were no similar income tax benefits or

provisions for the years ended March 31, 2009 and 2008. Our provision for income taxes in the amount of \$0.5 million and \$5.9 million for the years ended March 31, 2009 and 2008 primarily represents 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 we have recorded a full valuation allowance.

At March 31, 2010, we had approximately \$236.5 million of federal NOL carryforwards, \$57.8 million of state operating loss carryforwards, and \$18.7 million of foreign NOL and foreign capital loss carryforwards,

**Table of Contents**

which expire on various dates through the year 2030 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. We have a full valuation allowance of \$118.5 million, which was recorded based upon the uncertainty surrounding future utilization of our deferred tax assets.

**Liquidity and Capital Resources**

Our financial condition is summarized as follows:

	<b>March 31, 2010</b>	<b>March 31, 2009</b>
	<b>(In millions)</b>	
Cash and cash equivalents	\$ 79.3	\$ 86.9
Investments short-term	202.1	236.8
Investments long-term	68.8	80.8
Total cash, cash equivalents and investments	\$ 350.2	\$ 404.5
Working capital	\$ 247.1	\$ 307.1
Outstanding borrowings current and long-term	\$ 51.0	\$ 75.9

Our cash flows for the years ended March 31, 2010, 2009 and 2008 were as follows:

	<b>Years Ended March 31,</b>		
	<b>2010</b>	<b>2009</b>	<b>2008</b>
	<b>(In millions)</b>		
Cash and cash equivalents, beginning of period	\$ 86.9	\$ 101.2	\$ 80.5
Cash (used in) provided by operating activities	(12.3)	34.6	42.4
Cash provided by investing activities	28.0	45.4	61.9
Cash (used in) financing activities	(23.3)	(94.3)	(83.6)
Cash and cash equivalents, end of period	\$ 79.3	\$ 86.9	\$ 101.2

Our primary sources of liquidity are cash provided by operating activities, payments received under R&D arrangements and other arrangements with collaborators, private placements of debt securities and equipment financing arrangements. The decrease in cash, cash equivalents and investments during the year ended March 31, 2010, as compared to the years ended March 31, 2009 and 2008, was primarily due to the following:

During the year ended March 31, 2010, we made principal and interest payments on our non-recourse 7% Notes of \$30.6 million and entered into a collaboration and license agreement with Acceleron in exchange for a nonrefundable upfront payment of \$2.0 million and an equity investment of \$8.0 million.

We did not generate cash flows from operations during the year ended March 31, 2010 as we had in the years ended March 31, 2009 and 2008 due primarily to the termination of the VIVITROL collaboration with Cephalon, which resulted in an addition of approximately \$16.2 million in payments for sales and marketing costs as we hired a team of individuals to market and sell VIVITROL in the year ended March 31, 2010 as compared to the year ended March 31, 2009. Prior to the termination of the VIVITROL collaboration, our costs related to VIVITROL were shared with Cephalon. We also increased the number of R&D programs in the clinical or preclinical stage during the year ended March 31, 2010, as compared to March 31, 2009 and 2008.

During the year ended March 31, 2009, we received a \$40.0 million payment from Lilly in connection with the AIR Insulin Termination agreement and received a \$7.7 million payment for the release of escrowed funds related to the sale of our investment in Series C convertible, redeemable preferred stock

**Table of Contents**

of Reliant. Shortly after receiving the \$40.0 million payment, we announced an expansion of our common stock repurchase program by \$40.0 million, bringing the total repurchase authorization under the program to \$215.0 million, and purchased \$18.0 million of treasury stock under the repurchase program. In addition, we purchased an aggregate total of \$93.0 million principal amount of our non-recourse 7% Notes for \$89.4 million, which saves us \$12.9 million in interest payments through the scheduled maturity of the notes.

During the year ended March 31, 2008, we received \$166.9 million in exchange for our investment in Series C convertible, redeemable preferred stock of Reliant upon their acquisition by GSK and purchased \$93.4 million of treasury stock under our common stock repurchase program.

Our investments at March 31, 2010 consist of the following:

	<b>Amortized Cost</b>	<b>Gross Unrealized Gains      Losses</b>		<b>Estimated Fair Value</b>
		<b>(In millions)</b>		
Investments short-term	\$ 201,726	\$ 354	\$ (27)	\$ 202,053
Investments long-term available-for-sale	64,705	691	(2,437)	62,959
Investments long-term held-to-maturity	5,857			5,857
<b>Total</b>	<b>\$ 272,288</b>	<b>\$ 1,045</b>	<b>\$ (2,464)</b>	<b>\$ 270,869</b>

Our investment objectives are, first, to preserve liquidity and conservation of capital and, second, to obtain investment income. Our available-for-sale investments consist primarily of short and long-term U.S. government and agency debt securities, debt securities issued by foreign agencies and backed by foreign governments, corporate debt securities, including student loan backed auction rate securities and strategic equity investments, which includes the common stock of a public company we have a collaborative arrangement with. Our held-to-maturity investments consist of investments that are restricted and held as collateral under certain letters of credit related to certain of our lease agreements.

We classify available-for-sale investments in an unrealized loss position which do not mature within the upcoming 12 months as long-term investments. We have the intent and ability to hold these investments until recovery, which may be at maturity, and it is more likely than not that we would not be required to sell these securities before recovery of their amortized cost. At March 31, 2010, we performed an analysis of our investments with unrealized losses for impairment and determined that they are temporarily impaired.

At March 31, 2010, 4% of our investments are valued using unobservable, or Level 3, inputs to determine fair value as they are not actively trading and fair values could not be derived from quoted market prices. These investments consist primarily of student loan backed auction rate securities. At March 31, 2009, 18% of our investments were valued using Level 3 inputs and consisted primarily of investment grade subordinated, medium term, callable step-up floating rate notes ( FRN s ) issued by several large European and U.S. banks, student loan backed auction rate securities and asset backed debt securities. During the year ended March 31, 2010, we transferred, from a Level 3 classification to a Level 2 classification, all but one of our FRN investments as trading resumed for these securities. In addition, during the year ended March 31, 2010, \$22.6 million of Level 3 investments were redeemed at par by the issuers.

Our investments in auction rate securities consist of taxable student loan revenue bonds issued by the Colorado Student Obligation Bond Authority ( Colorado ), with a cost of \$5.0 million and an estimated fair value of \$4.4 million, and Brazos Higher Education Service Corporation ( Brazos ), with a cost of \$5.0 million and an estimated fair value of \$4.2 million. The bonds service student loans under the Federal Family Education Loan Program ( FFELP ) 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. The Colorado and Brazos securities were rated Aaa and Baa3 by Moody s, respectively, at March 31, 2010. Liquidity for these securities is typically provided by an auction process that resets the applicable interest rate at pre-determined intervals; however, the auctions have repeatedly failed since January 2008. In making the determination that the decline in the fair value of the auction rate securities was temporary, we considered various factors, including, but not limited to: the length of time each security was in an unrealized loss

**Table of Contents**

position; the extent to which fair value was less than cost; financial condition and near term prospects of the issuers; and the intent not to sell these securities and assessment that it is more likely than not that we would not be required to sell these securities before the recovery of their amortized cost basis. The estimated fair value of the auction rate securities could change significantly based on future financial market conditions or the financial condition of the issuers. We continue to monitor the financial markets and the issuers and if there is continued deterioration, the fair value of these securities could decline further, which may result in an other-than-temporary impairment charge. On May 11, 2010, we received a notice that the Colorado securities will be called at their par value on May 27, 2010.

During the year ended March 31, 2010, the illiquidity of our Level 3 investments did not have a material impact on our overall liquidity, operations, financial flexibility or stability. We expect to incur significant additional R&D costs and other costs as we expand the development of our proprietary product candidates, including costs related to preclinical studies and clinical trials. Our costs, including R&D costs for our product candidates, manufacturing, and sales, marketing and promotional expenses for any current or future products marketed by us or our collaborators, if any, may exceed revenues in the future, which may result in losses from operations. We believe that our current cash and cash equivalents and short and long-term investments, combined with anticipated revenues and anticipated interest income will generate sufficient cash flows to meet our current anticipated liquidity and capital requirements for the foreseeable future.

We expect to spend approximately \$5.0 million during the year ended March 31, 2011 for capital expenditures. We spent \$10.3 million more for capital expenditures during the year ended March 31, 2010, as compared to the year ended March 31, 2009, primarily due to the relocation of our corporate headquarters from Cambridge, Massachusetts to Waltham, Massachusetts, which occurred during the fourth quarter of fiscal year 2010. We spent \$16.4 million less on capital expenditures during the year ended March 31, 2009, as compared to the year ended March 31, 2008, primarily due to the completion of work on our RISPERDAL CONSTA manufacturing lines and the purchase of equipment in connection with the BYDUREON program, which was later sold to Amylin at our cost.

Amounts included as construction in progress in the consolidated balance sheets primarily include costs incurred for the expansion of our manufacturing facilities in Ohio. We continue to evaluate our manufacturing capacity based on expectations of demand for our products and will continue to record such amounts within construction in progress until such time as the underlying assets are placed into service, or we determine we have sufficient existing capacity and the assets are no longer required, at which time we would recognize an impairment charge. We continue to periodically evaluate whether facts and circumstances indicate that the carrying value of these long-lived assets to be held and used may not be recoverable.

***Borrowings***

At March 31, 2010, our borrowings consisted of \$51.3 million principal amount of our non-recourse 7% Notes, which have a carrying value of \$51.0 million. The non-recourse 7% Notes were originally issued on February 1, 2005, with principal and interest payments on the non-recourse 7% Notes due quarterly. On May 11, 2010, we delivered a notice to the trustee of the non-recourse 7% Notes exercising our option to redeem these notes in full on July 1, 2010 in accordance with the provisions of the purchase and sale agreement. The price of the redemption will be 101.75% of the principal balance on the redemption date. Accordingly, at March 31, 2010, we classified the entire balance of the non-recourse 7% Notes balance at March 31, 2010 as a current liability in the accompanying consolidated balance sheets. As a result of expected July 2010 redemption, we expect to save an additional \$2.4 million in interest through the scheduled maturity date in addition to the \$12.9 million we saved as a result of purchases we made during the year ended March 31, 2009.

**Table of Contents****Contractual Obligations**

The following table summarizes our obligations to make future payments under current contracts at March 31, 2010:

<b>Contractual Cash Obligations</b>	<b>Total</b>	<b>Less</b>	<b>One to</b>	<b>Three to</b>	<b>More</b>
		<b>Than</b>	<b>Three</b>	<b>Five</b>	<b>Than</b>
		<b>One Year</b>	<b>Years</b>	<b>Years</b>	<b>Five Years</b>
		<b>(Fiscal</b>	<b>(Fiscal</b>	<b>(Fiscal</b>	<b>(After</b>
		<b>2011)</b>	<b>2012-</b>	<b>2014-</b>	<b>Fiscal</b>
			<b>2013)</b>	<b>2015)</b>	<b>2016)</b>
			<b>(In thousands)</b>		
7% Notes principal(1)	\$ 51,333	\$ 25,666	\$ 25,667	\$	\$
7% Notes interest(1)	4,043	2,920	1,123		
Operating lease obligations	56,908	12,581	19,219	7,526	17,582
Purchase obligations	29,530	29,530			
Capital expansion programs	2,351	2,351			
<b>Total contractual cash obligations</b>	<b>\$ 144,165</b>	<b>\$ 73,048</b>	<b>\$ 46,009</b>	<b>\$ 7,526</b>	<b>\$ 17,582</b>

(1) The non-recourse 7% Notes were issued by Royalty Sub. The non-recourse 7% Notes are non-recourse to Alkermes, Inc. (see Note 9 to the consolidated financial statements included in this Form 10-K). The non-recourse 7% Notes mature on January 1, 2012, however, on May 11, 2010, we delivered a notice to the trustee of the non-recourse 7% Notes exercising our option to redeem these notes in full on July 1, 2010.

This table 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. We have approximately \$0.2 million of long term liabilities associated with uncertain tax positions at March 31, 2010.

In September 2006, we entered into a license agreement with RPI which granted us exclusive rights to a family of opioid receptor compounds discovered at RPI. 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 are responsible for the continued research and development of any resulting product candidates. We 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 to date under this license agreement have been expensed and are included in R&D expense.

In December 2009, we entered into a collaboration and license agreement with Acceleron which granted us an exclusive license to Acceleron's proprietary long-acting Fc fusion technology platform, called the MEDIFUSION technology, which is designed to extend the circulating half-life of proteins and peptides in exchange for a nonrefundable upfront payment of \$2.0 million and an equity investment in Acceleron of \$8.0 million and certain potential milestone payments and royalties. In addition, we will reimburse Acceleron for any time, at an agreed-upon FTE rate, and materials Acceleron incurs on product development and we are obligated to make developmental and sales milestone payments in the aggregate of up to \$110.0 million per product in the event that certain development



and sales goals are achieved. We are also obligated to make tiered royalty payments in the mid-single digits on annual net sales in the event any products developed under the agreement are commercialized. All amounts paid to Acceleron to date under this license and collaboration agreement have been expensed and are included in R&D expense, except for the \$8.0 million equity investment which is included in other assets in our consolidated balance sheet at March 31, 2010.

Due to the contingent nature of the payments under the RPI and Acceleron arrangements, we cannot predict the amount or period in which royalty, milestone and other payments may be made and accordingly they are not included in the table of contractual maturities.

**Table of Contents**

**Off-Balance Sheet Arrangements**

At March 31, 2010, we were not a party to any off-balance sheet arrangements that have, or are reasonably likely to have, a current or future effect on our financial condition, changes in financial condition, revenue or expenses, results of operations, liquidity, capital expenditures or capital resources.

**Critical Accounting Estimates**

Our consolidated financial statements are prepared in accordance with generally accepted accounting principles in the United States ( GAAP ), which require management to make estimates, judgments and assumptions that affect the amounts reported in the consolidated financial statements and accompanying notes. We believe that our most critical accounting estimates are in the areas of revenue recognition, investments, share-based compensation and income taxes.

***Manufacturing Revenues, Royalty Revenues and Product Sales, Net***

For the year ended March 31, 2010, our manufacturing revenues consisted of sales from RISPERDAL CONSTA, polymer for use in BYDUREON and sales from VIVITROL for resale in Russia. RISPERDAL CONSTA is sold exclusively to Janssen under a license agreement in which we granted Janssen an exclusive worldwide license to use and sell RISPERDAL CONSTA. We record manufacturing revenues from sales of RISPERDAL CONSTA when the product is shipped to Janssen at a price based on 7.5% of Janssen's net unit sales price for RISPERDAL CONSTA for the calendar year. As the sales price is based on information supplied to us by Janssen, this may require estimates to be made. Differences between the actual RISPERDAL CONSTA revenues and estimated RISPERDAL CONSTA revenues are reconciled and adjusted in the period in which they become known. We also receive a royalty from Janssen equal to 2.5% of net sales of RISPERDAL CONSTA in the period the product is sold by Janssen.

We sell polymer to Amylin for use in the formulation of BYDUREON. Under our arrangement with Amylin, we record manufacturing revenues at an agreed upon price when polymer is shipped to them. We sell VIVITROL to Cilag for resale in Russia and the CIS. Under our arrangement with Cilag, we record manufacturing revenues when VIVITROL is shipped to them at an agreed upon price. We also earn a royalty equal to a minimum of 15% of net sales of VIVITROL in Russia and the CIS in the period the product is sold by Cilag.

We recognize revenue from product sales of VIVITROL when persuasive evidence of an arrangement exists, title to the product and associated risk of loss has passed to the customer, which is considered to have occurred when the product has been received by the customer, when the sales price is fixed or determinable and collectibility is reasonably assured. We sell VIVITROL to wholesalers, specialty distributors and specialty pharmacies.

We record VIVITROL product sales net of the following categories of sales reserves and allowances: chargebacks; wholesaler fees; inventory in the channel; Medicaid discounts; and other discounts. Calculating each of these items involves estimates and judgments and requires us to use information from external sources. We believe we are able to make reasonable estimates of sales allowance based on the history of VIVITROL sales, known market events and trends, third party data, customer buying patterns and knowledge of contractual and statutory requirements. We establish sales allowance provisions in the period that the related sales are recorded. The following is a description of our significant sales allowances:

*Chargebacks* Wholesaler and specialty pharmacy chargebacks are discounts that occur when contracted customers purchase directly from an intermediary wholesale purchaser. Contracted customers, which primarily consist of federal government agencies purchasing under the federal supply schedule, generally purchase the product at its contracted price, plus a mark-up from the wholesaler. The wholesaler, in-turn, charges back to us

the difference between the price initially paid by the wholesaler and the contracted price paid to the wholesaler by the customer. The allowance for wholesaler chargebacks is based on expected utilization of these programs.  
Wholesaler chargebacks

**Table of Contents**

could exceed historical experience and our estimates of future participation in these programs. To date, actual wholesaler chargebacks have not differed materially from our estimates.

*Reserve for inventory in the channel* we defer the recognition of revenue on shipments of VIVITROL to our customers until the product has left the distribution channel. We estimate product shipments out of the distribution channel through data provided by external sources, including information on inventory levels provided by our customers in the distribution channel, as well as prescription information. In order to match the cost of goods related to products shipped to customers with the associated revenue, we defer the recognition of the cost of goods to the period in which the associated revenue is recognized.

*Wholesaler Fees* we maintain distribution service agreements with a number of wholesaler and specialty pharmacy customers that provide them with the opportunity to earn discounts in exchange for the performance of certain services.

*Medicaid Rebates* we record accruals for rebates to states under the Medicaid Drug Rebate Program as a reduction of sales when the product is shipped into the distribution channel. We rebate individual states for all eligible units purchased under the Medicaid program based on a rebate per unit calculation, which is based on our Average Manufacturer Price ( AMP ). We estimate expected unit sales and rebates per unit under the Medicaid program and adjust our rebate estimates based on actual unit sales and rebates per unit.

***Investments***

At March 31, 2010, we held investments in U.S. government and agency obligations, debt securities issued by foreign agencies and backed by foreign governments, corporate debt securities, auction rate securities and asset backed debt securities. In addition, we hold strategic equity investments, which include the common stock of a public company we have a collaborative arrangement with. Substantially all of our investments are classified as available-for-sale and are recorded at their estimated fair value. The valuation of our available-for-sale securities for purposes of determining the amount of gains and losses is based on the specific identification method. Our held-to-maturity investments are restricted investments held as collateral under certain letters of credit related to our lease arrangements and are recorded at amortized cost.

The earnings on our investment portfolio 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 amortized cost. If the fair market value of a security is less than its carrying value, we perform an analysis to assess whether we intend to sell or whether we would more likely than not be required to sell the security before the expected recovery of the amortized cost basis. Where we intend to sell a security, or may be required to do so, the security's decline in fair value is deemed to be other-than-temporary and the full amount of the unrealized loss is recorded within earnings as an impairment loss. Regardless of our intent to sell a security, we perform additional analysis on all securities with unrealized losses to evaluate losses associated with the creditworthiness of the security. Credit losses are identified where we do not expect to receive cash flows sufficient to recover the amortized cost basis of a security.

For equity securities, when assessing whether a decline in fair value below our cost basis is other-than-temporary, we consider the fair market value of the security, the duration of the security's decline, and the financial condition of the issuer. We then consider our intent and ability to hold the equity security for a period of time sufficient to recover our carrying value. Where we have determined that we lack the intent and ability to hold an equity security to its expected recovery, the security's decline in fair value is deemed to be other-than-temporary and is recorded within earnings as an impairment loss.

We classify our financial assets and liabilities as Level 1, 2 or 3 within the fair value hierarchy. Fair values determined by Level 1 inputs utilize quoted prices (unadjusted) in active markets for identical assets or liabilities. Fair values determined by Level 2 inputs are based on a market approach using quoted prices obtained from brokers or dealers for similar securities or for securities for which we have limited visibility

**Table of Contents**

into their trading volumes. Valuations of these financial instruments do not require a significant degree of judgment. Fair values determined by Level 3 inputs utilize unobservable data points for the asset. Our Level 3 investments are valued using discounted cash flow models. While we believe the valuation methodologies are appropriate, the use of valuation methodologies is highly judgmental and changes in methodologies can have a material impact on our results of operations.

Our investment in FRN s issued by RBS, auction rate securities and asset backed debt securities are all valued using a discounted cash flow model. The assumptions used in the discounted cash flow models include estimates for interest rates, the timing of cash flows, expected holding periods and risk adjusted discount rates, which include provisions for default and liquidity risk, which we believe to be the most critical assumptions utilized within the analysis. We also consider assumptions market participants would use in their estimate of fair value, such as collateral underlying the securities, the creditworthiness of the issuers, associated guarantees and callability features,

***Share-based Compensation***

In connection with valuing stock options, we utilize the Black-Scholes option-pricing model, which requires us to estimate certain subjective assumptions. These assumptions 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, which is developed using both the historical volatility of our common stock and implied volatility from our publicly traded options, the risk-free interest rate over the option s expected term, and an expected annual dividend yield. Due to the differing exercise and post-vesting termination behavior of our employees and non-employee directors, we establish separate Black-Scholes input assumptions for three distinct employee populations: our senior management; our non-employee directors; and all other employees. For the year ended March 31, 2010, the ranges in weighted-average assumptions were as follows:

Expected option term	5 - 7 years
Expected stock volatility	38% - 49%
Risk-free interest rate	1.83% - 3.05%
Expected annual dividend yield	

In addition to the above, we apply judgment in developing estimates of award forfeitures. For the year ended March 31, 2010, we used a forfeiture estimate of 0% for our non-employee directors, 5% for members of senior management and 14.5% for all other employees.

For all of the assumptions used in valuing stock options and estimating award forfeitures, our historical experience is generally the starting point for developing our assumptions, 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.

During the year ended March 31, 2010, we granted restricted stock units ( RSU s ) to certain of our executives that vest upon the achievement of certain performance criteria. The estimated fair value of these RSU s is based on the market value of our stock on the date of grant. Compensation expense for RSU s that vest upon the achievement of performance criteria is recognized from the moment we determine the performance criteria will be met to the date we deem the event is likely to occur. Cumulative adjustments are recorded quarterly to reflect subsequent changes in the estimated outcome of performance-related conditions until the date results are determined.

During the year ended March 31, 2009, we granted RSU s to certain of our executives that vest upon the achievement of a market condition. The estimated fair value of these RSU s was determined through the use of a Monte Carlo

simulation model, which utilizes input variables that determine the probability of satisfying

**Table of Contents**

the market condition stipulated in the award and calculates the fair market value for the performance award. The Monte Carlo simulation model used the following assumptions:

<b>Grant Date</b>	<b>Weighted-Average Expected Volatility</b>	<b>Expected Dividend Yield</b>	<b>Risk-Free Interest Rate</b>
May 27, 2008	42.7%		2.5%

Compensation expense for these RSU s was recognized over a service period derived from the Monte Carlo simulation model.

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

We review the carrying value of long-lived assets for potential impairment on a periodic basis and whenever events or changes in circumstances indicate the carrying value of an asset may not be recoverable. We determine impairment by comparing the projected undiscounted cash flows to be generated by the asset to its carrying value. If an impairment is identified, a loss is recorded equal to the excess of the asset s net book value over its fair value, and the cost basis is adjusted. The estimated future cash flows, based on reasonable and supportable assumptions and projections, require management s judgment. Actual results could vary from these estimates.

***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, 2010, 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 using a more-likely-than-not threshold for recognizing and resolving uncertain tax positions. The evaluation of uncertain tax positions is based on factors that include, but are not limited to, changes in tax law, the measurement of tax positions taken or expected to be taken in tax returns, the effective settlement of matters subject to audit, new audit activity and changes in facts or circumstances related to a tax position. We evaluate uncertain tax positions on a quarterly basis and adjust the level of the liability to reflect any subsequent changes in the relevant facts surrounding the uncertain positions. Our liabilities for uncertain tax positions can be relieved only if the contingency becomes legally extinguished through either payment to the taxing authority or the expiration of the statute of limitations, the recognition of the benefits associated with the position meet the more-likely-than-not threshold or the liability becomes effectively settled through the examination process. We consider matters to be effectively settled once the taxing authority has completed all of its required or expected examination procedures, including all appeals and administrative reviews; we have no plans to appeal or litigate any aspect of the tax position;



and we believe that it is highly unlikely that the taxing authority would examine or re-examine the related tax position. We also accrue for potential interest and penalties related to unrecognized tax benefits in income tax expense.

**Recent Accounting Pronouncements**

Please refer to Note 1, *New Accounting Pronouncements* in our Consolidated Financial Statements for a discussion of new accounting standards.

**Table of Contents**

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

We hold securities in our investment portfolio that are sensitive to market risks. Our securities with fixed interest rates 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 \$0.5 million over an annual period. Due to the conservative nature of our short-term and long-term investments and our investment policy, we do not believe that we have a material exposure to interest rate risk. Although our investments are subject to credit risk, our investment policies specify credit quality standards for our investments and limit the amount of credit exposure from any single issue, issuer or type of investment.

Our investments that are subject to the greatest liquidity and credit risk at this time are our investments in auction rate securities. Holding all other factors constant, if we were to increase the discount rate utilized in our valuation analysis of the auction rate securities by 50 basis points (one-half of a percentage point), this change would have the effect of reducing the fair value of these investments by \$0.2 million at March 31, 2010. Also, holding all other factors constant, if we were to increase the average expected term utilized in our fair value analysis by one year, this change would have the effect of reducing the fair value of the auction rate securities by approximately \$0.4 million at March 31, 2010.

At March 31, 2010, the fair value of our non-recourse 7% Notes was \$48.7 million and the carrying value was \$51.0 million. The interest rate on these notes are fixed and therefore not subject to interest rate risk.

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

**Foreign Currency Exchange Rate Risk**

The manufacturing and royalty revenues we receive on RISPERDAL CONSTA are a percentage of the net sales made by our collaborative partner, Janssen. A majority of these sales are made in foreign countries and are denominated in currencies in which the product is sold. The manufacturing and royalty payments on these foreign sales are 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. For the year ended March 31, 2010, an average 10% strengthening of the U.S. dollar relative to the currencies in which RISPERDAL CONSTA is sold would have resulted in our RISPERDAL CONSTA manufacturing and royalty revenues being reduced by approximately \$6.5 million and \$2.4 million, respectively.

**Table of Contents****Item 8. Financial Statements and Supplementary Data*****Selected Quarterly Financial Data***

	<b>First Quarter</b>	<b>Second Quarter</b>	<b>Third Quarter</b>	<b>Fourth Quarter</b>
	<b>(In thousands, except per share data)</b>			
<b>Year Ended March 31, 2010</b>				
<b>REVENUES:</b>				
Manufacturing revenues	\$ 28,804	\$ 32,835	\$ 28,650	\$ 22,649
Royalty revenues	8,701	8,818	9,970	9,490
Product sales, net	4,226	4,643	5,451	5,925
Research and development revenue under collaborative arrangements	1,450	1,174	81	412
Net collaborative profit(1)	4,315	687		
<b>Total revenues</b>	<b>47,496</b>	<b>48,157</b>	<b>44,152</b>	<b>38,476</b>
<b>EXPENSES:</b>				
Cost of goods manufactured and sold	12,666	15,092	10,072	11,608
Research and development	25,586	20,664	22,577	26,536
Selling, general and administrative	19,268	20,625	17,739	18,882
<b>Total expenses</b>	<b>57,520</b>	<b>56,381</b>	<b>50,388</b>	<b>57,026</b>
<b>OPERATING LOSS</b>	<b>(10,024)</b>	<b>(8,224)</b>	<b>(6,236)</b>	<b>(18,550)</b>
<b>OTHER EXPENSE</b>	<b>(211)</b>	<b>(545)</b>	<b>(566)</b>	<b>(345)</b>
<b>LOSS BEFORE INCOME TAXES</b>	<b>(10,235)</b>	<b>(8,769)</b>	<b>(6,802)</b>	<b>(18,895)</b>
<b>INCOME TAX (BENEFIT) PROVISION</b>	<b>(70)</b>	<b>(60)</b>	<b>15</b>	<b>(4,960)</b>
<b>NET LOSS</b>	<b>\$ (10,165)</b>	<b>\$ (8,709)</b>	<b>\$ (6,817)</b>	<b>\$ (13,935)</b>
<b>BASIC NET LOSS PER SHARE</b>	<b>\$ (0.11)</b>	<b>\$ (0.09)</b>	<b>\$ (0.07)</b>	<b>\$ (0.15)</b>
<b>DILUTED NET LOSS PER SHARE</b>	<b>\$ (0.11)</b>	<b>\$ (0.09)</b>	<b>\$ (0.07)</b>	<b>\$ (0.15)</b>
<b>Year Ended March 31, 2009</b>				
<b>REVENUES:</b>				
Manufacturing revenues	\$ 38,610	\$ 33,039	\$ 20,533	\$ 24,662
Royalty revenues	8,581	8,439	7,970	8,257
Product sales, net				4,467
Research and development revenue under collaborative arrangements	31,450	5,252	3,736	1,649
Net collaborative profit(1)	1,351	581	123,422	4,840

Edgar Filing: ALKERMES INC - Form 10-K

Total revenues	79,992	47,311	155,661	43,875
<b>EXPENSES:</b>				
Cost of goods manufactured and sold	14,314	12,071	5,536	11,475
Research and development	22,261	19,710	22,669	24,838
Selling, general and administrative	11,926	11,679	14,568	20,835
Total expenses	48,501	43,460	42,773	57,148
OPERATING INCOME (LOSS)	31,491	3,851	112,888	(13,273)
OTHER EXPENSE	(774)	(2,216)	(503)	(452)
INCOME (LOSS) BEFORE INCOME TAXES	30,717	1,635	112,385	(13,725)
INCOME TAX PROVISION (BENEFIT)	1,030	(63)	(330)	(130)
NET INCOME (LOSS)	\$ 29,687	\$ 1,698	\$ 112,715	\$ (13,595)
BASIC NET INCOME (LOSS) PER SHARE	\$ 0.31	\$ 0.02	\$ 1.18	\$ (0.14)
DILUTED NET INCOME (LOSS) PER SHARE	\$ 0.31	\$ 0.02	\$ 1.18	\$ (0.14)

(1) Includes \$120.7 million recognized as revenue upon the termination of the VIVITROL collaboration with Cephalon during the three months ended December 31, 2008.

**Table of Contents**

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***

Not applicable.

**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) under the Securities Exchange Act of 1934, as amended, or the Exchange Act). Based on that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective as of March 31, 2010 to provide reasonable assurance that information required to be disclosed by us in the reports that we file under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate to allow timely decisions regarding required disclosure.

(b) Evaluation of internal control over financial reporting

Management's Annual Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over our financial reporting. Internal control over financial reporting is defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act as the process designed by, or under the supervision of, our Chief Executive Officer and Chief Financial Officer, and effected by our board of directors, management and other personnel, to provide reasonable assurance regarding the reliability of our financial reporting and the preparation of our financial statements for external purposes in accordance with generally accepted accounting principles, and includes those policies and procedures that:

- 1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of assets;
- 2) 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 are being made only in accordance with the authorizations of management and directors; and
- 3) provide reasonable assurance regarding the prevention or timely detection of unauthorized acquisition, use or disposition of assets that could have a material effect on our financial statements.

Under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting based on the framework provided in *Internal Control - Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission. In completing our assessment, no material weaknesses in our internal controls over financial reporting as of March 31, 2010 were identified. Based on this assessment, our management

concluded that our internal control over financial reporting was effective as of March 31, 2010.

The effectiveness of our internal controls over financial reporting as of March 31, 2010 has been attested to PricewaterhouseCoopers LLP, an independent registered public accounting firm, as stated in their report set forth under the heading Report of Independent Registered Public Accounting Firm, which is included in Part II, Item 8 of this Form 10-K.

**Table of Contents**

(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, 2010 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

(d) Inherent Limitations of Disclosure Controls and Procedures 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.

**PART III**

**Item 10. *Directors, Executive Officers and Corporate Governance***

The information required by this item is incorporated herein by reference to our Proxy Statement for our annual shareholders meeting (the 2010 Proxy Statement ).

**Item 11. *Executive Compensation***

The information required by this item is incorporated herein by reference to the 2010 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 2010 Proxy Statement.

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

The information required by this item is incorporated herein by reference to the 2010 Proxy Statement.

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

The information required by this item is incorporated herein by reference to the 2010 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 the absence of conditions under which they are required or because the required information is included in the consolidated financial statements or notes thereto.



**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 our Annual 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 our 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 our 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 our 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 our 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 our Annual 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 our 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 our 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 our 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 our Annual 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 our 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 our Quarterly 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 our Quarterly Report on Form 10-Q for the quarter ended December 31, 2000 (File No. 001-14131).)
- 10.5 Lease Agreement, dated as of April 22, 2009 between PDM Unit 850, LLC, and Alkermes, Inc. (Incorporated by reference to Exhibit 10.5 to our Annual Report on Form 10-K for the fiscal year ended March 31, 2009.)
- 10.5(a) First Amendment to Lease Agreement between Alkermes, Inc. and PDM Unit 850, LLC, dated as of June 18, 2009 (Incorporated by reference to Exhibit 10.2 to our Quarterly Report on Form 10-Q for the quarter ended June 30, 2009.)
- 10.6

Edgar Filing: ALKERMES INC - Form 10-K

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 our Annual Report on Form 10-K for the fiscal year ended March 31, 1996 (File No. 000-19267).)\*

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

- 10.7 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 our Annual Report on Form 10-K for the fiscal year ended March 31, 1996 (File No. 000-19267).)\*
- 10.8 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 our Annual Report on Form 10-K for the fiscal year ended March 31, 2002 (File No. 001-14131).)\*\*\*
- 10.8(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 our Quarterly Report on Form 10-Q for the quarter ended December 31, 2004.)\*\*\*\*
- 10.8(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 our Quarterly Report on Form 10-Q for the quarter ended December 31, 2004.)\*\*\*\*
- 10.8(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 our Annual Report on Form 10-K for the fiscal year ended March 31, 2002 (File No. 001-14131).)\*\*\*
- 10.8(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 our Annual Report on Form 10-K for the fiscal year ended March 31, 2002.)\*\*\*
- 10.8(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 our Quarterly Report on Form 10-Q for the quarter ended December 31, 2004.)\*\*\*\*
- 10.8(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 our Quarterly Report on Form 10-Q for the quarter ended December 31, 2004.)\*\*\*\*
- 10.9 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 our Quarterly Report on Form 10-Q for the quarter ended December 31, 2004.)\*\*\*\*
- 10.9(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 our Quarterly Report on Form 10-Q for the quarter ended December 31, 2004.)\*\*\*\*
- 10.10

Edgar Filing: ALKERMES INC - Form 10-K

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 our Annual Report on Form 10-K for the fiscal year ended March 31, 1999 (File No. 001-14131).)\*\*

69

---

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

- 10.11 Employment agreement, dated as of December 12, 2007, by and between Richard F. Pops and Alkermes, Inc. (Incorporated by reference to Exhibit 10.1 to our Quarterly Report on Form 10-Q for the quarter ended December 31, 2007.)+
- 10.11(a) Amendment to Employment Agreement by and between Alkermes, Inc. and Richard F. Pops. (Incorporated by reference to Exhibit 10.5 to our Current Report on Form 8-K filed on October 7, 2008.)+
- 10.11(b) Amendment No. 2 to Employment Agreement by and between Alkermes, Inc. and Richard F. Pops, dated September 10, 2009. (Incorporated by reference to Exhibit 10.2 to our Current Report on Form 8-K filed on September 11, 2009.)+
- 10.12 Employment agreement, dated as of December 12, 2007, by and between David A. Broecker and Alkermes, Inc. (Incorporated by reference to Exhibit 10.2 to our Quarterly Report on Form 10-Q for the quarter ended December 31, 2007.)+
- 10.12(a) Amendment to Employment Agreement by and between Alkermes, Inc. and David A. Broecker. (Incorporated by reference to Exhibit 10.6 to our Current Report on Form 8-K filed on October 7, 2008.)+
- 10.13 Separation Agreement by and between Alkermes, Inc. and David A. Broecker, dated September 10, 2009. (Incorporated by reference to Exhibit 10.1 to our Current Report on Form 8-K filed on September 11, 2009.)+
- 10.14 Form of Employment Agreement, dated as of December 12, 2007, by and between Alkermes, Inc. 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 our Quarterly Report on Form 10-Q for the quarter ended December 31, 2007.)+
- 10.14(a) Form of Amendment to Employment Agreement by and between Alkermes, Inc. and each of each of Kathryn L. Biberstein, Elliot W. Ehrich, M.D., James M. Frates, Michael J. Landine, Gordon G. Pugh. (Incorporated by reference to Exhibit 10.7 to our Current Report on Form 8-K filed on October 7, 2008.)+
- 10.15 Form of Covenant Not to Compete, of various dates, by and between Alkermes, Inc. and each of Kathryn L. Biberstein and James M. Frates. (Incorporated by reference to Exhibit 10.15 to our Annual Report on Form 10-K for the year ended March 31, 2007.)+
- 10.15(a) Form of Covenant Not to Compete, of various dates, by and between Alkermes, Inc. and each of Elliot W. Ehrich, M.D., Michael J. Landine, and Gordon G. Pugh. (Incorporated by reference to Exhibit 10.15(a) to our Annual Report on Form 10-K for the year ended March 31, 2007.)+
- 10.16 Form of Indemnification Agreement by and between Alkermes, Inc. and each of its directors and executive officers (Incorporated by reference to Exhibit 10.1 to our Current Report on Form 8-K filed on March 25, 2010.)+
- 10.17 License and Collaboration Agreement between Alkermes, Inc. and Cephalon, Inc. dated as of June 23, 2005. (Incorporated by reference to Exhibit 10.1 to our Quarterly Report on Form 10-Q for the quarter ended June 30, 2005.)\*\*\*\*\*
- 10.17(a) Supply Agreement between Alkermes, Inc. and Cephalon, Inc. dated as of June 23, 2005. (Incorporated by reference to Exhibit 10.2 to our Quarterly Report on Form 10-Q for the quarter ended June 30, 2005.)\*\*\*\*\*
- 10.17(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 our Annual Report on Form 10-K for the year ended March 31, 2007.)\*\*\*\*\*
- 10.17(c)

Edgar Filing: ALKERMES INC - Form 10-K

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 our Annual Report on Form 10-K for the year ended March 31, 2007.)\*\*\*\*\*

- 10.18 Accelerated Share Repurchase Agreement, dated as of February 7, 2008, between Morgan Stanley & Co. Incorporated and Alkermes, Inc. (Incorporated by reference to Exhibit 10.17 to our Annual Report on Form 10-K for the year ended March 31, 2008.)

70

---

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

- 10.19 Alkermes, Inc. 1998 Equity Incentive Plan as Amended and Approved on November 2, 2006. (Incorporated by reference to Exhibit 10.1 to our Quarterly Report on Form 10-Q for the fiscal quarter ended December 31, 2006.)+
- 10.19(a) Form of Stock Option Certificate pursuant to Alkermes, Inc. 1998 Equity Incentive Plan. (Incorporated by reference to Exhibit 10.37 to our Annual Report on Form 10-K for the fiscal year ended March 31, 2006.)+
- 10.20 Alkermes, Inc. Amended and Restated 1999 Stock Option Plan. (Incorporated by reference to Appendix A to our Definitive Proxy Statement on Form DEF 14/A filed on July 27, 2007.)+
- 10.20(a) Form of Incentive Stock Option Certificate pursuant to the 1999 Stock Option Plan, as amended. (Incorporated by reference to Exhibit 10.35 to our Annual Report on Form 10-K for the fiscal year ended March 31, 2006.)+
- 10.20(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 our Annual Report on Form 10-K for the fiscal year ended March 31, 2006.)+
- 10.21 Alkermes, Inc. 2002 Restricted Stock Award Plan as Amended and Approved on November 2, 2006. (Incorporated by reference to Exhibit 10.3 to our Quarterly Report on Form 10-Q for the fiscal quarter ended December 31, 2006.)+
- 10.21(a) Amendment to Alkermes, Inc. 2002 Restricted Stock Award Plan. (Incorporated by reference to Appendix B to our Definitive Proxy Statement on Form DEF 14/A filed on July 27, 2007.)+
- 10.22 2006 Stock Option Plan for Non-Employee Directors. (Incorporated by reference to Exhibit 10.4 to our Quarterly Report on Form 10-Q for the fiscal quarter ended September 30, 2006.)+
- 10.22(a) Amendment to 2006 Stock Option Plan for Non-Employee Directors. (Incorporated by reference to Appendix C to our Definitive Proxy Statement on Form DEF 14/A filed on July 27, 2007.)+
- 10.23 Alkermes Fiscal 2008 Named-Executive Bonus Plan. (Incorporated by reference to Exhibit 10.1 to our Current Report on Form 8-K filed on April 26, 2007.)+
- 10.24 Alkermes Fiscal Year 2009 Reporting Officer Performance Pay Plan. (Incorporated by reference to Exhibit 10.1 to our Current Report on Form 8-K filed on May 16, 2008.)+
- 10.25 Alkermes Fiscal Year 2010 Reporting Officer Performance Pay Plan. (Incorporated by reference to Exhibit 10.1 to our Current Report on Form 8-K filed on July 15, 2009.)+
- 10.26 Alkermes Fiscal 2011 Reporting Officer Performance Pay Plan. (Incorporated by reference to Exhibit 10.2 to our Current Report on Form 8-K filed on March 25, 2010.)+
- 10.27 Alkermes, Inc., 2008 Stock Option and Incentive Plan (Incorporated by reference to Exhibit 10.1 to our Current Report on Form 8-K filed on October 7, 2008.)+
- 10.27(a) Alkermes, Inc. 2008 Stock Option and Incentive Plan, Stock Option Award Certificate (Incentive Stock Option) , as amended #
- 10.27(b) Alkermes, Inc. 2008 Stock Option and Incentive Plan, Stock Option Award Certificate (Non-Qualified Option) , as amended #
- 10.27(c) Alkermes, Inc. 2008 Stock Option and Incentive Plan, Stock Option Award Certificate (Non-Employee Director) (Incorporated by reference to Exhibit 10.4 to our Current Report on Form 8-K filed on October 7, 2008.)+
- 10.27(d) Alkermes, Inc. 2008 Stock Option and Incentive Plan, Restricted Stock Unit Award Certificate (Time Vesting Only). (Incorporated by reference to Exhibit 10.1 to our Current Report on Form 8-K filed on May 22, 2009.)+
- 10.27(e) Alkermes, Inc. 2008 Stock Option and Incentive Plan, Restricted Stock Unit Award Certificate (Performance Vesting Only). (Incorporated by reference to Exhibit 10.2 to our Current Report on

Edgar Filing: ALKERMES INC - Form 10-K

Form 8-K filed on May 22, 2009.)+

- 10.28 Development and License Agreement, dated as of May 15, 2000, by and between Alkermes Controlled Therapeutics Inc. II and Amylin Pharmaceuticals, Inc., as amended on October 24, 2005 and July 17, 2006 (assigned, as amended, to Alkermes, Inc. in July 2006). #\*\*\*\*\*
- 21.1 Subsidiaries of Alkermes, Inc..#



**Table of Contents**

**Exhibit  
No.**

- 23.1 Consent of Independent Registered Public Accounting Firm PricewaterhouseCoopers 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.

\*\*\*\*\* Confidential treatment status has been requested as to certain portions thereof, which portions are omitted and filed separately with the Securities and Exchange 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/ Richard F. Pops

Richard F. Pops  
Chairman, President and Chief Executive Officer

May 21, 2010

**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 Richard F. Pops 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/ Richard F. Pops Richard F. Pops	Chairman, President and Chief Executive Officer (Principal Executive Officer)	May 21, 2010
/s/ James M. Frates James M. Frates	Senior Vice President, Chief Financial Officer and Treasurer (Principal Financial and Accounting Officer)	May 21, 2010
/s/ David W. Anstice David W. Anstice	Director	May 21, 2010
/s/ Floyd E. Bloom Floyd E. Bloom	Director	May 21, 2010
/s/ Robert A. Breyer Robert A. Breyer	Director	May 21, 2010

/s/ Gerri Henwood	Director	May 21, 2010
Gerri Henwood		
/s/ Paul J. Mitchell	Director	May 21, 2010
Paul J. Mitchell		

**Table of Contents**

<b>Signature</b>	<b>Title</b>	<b>Date</b>
/s/ Alexander Rich Alexander Rich	Director	May 21, 2010
/s/ Mark B. Skaletsky Mark B. Skaletsky	Director	May 21, 2010
/s/ Michael A. Wall Michael A. Wall	Director and Chairman Emeritus	May 21, 2010

**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 sheets and the related consolidated statements of operations and comprehensive (loss) income, shareholders' equity and cash flows present fairly, in all material respects, the financial position of Alkermes, Inc. and its subsidiaries at March 31, 2010 and 2009, and the results of their operations and their cash flows for each of the three years in the period ended March 31, 2010 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, 2010, 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 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 audits 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 audits 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 audits also included performing such other procedures as we considered necessary in the circumstances. We believe that our audits provide 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/ PricewaterhouseCooperLLP

Boston, Massachusetts  
May 21, 2010



**Table of Contents****ALKERMES, INC. AND SUBSIDIARIES****CONSOLIDATED BALANCE SHEETS****March 31, 2010 and 2009**

	<b>2010</b>	<b>2009</b>
	<b>(In thousands, except share and per share amounts)</b>	
<b>ASSETS</b>		
<b>CURRENT ASSETS:</b>		
Cash and cash equivalents	\$ 79,324	\$ 86,893
Investments short-term	202,053	236,768
Receivables	25,316	24,588
Inventory	20,653	20,297
Prepaid expenses and other current assets	10,936	7,500
Total current assets	338,282	376,046
PROPERTY, PLANT AND EQUIPMENT, NET	96,905	106,461
INVESTMENTS LONG-TERM	68,816	80,821
OTHER ASSETS	11,597	3,158
TOTAL ASSETS	\$ 515,600	\$ 566,486
<b>LIABILITIES AND SHAREHOLDERS EQUITY</b>		
<b>CURRENT LIABILITIES:</b>		
Accounts payable and accrued expenses	\$ 37,881	\$ 36,483
Deferred revenue current	2,220	6,840
Non-recourse RISPERDAL CONSTA secured 7% notes current	51,043	25,667
Total current liabilities	91,144	68,990
NON-RECOURSE RISPERDAL CONSTA SECURED 7% NOTES LONG-TERM		50,221
DEFERRED REVENUE LONG-TERM	5,105	5,238
OTHER LONG-TERM LIABILITIES	6,735	7,149
TOTAL LIABILITIES	102,984	131,598
<b>COMMITMENTS AND CONTINGENCIES (Note 15)</b>		
<b>SHAREHOLDERS EQUITY:</b>		
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; 104,815,328 and 104,044,663 shares issued; 94,870,063 and 94,536,212 shares	1,047	1,040

Edgar Filing: ALKERMES INC - Form 10-K

outstanding at March 31, 2010 and 2009, respectively

Non-voting common stock, par value, \$0.01 per share; 450,000 shares authorized;  
382,632 shares issued and outstanding at March 31, 2010 and 2009

	4	4
Treasury stock, at cost (9,945,265 and 9,508,451 shares at March 31, 2010 and 2009, respectively)	(129,681)	(126,025)
Additional paid-in capital	910,326	892,415
Accumulated other comprehensive loss	(3,392)	(6,484)
Accumulated deficit	(365,688)	(326,062)
<b>TOTAL SHAREHOLDERS EQUITY</b>	<b>412,616</b>	<b>434,888</b>
<b>TOTAL LIABILITIES AND SHAREHOLDERS EQUITY</b>	<b>\$ 515,600</b>	<b>\$ 566,486</b>

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



**Table of Contents****ALKERMES, INC. AND SUBSIDIARIES****CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE (LOSS) INCOME  
Years Ended March 31, 2010, 2009 and 2008**

	<b>2010</b>	<b>2009</b>	<b>2008</b>
	<b>(In thousands, except per share amounts)</b>		
<b>REVENUES:</b>			
Manufacturing revenues	\$ 112,938	\$ 116,844	\$ 101,700
Royalty revenues	36,979	33,247	29,457
Product sales, net	20,245	4,467	
Research and development revenue under collaborative arrangements	3,117	42,087	89,510
Net collaborative profit	5,002	130,194	20,050
<b>Total revenues</b>	<b>178,281</b>	<b>326,839</b>	<b>240,717</b>
<b>EXPENSES:</b>			
Cost of goods manufactured and sold	49,438	43,396	40,677
Research and development	95,363	89,478	125,268
Selling, general and administrative	76,514	59,008	59,508
Impairment of long-lived assets			11,630
Restructuring			6,423
<b>Total expenses</b>	<b>221,315</b>	<b>191,882</b>	<b>243,506</b>
<b>OPERATING (LOSS) INCOME</b>	<b>(43,034)</b>	<b>134,957</b>	<b>(2,789)</b>
<b>OTHER (EXPENSE) INCOME:</b>			
Interest income	4,667	11,400	17,834
Interest expense	(5,974)	(13,756)	(16,370)
Gain on sale of investment in Reliant Pharmaceuticals, Inc.			174,631
Other expense, net	(360)	(1,589)	(476)
<b>Total other (expense) income, net</b>	<b>(1,667)</b>	<b>(3,945)</b>	<b>175,619</b>
<b>(LOSS) INCOME BEFORE INCOME TAXES</b>	<b>(44,701)</b>	<b>131,012</b>	<b>172,830</b>
<b>(BENEFIT) PROVISION FOR INCOME TAXES</b>	<b>(5,075)</b>	<b>507</b>	<b>5,851</b>
<b>NET (LOSS) INCOME</b>	<b>\$ (39,626)</b>	<b>\$ 130,505</b>	<b>\$ 166,979</b>
<b>EARNINGS PER COMMON SHARE:</b>			
<b>BASIC</b>	<b>\$ (0.42)</b>	<b>\$ 1.37</b>	<b>\$ 1.66</b>
<b>DILUTED</b>	<b>\$ (0.42)</b>	<b>\$ 1.36</b>	<b>\$ 1.62</b>

WEIGHTED AVERAGE NUMBER OF COMMON  
SHARES OUTSTANDING:

BASIC	94,839	95,161	100,742
DILUTED	94,839	96,252	102,923
COMPREHENSIVE (LOSS) INCOME:			
Net (loss) income	\$ (39,626)	\$ 130,505	\$ 166,979
Unrealized losses on marketable securities:			
Holding gains (losses), net of tax	2,998	(6,153)	(3,849)
Less: Reclassification adjustment for losses included in net (loss) income	94	1,195	1,570
Unrealized gains (losses) on marketable securities	3,092	(4,958)	(2,279)
COMPREHENSIVE (LOSS) INCOME	\$ (36,534)	\$ 125,547	\$ 164,700

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

Table of Contents

## ALKERMES, INC. AND SUBSIDIARIES

**CONSOLIDATED STATEMENTS OF SHAREHOLDERS' EQUITY**  
**Years Ended March 31, 2010, 2009 and 2008**

	Common Stock		Non-voting Common Stock		Additional Paid-In Capital	Currency Translation Adjustments	Accumulated Other Comprehensive (Loss) Income Foreign Unrealized Gain/(Loss) on Marketable Securities	Accumulated Deficit	Treasury Stock	Stock Amount
	Shares	Amount	Shares	Amount				Shares	Amount	
(In thousands, except share data)										
March 31, 2007	101,550,673	\$ 1,015	382,632	\$ 4	\$ 837,727	\$ (142)	\$ 895	\$ (623,546)	(823,677)	\$ (12,000)
Issuance of common stock	1,426,675	15			11,144					
Issuance of preferred stock										
Repurchase of common stock					1,480				(85,769)	(1,480)
Repurchase of non-voting common stock					19,222				(6,968,736)	(19,222)
Repurchase of common stock from conversion					122					(122)
Repurchase of common stock							(2,279)			(2,279)
								166,979		
March 31, 2008	102,977,348	\$ 1,030	382,632	\$ 4	\$ 869,695	\$ (142)	\$ (1,384)	\$ (456,567)	(7,878,182)	\$ (107,000)
Issuance of common stock	1,067,315	10			7,049					
Issuance of preferred stock										
Repurchase of common stock					707				(61,067)	(707)

non									(1,569,202)	(17
t cost										
nsation										
om										
sation										
s									(4,958)	
									130,505	
h 31,										
	104,044,663	\$ 1,040	382,632	\$ 4	\$ 892,415	\$ (142)	\$ (6,342)	\$ (326,062)	(9,508,451)	\$ (126
a stock										
ck										
	770,665	7			2,586					
s stock										
tstock										
olding										
o stock										
									972	
non									(108,410)	(
t cost									(328,404)	(2
nsation										
om										
sation										
s, net										
									3,092	
									(39,626)	
h 31,										
	104,815,328	\$ 1,047	382,632	\$ 4	\$ 910,326	\$ (142)	\$ (3,250)	\$ (365,688)	(9,945,265)	\$ (129

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

**Table of Contents****ALKERMES, INC. AND SUBSIDIARIES****CONSOLIDATED STATEMENTS OF CASH FLOWS**  
**Years Ended March 31, 2010, 2009 and 2008**

	<b>2010</b>	<b>2009</b>	<b>2008</b>
	<b>(In thousands)</b>		
<b>CASH FLOWS FROM OPERATING ACTIVITIES:</b>			
Net (loss) income	\$ (39,626)	\$ 130,505	\$ 166,979
Adjustments to reconcile net income to cash flows from operating activities:			
Share-based compensation expense	13,921	14,810	19,445
Depreciation	25,026	10,265	12,138
Impairment of long-lived assets			11,630
Gain on sale of investment in Reliant Pharmaceuticals, Inc.			(174,631)
Realized losses on investments	94	1,195	1,570
Loss on purchase of non-recourse RISPERDAL CONSTA secured 7% Notes		2,512	
Other non-cash charges	3,739	4,283	3,732
Changes in assets and liabilities:			
Receivables	(728)	13,710	15,041
Inventory, prepaid expenses and other assets	(4,037)	(5,140)	(1,450)
Accounts payable and accrued expenses	(2,064)	2,014	(8,033)
Unearned milestone revenue		(117,657)	(11,093)
Deferred revenue	(4,753)	(14,525)	6,961
Other long-term liabilities	(1,638)	(1,366)	135
Payment or purchase of non-recourse RISPERDAL CONSTA secured 7% notes attributable to original issue discount	(2,181)	(6,016)	
Cash flows (used in) provided by operating activities	(12,247)	34,590	42,424
<b>CASH FLOWS FROM INVESTING ACTIVITIES:</b>			
Additions to property, plant and equipment	(15,787)	(5,502)	(21,890)
Proceeds from the sale of equipment	248	7,717	
Investment in Acceleron Pharmaceuticals, Inc.	(8,000)		
Proceeds from the sale of investment in Reliant Pharmaceuticals, Inc.		7,766	166,865
Purchases of investments	(465,387)	(609,741)	(639,582)
Sales and maturities of investments	516,935	645,120	556,572
Cash flows provided by investing activities	28,009	45,360	61,965
<b>CASH FLOWS FROM FINANCING ACTIVITIES:</b>			
Proceeds from the issuance of common stock for share-based compensation arrangements	2,593	7,059	11,159
Excess tax benefit from share-based compensation	246	80	122
Payment of debt and capital leases		(47)	(1,579)

Edgar Filing: ALKERMES INC - Form 10-K

Payment or purchase of non-recourse RISPERDAL CONSTA secured 7% notes	(23,486)	(83,394)	
Purchase of common stock for treasury	(2,684)	(17,996)	(93,350)
Cash flows used-in financing activities	(23,331)	(94,298)	(83,648)
NET (DECREASE) INCREASE IN CASH AND CASH EQUIVALENTS	(7,569)	(14,348)	20,741
CASH AND CASH EQUIVALENTS Beginning of period	86,893	101,241	80,500
CASH AND CASH EQUIVALENTS End of period	\$ 79,324	\$ 86,893	\$ 101,241
SUPPLEMENTAL CASH FLOW DISCLOSURE:			
Cash paid for interest	\$ 4,918	\$ 15,342	\$ 12,002
Cash paid for taxes	\$ 114	\$ 860	\$ 5,300
Non-cash investing and financing activities:			
Purchased capital expenditures included in accounts payable and accrued expenses	\$ 2,798	\$ 1,774	\$ 3,074
Sales of property, plant and equipment included in receivables	\$	\$	\$ 7,717
Net share exercise of warrants into common stock of the issuer	\$	\$	\$ 2,994
Funds held in escrow for the sale of investment in Reliant Pharmaceuticals, Inc.	\$	\$	\$ 7,766

The accompanying notes are an integral part of these 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 our subsidiaries, Alkermes or the Company) is a fully integrated biotechnology company committed to developing innovative medicines to improve patients' lives. The Company developed, manufactures and commercializes VIVITROL® (naltrexone for extended-release injectable suspension) for alcohol dependence and manufactures RISPERDAL® CONSTA® [(risperidone) long-acting injection] for schizophrenia and bipolar I disorder. The Company's pipeline includes extended-release injectable and oral products for the treatment of prevalent, chronic diseases, such as central nervous system (CNS) disorders, reward disorders, addiction, diabetes and autoimmune disorders. The Company has a research facility in Massachusetts and a commercial manufacturing facility in Ohio. In January 2010, the Company relocated its corporate headquarters from Cambridge, Massachusetts, to Waltham, Massachusetts.

**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 non-recourse 7% Notes), and the assets of Alkermes are not available to satisfy obligations of Royalty Sub. 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 (U.S.) (GAAP) necessarily requires management to make estimates and assumptions that affect the following: reported amounts of assets and liabilities; disclosure of contingent assets and liabilities at the date of the consolidated financial statements; and 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 considers only those investments which are highly liquid, readily convertible into cash and that mature within three months from the date of purchase to be cash equivalents.

***Investments***

The Company has investments in various types of securities including U.S. government and agency obligations, debt securities issued by foreign agencies and backed by foreign governments, corporate debt securities, student loan backed auction rate securities and asset backed debt securities. The Company also has strategic equity investments which include the common stock of a public company with which the Company has a collaborative arrangement. The Company generally holds its interest-bearing investments with major financial institutions and in accordance with documented investment policies, the Company limits the amount of credit exposure to any one financial institution or

corporate issuer. At March 31, 2010, substantially all these investments are classified as available-for-sale and are recorded at fair value. Holding gains and losses on these investments are considered unrealized and are reported within Accumulated other comprehensive (loss) income, a component of shareholders equity. Certain of the Company s money market funds and



**Table of Contents**

**ALKERMES, INC. AND SUBSIDIARIES**

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

held-to-maturity investments are restricted investments held as collateral under certain letters of credit related to certain of the Company's service provider agreements and lease agreements, respectively, and are included in Investments short-term and Investments long-term, respectively, in the consolidated balance sheets.

In April 2009, the Company adopted new accounting guidance issued by the Emerging Issues Task Force (EITF) of the Financial Accounting Standards Board (FASB), which provides guidance for the recognition, measurement and presentation of other-than-temporary impairments. This standard amended the other-than-temporary impairment model for debt securities and requires additional disclosures regarding the calculation of credit losses and the factors considered in reaching a conclusion that an investment is other-than-temporarily impaired. The impairment model for equity securities was not affected. Other-than-temporary impairments must be recognized through earnings if an investor has the intent to sell the debt security or if it is more likely than not that the investor will be required to sell the debt security before recovery of its amortized cost basis. However, even if an investor does not expect to sell a debt security, expected cash flows to be received must be evaluated to determine if a credit loss has occurred. In the event of a credit loss, only the amount associated with the credit loss is recognized in income. The amount of losses relating to other factors, including those resulting from changes in interest rates, are recorded in accumulated other comprehensive (loss) income. The adoption of this guidance did not have a material impact on our financial position or results of operations.

The Company conducts periodic reviews to identify and evaluate each investment that has an unrealized loss, in accordance with the meaning of other-than-temporary impairment and its application to certain investments, as required by GAAP. An unrealized loss exists when the current fair value of an individual security is less than its amortized cost basis. Unrealized losses on available-for-sale securities that are determined to be temporary, and not related to credit loss, are recorded in accumulated other comprehensive (loss) income.

For available-for-sale debt securities with unrealized losses, the Company performs an analysis to assess whether it intends to sell or whether it would more likely than not be required to sell the security before the expected recovery of the amortized cost basis. Where the Company intends to sell a security, or may be required to do so, the security's decline in fair value is deemed to be other-than-temporary and the full amount of the unrealized loss is recorded within earnings as an impairment loss. Regardless of the Company's intent to sell a security, the Company performs additional analysis on all securities with unrealized losses to evaluate losses associated with the creditworthiness of the security. Credit losses are identified where the Company does not expect to receive cash flows sufficient to recover the amortized cost basis of a security.

For equity securities, when assessing whether a decline in fair value below the cost basis is other-than-temporary, the Company considers the fair market value of the security, the duration of the security's decline, and the financial condition of the issuer. The Company then considers its intent and ability to hold the equity security for a period of time sufficient to recover its carrying value. Where the Company has determined that it lacks the intent and ability to hold an equity security to its expected recovery, the security's decline in fair value is deemed to be other-than-temporary and is recorded within operations as an impairment loss.

***Fair Value of Financial Instruments***

The Company's financial assets and liabilities are recorded at fair value and are classified as Level 1, 2 or 3 within the fair value hierarchy, as described in the accounting standards for fair value measurement. The



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

Company's financial assets and liabilities consist of cash equivalents and investments and are classified within the fair value hierarchy as follows:

*Level 1* these valuations are based on a market approach using quoted prices in active markets for identical assets. Valuations of these products do not require a significant degree of judgment. Assets utilizing Level 1 inputs include investments in money market funds, U.S. government and agency debt securities, debt securities issued and backed by foreign governments, and strategic equity investments;

*Level 2* these valuations are based on a market approach using quoted prices obtained from brokers or dealers for similar securities or for securities for which the Company has limited visibility into their trading volumes. Valuations of these financial instruments do not require a significant degree of judgment. Assets utilizing Level 2 inputs include investments in corporate debt securities that are trading in the credit markets;

*Level 3* these valuations are based on an income approach using certain inputs that are unobservable and are significant to the overall fair value measurement. Valuations of these products require a significant degree of judgment. Assets utilizing Level 3 inputs primarily consist of investments in certain corporate debt securities, auction rate securities and asset backed securities that are not trading in the credit markets.

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 following table sets forth the carrying values and estimated fair values of the Company's non-recourse 7% Notes, which are not re-measured and reported at fair value at March 31:

	<b>2010</b>		<b>2009</b>	
	<b>Carrying Value</b>	<b>Fair Value</b>	<b>Carrying Value</b>	<b>Fair Value</b>
	<b>(In thousands)</b>			
Non-recourse 7% Notes	\$ 51,043	\$ 48,732	\$ 75,888	\$ 74,690

The estimated fair value of the non-recourse 7% Notes was based on a discounted cash flow model.

On April 1, 2009, the Company adopted new accounting guidance issued by the FASB for fair value measurements of all nonfinancial assets and nonfinancial liabilities not recognized or disclosed at fair value in the financial statements on a recurring basis. The adoption of this standard did not impact the Company's financial position or results of operations; however, this standard may impact the Company in subsequent periods and require additional disclosures. Also, on April 1, 2009, the Company adopted new accounting guidance issued by the FASB in determining whether a market is active or inactive and whether third party transactions with similar assets and liabilities are distressed in determining the fair value of its assets and liabilities measured at fair value on a recurring basis. The adoption of this standard did not impact the Company's financial position or results of operations.

***Inventory***

Inventory is stated at the lower of cost or market value. Cost is determined using the first-in, first-out method. Included in inventory are raw materials used in production of pre-clinical and clinical products, which have alternative future use and are charged to research and development ( R&D ) expense when consumed. VIVITROL inventory that is in the sales distribution channel is classified as consigned-out inventory.

***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. Expenditures for repairs and maintenance are charged to expense as incurred and major renewals and improvements are

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

capitalized. 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 - 10 years)

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

The Company reviews long-lived assets to be held and used, including property, plant and equipment, 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 them.

***Asset Retirement Obligations***

The Company 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, 2010 and 2009, was \$1.5 million and \$1.4 million, respectively, and is included within "Other Long-Term Liabilities" in the accompanying 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, 2010 and 2009:

	<b>Carrying Amount (In thousands)</b>
Balance, April 1, 2008	\$ 1,267
Accretion expense	130
Balance, March 31, 2009	1,397
Accretion expense	140
Balance, March 31, 2010	\$ 1,537

***Revenue Recognition***

*Manufacturing revenues* The Company recognizes manufacturing revenues from the sale of RISPERDAL CONSTA to Janssen Pharmaceutica, Inc., a division of Ortho-McNeil-Janssen Pharmaceuticals, Inc. and Janssen Pharmaceutica International, a division of Cilag International (together, Janssen ), from the sale of polymer to Amylin Pharmaceuticals, Inc., ( Amylin ) for use in BYDUREON, from the sale of VIVITROL to Cilag GmbH International ( Cilag ), an affiliate of Janssen, for sale in Russia and other countries in the Commonwealth of Independent States ( CIS ), and from the sale of VIVITROL to Cephalon, Inc. ( Cephalon ) prior to the termination of the collaboration on December 1, 2008.

Manufacturing revenues are recognized when persuasive evidence of an arrangement exists, delivery has occurred and title to the product and associated risk of loss has passed to the customer, the sales price is fixed

**Table of Contents**

**ALKERMES, INC. AND SUBSIDIARIES**

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

or determinable, and collectibility is reasonably assured. Manufacturing revenues recognized by the Company for RISPERDAL CONSTA are based on information supplied to the Company by Janssen and require estimates to be made. Differences between the actual manufacturing revenues and estimated manufacturing revenues are reconciled and adjusted for in the period in which they become known. The Company records manufacturing revenues under its agreements with Amylin and Cilag at an agreed upon price upon shipment of the product.

Prior to December 1, 2008, the Company manufactured and sold VIVITROL exclusively to Cephalon for sale of the product in the U.S. under certain manufacturing and supply arrangements. The Company recorded manufacturing revenues upon shipment of the product to Cephalon at cost plus a manufacturing profit of 10%.

*Royalty revenue* The Company receives royalties related to the sale of RISPERDAL CONSTA under certain license arrangements with Janssen. The Company also receives royalties related to the sale of VIVITROL in Russia under a license arrangement with Cilag. Royalty revenues are earned in the period the products are sold by Janssen and Cilag.

*Product sales, net* The Company's product sales consist of sales of VIVITROL in the U.S. to wholesalers, specialty distributors and specialty pharmacies. The Company started to record product sales, net, upon the termination of the VIVITROL collaboration with Cephalon in December 2008. Product sales are recognized from the sale of VIVITROL when persuasive evidence of an arrangement exists, title to the product and associated risk of loss has passed to the customer, which is considered to occur when the product has been received by the customer, the sales price is fixed or determinable, and collectibility is reasonably assured. The Company defers the recognition of product sales on shipments of VIVITROL to its customers until the product has left the distribution channel, as it does not yet have sufficient sales history to reasonably estimate returns related to these shipments. The Company estimates product shipments out of the distribution channel through data provided by external sources, including information on inventory levels provided by its customers in the distribution channel, as well as prescription information. In order to match the cost of goods sold related to products shipped to customers with the associated revenue, the Company defers the recognition of the cost of goods sold to the period in which the associated revenue is recognized.

The Company records estimated sales discounts and allowances, including chargebacks, wholesaler fee-for-service discounts, rebates payable under governmental and managed care programs, payment term discounts and other discounts as a reduction of product sales at the time VIVITROL is shipped into the distribution channel. These sales discounts and allowances are adjusted for inventory in the distribution channel. Reserves established for these discounts and allowances are classified as reductions of accounts receivable, if the amount is payable to a customer, or a liability, if the amount is payable to a party other than a customer. The Company's calculations related to its sales discounts and allowance reserves require estimates to be made. The Company updates its estimates and assumptions each period and records any necessary adjustments.

*Research and development revenue under collaborative arrangements* R&D revenue under collaborative arrangements consists of nonrefundable R&D funding under collaborative arrangements with various collaborative partners. R&D 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 direct external costs, if any.

The Company recognizes R&D 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

F-10

---



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

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, in full, when there are 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.

*Net collaborative profit* Net collaborative profit relates to the Company's revenue recognition in connection with the License and Collaboration Agreement and Supply Agreement (together, the Agreements) entered into with Cephalon in June 2005, later amended in October 2006 (the Amendments), for sale of VIVITROL in the U.S. For purposes of revenue recognition, the deliverables under these Agreements were separated into three units of accounting: (i) net losses on the products; (ii) manufacturing of the products; and (iii) the product license.

As discussed in Note 13, Collaborative Arrangements, the Company and Cephalon agreed to end the VIVITROL collaboration, effective December 1, 2008 (the Termination Date). In connection with the termination of the collaboration, the Company recognized \$120.7 million of net collaborative profit, consisting of \$113.9 million of unearned milestone revenue and \$6.8 million of deferred revenue remaining at the Termination Date. The Company received \$11.0 million from Cephalon as payment to fund its share of estimated VIVITROL product losses during the one-year period following the Termination Date, and the Company recognized this payment as net collaborative profit through the application of a proportional performance model based on VIVITROL product losses.

***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	2010		2009		2008	
	Receivables	Revenue	Receivables	Revenue	Receivables	Revenue
Janssen	86%	83%	84%	46%	33%	52%
Amylin	1%	2%	1%	3%	31%	14%
Cephalon		3%	15%	41%	5%	11%
Eli Lilly and Company				8%	30%	23%

The Company generally holds its interest-bearing investments with major financial institutions and in accordance with documented investment policies, the Company limits the amount of credit exposure to any one financial institution or corporate issuer. The Company's investment objectives are, first, to assure liquidity and conservation of capital and, second, to obtain investment income.

***Shipping and Handling Costs***

Shipping and handling costs incurred for product shipments are included in cost of goods manufactured and sold in the accompanying consolidated statements of operations and comprehensive (loss) income.

***Research and Development Expenses***

The Company's R&D expenses include internally and externally generated costs incurred in conjunction with the development of the Company's technologies, proprietary product candidates, collaborators' product

**Table of Contents**

**ALKERMES, INC. AND SUBSIDIARIES**

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

candidates and in-licensing arrangements. Internally generated costs include employee compensation, laboratory supplies, temporary help costs, external research costs, consulting costs, occupancy costs, depreciation expense and other allocable costs directly related to the Company's R&D activities. External research costs relate to toxicology and pharmacokinetic studies and clinical trials that are performed for the Company under contract by external companies, hospitals or medical centers as well as upfront fees and milestones paid to collaborators.

A significant portion of the Company's internally generated R&D 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. Externally generated R&D expenses are tracked by project and certain of these expenses are reimbursed to the Company by its partners. The Company accounts for its R&D 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 grant awards which include stock options and restricted stock units (RSU), which vest with the passage of time and to a limited extent, vest based on the achievement of certain performance or market criteria. Certain of the Company's employees are retirement eligible under the terms of the Company's stock option plans (the Plans) and stock option 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.

***Stock Options***

Stock option grants to employees generally expire ten years from the grant date and generally vest one-fourth per year over four years from the anniversary of the date of grant, provided the employee remains continuously employed with the Company, except as otherwise provided in the plan. Stock option grants to directors are for ten-year terms and generally vest over a 6-month period provided the director continues to serve on the Company's board of directors through the vesting date, except as otherwise provided in the plan. The estimated fair value of options is recognized over the requisite service period, which is generally the vesting period. Share-based compensation expense is based on awards ultimately expected to vest. Forfeitures are estimated based on historical experience at the time of grant and revised in subsequent periods if actual forfeitures differ from those estimates.

The fair value of stock option grants is based on estimates as of the date of grant using a Black-Scholes option valuation model. 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 are 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 are 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 is 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 is based on the U.S. treasury yield curve in effect at the time of grants. The dividend yield on the Company's common stock is estimated to be zero as the Company has not paid and does not expect to pay dividends. The exercise price of options granted prior to October 7, 2008 equals the average of the high and low of the Company's common stock traded on the NASDAQ Select Stock Global Market on the date of grant. Beginning with the adoption of the

Alkermes, Inc. 2008 Stock Option and Incentive Plan (the 2008 Plan ), the exercise price of option grants made after

F-12

---

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

October 7, 2008 is equal to the closing price of the Company's common stock traded on the NASDAQ Select Stock Global Market on the date of grant.

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>2010</b>	<b>2009</b>	<b>2008</b>
Expected option term	5 - 7 years	5 - 7 years	4 - 7 years
Expected stock volatility	38% - 49%	36% - 46%	38% - 50%
Risk-free interest rate	1.83% - 3.05%	1.66% - 3.52%	2.78% - 5.07%
Expected annual dividend yield			

*Time-Vested Restricted Stock Units*

Time-vested RSU's awarded to employees generally vest one-fourth per year over four years from the anniversary of the date of grant, provided the employee remains continuously employed with the Company. Shares of the Company's common stock are delivered to the employee upon vesting, subject to payment of applicable withholding taxes. The fair value of time-vested RSU's is based on the market value of the Company's stock on the date of grant. Compensation expense, including the effect of forfeitures, is recognized over the applicable service period.

*Performance-Based Restricted Stock Units*

The Company has RSU's that vest upon the achievement of certain performance criteria and RSU's that vest upon the achievement of a market condition. Shares of the Company's common stock are delivered to the employee upon vesting, subject to payment of applicable withholding taxes. The estimated fair value of the RSU's that vest upon the achievement of certain performance criteria is based on the market value of the Company's stock on the date of grant. The estimated fair value of the restricted stock units that vest upon the achievement of a market condition was determined through the use of a Monte Carlo simulation model, which utilizes input variables that determine the probability of satisfying the market condition stipulated in the award and calculates the fair market value for the performance award. The Monte Carlo simulation model used the following assumptions:

<b>Grant Date</b>	<b>Weighted-Average Expected Volatility</b>	<b>Expected Dividend Yield</b>	<b>Risk-Free Interest Rate</b>
May 27, 2008	42.7%		2.5%

Compensation expense for RSU's that vest upon the achievement of performance criteria is recognized from the moment the Company determines the performance criteria will be met to the date the Company deems the event is likely to occur. Cumulative adjustments are recorded quarterly to reflect subsequent changes in the estimated outcome of performance-related conditions until the date results are determined. Compensation expense for RSU's that vest

upon the achievement of a market condition is recognized over a derived service period as determined by the Monte Carlo simulation model. The vesting of these awards is subject to the respective employees' continued employment.

***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 the 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.

**Table of Contents**

**ALKERMES, INC. AND SUBSIDIARIES**

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

The Company accounts for uncertain tax positions using a more-likely-than-not threshold for recognizing and resolving uncertain tax positions. The evaluation of uncertain tax positions is based on factors including, but not limited to, changes in tax law, the measurement of tax positions taken or expected to be taken in tax returns, the effective settlement of matters subject to audit, new audit activity and changes in facts or circumstances related to a tax position. The Company evaluates this tax position on a quarterly basis. The Company also accrues for potential interest and penalties, related to unrecognized tax benefits in income tax expense.

***Comprehensive (Loss) Income***

Comprehensive income consists of net (loss) income and other comprehensive (loss) income. Other comprehensive (loss) income includes changes in equity that are excluded from net (loss) income, such as unrealized holding gains and losses on available-for-sale marketable securities.

***Earnings per Share***

Basic earnings per share is calculated based upon net (loss) 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 and restricted stock units.

***Segment Information***

The Company operates as one segment, which is the business of developing, manufacturing and commercializing innovative medicines for the treatment of prevalent, chronic diseases. The Company's chief decision maker, the Chairman, President and Chief Executive Officer, reviews the Company's operating results on an aggregate basis and manages the Company's operations as a single operating unit.

***Employee Benefit Plans***

The Company maintains a 401(k) retirement savings plan (the 401(k) Plan), which 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 50% of the first 6% of employee pay, and employee and Company contributions are fully vested when made. During the years ended March 31, 2010, 2009 and 2008, the Company contributed approximately \$1.8 million, \$1.7 million and \$1.6 million, respectively, to match employee deferrals under the 401(k) Plan.

***New Accounting Pronouncements***

In June 2009, the FASB issued accounting guidance regarding the accounting for transfers of financial assets that will improve the relevance, representational faithfulness and comparability of the information that a reporting entity provides in its financial statements about a transfer of financial assets, the effects of such a transfer on its financial position, financial performance and cash flows, and provide information as to a transferor's continuing involvement, if any, in transferred financial assets. The guidance is effective for the Company's fiscal year beginning April 1, 2010, and the Company does not expect the adoption of this standard to have a significant impact on its financial position or results of operations.

In June 2009, the FASB issued an update to the accounting requirements for the consolidation of variable interest entities ( VIE s ). This update requires a qualitative approach to identifying a controlling financial interest in a VIE, and requires ongoing assessment of whether an entity is a VIE and whether an interest in a VIE makes the holder the primary beneficiary of the VIE. This guidance is effective for the Company s fiscal

F-14

---



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

year beginning April 1, 2010 and the Company does not expect the adoption of this standard to have a significant impact on its financial position or results of operations.

In September 2009, the EITF issued accounting guidance related to revenue recognition that amends the previous guidance on arrangements with multiple deliverables. The new guidance provides accounting principles and application guidance on whether multiple deliverables exist, how the arrangement should be separated, and the consideration allocated. The new guidance eliminates the requirement to establish the fair value of undelivered products and services and instead provides for separate revenue recognition based upon management's estimate of the selling price for an undelivered item when there is no other means to determine the fair value of that undelivered item. Accounting guidance previously required that the fair value of the undelivered item be the price of the item either sold in a separate transaction between unrelated third parties or the price charged for each item when the item is sold separately by the vendor. This was difficult to determine when the product was not individually sold because of its unique features. Under the previous guidance, if the fair value of all of the elements in the arrangement was not determinable, then revenue was deferred until all of the items were delivered or fair value was determined. This guidance is effective prospectively for revenue arrangements entered into or materially modified the Company's fiscal year beginning April 1, 2011 and the Company is currently evaluating the potential impact of this standard on its consolidated financial statements.

**3. EARNINGS PER SHARE**

Basic and diluted earnings per share is as follows:

	<b>Year Ended March 31,</b>		
	<b>2010</b>	<b>2009</b>	<b>2008</b>
	<b>(In thousands)</b>		
Numerator:			
Net (loss) income	\$ (39,626)	\$ 130,505	\$ 166,979
Denominator:			
Weighted average number of common shares outstanding	94,839	95,161	100,742
Effect of dilutive securities:			
Stock options		884	2,101
Restricted stock units		207	80
Dilutive common share equivalents		1,091	2,181
Shares used in calculating diluted earnings per share	94,839	96,252	102,923

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

	<b>Year Ended March 31,</b>		
	<b>2010</b>	<b>2009</b>	<b>2008</b>
	<b>(In thousands)</b>		
Denominator:			
Stock options	17,675	15,647	12,300
Restricted stock units	419		
Total	18,094	15,647	12,300

F-15

---

Table of Contents

## ALKERMES, INC. AND SUBSIDIARIES

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

## 4. INVESTMENTS

Investments consist of the following:

	Amortized Cost	Gains	Gross Unrealized Losses		Estimated Fair Value
			Less than One Year (In thousands)	Greater than One Year	
<b>March 31, 2010</b>					
Short-term investments:					
Available-for-sale securities:					
U.S. government and agency debt securities	\$ 160,876	\$ 204	\$	\$	\$ 161,080
International government agency debt securities	23,441	136		(1)	23,576
Corporate debt securities	15,225	14		(2)	15,237
Asset backed debt securities	983			(24)	959
	200,525	354		(27)	200,852
Money market funds	1,201				1,201
Total short-term investments	201,726	354		(27)	202,053
Long-term investments:					
Available-for-sale securities:					
Corporate debt securities	26,109			(942)	25,167
U.S. government and agency debt securities	24,727		(39)		24,688
Auction rate securities	10,000			(1,454)	8,546
International government agency debt securities	3,225		(2)		3,223
Strategic investments	644	691			1,335
	64,705	691	(41)	(2,396)	62,959
Held-to-maturity securities:					
Certificates of deposit	5,440				5,440
U.S. government obligations	417				417
	5,857				5,857

Edgar Filing: ALKERMES INC - Form 10-K

Total long-term investments	70,562	691	(41)	(2,396)	68,816
Total investments	\$ 272,288	\$ 1,045	\$ (41)	\$ (2,423)	\$ 270,869

**March 31, 2009**

Short-term investments:

Available-for-sale securities:

U.S. government and agency debt securities	\$ 219,330	\$ 2,633	\$ (6)	\$	\$ 221,957
--	------------	----------	--------	----	------------

International government agency debt securities

	6,160	2			6,162
--	-------	---	--	--	-------

Corporate debt securities	8,160	9			8,169
---------------------------	-------	---	--	--	-------

Asset backed debt securities	500			(20)	480
------------------------------	-----	--	--	------	-----

Total short-term investments	234,150	2,644	(6)	(20)	236,768
------------------------------	---------	-------	-----	------	---------

Long-term investments:

Available-for-sale securities:

U.S. government and agency debt securities	10,149		(3)		10,146
--	--------	--	-----	--	--------

International government agency debt securities

	5,551			(220)	5,331
--	-------	--	--	-------	-------

Corporate debt securities	52,336			(6,106)	46,230
---------------------------	--------	--	--	---------	--------

Auction rate securities	10,000			(1,924)	8,076
-------------------------	--------	--	--	---------	-------

Asset backed debt securities	6,350			(759)	5,591
------------------------------	-------	--	--	-------	-------

Strategic investments	738	53			791
-----------------------	-----	----	--	--	-----

	85,124	53	(3)	(9,009)	76,165
--	--------	----	-----	---------	--------

Held-to-maturity securities:

U.S. government obligations	416				416
-----------------------------	-----	--	--	--	-----

Certificates of deposit	4,240				4,240
-------------------------	-------	--	--	--	-------

	4,656				4,656
--	-------	--	--	--	-------

Total long-term investments	89,780	53	(3)	(9,009)	80,821
-----------------------------	--------	----	-----	---------	--------

Total investments	\$ 323,930	\$ 2,697	\$ (9)	\$ (9,029)	\$ 317,589
-------------------	------------	----------	--------	------------	------------

**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 equity investments, which were primarily reinvested and resulted in realized gains and losses, were as follows:

	<b>Year Ended March 31,</b>		
	<b>2010</b>	<b>2009</b>	<b>2008</b>
	<b>(In thousands)</b>		
Proceeds from the sales and maturities of marketable securities	\$ 516,935	\$ 645,122	\$ 556,572
Realized gains	\$ 251	\$ 621	\$ 172
Realized losses	\$ 43	\$ 131	\$ 48

The Company's available-for-sale and held-to-maturity securities at March 31, 2010 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	\$ 71,836	\$ 71,879	\$ 5,857	\$ 5,857
After 1 year through 5 years(1)	149,304	149,413		
After 5 years through 10 years(1)	33,446	32,638		
After 10 years	10,000	8,546		
Total	\$ 264,586	\$ 262,476	\$ 5,857	\$ 5,857

(1) Investments in available-for-sale securities within these categories, with an amortized cost of \$133.3 million and an estimated fair value of \$132.5 million, have issuer call dates prior to May 2011.

As of March 31, 2010, the Company believes that the unrealized losses on its available-for-sale investments are temporary. The investments primarily consist of corporate debt securities and auction rate debt securities. In making the determination that the decline in fair value of these securities was temporary, the Company considered various factors, including but not limited to: the length of time each security was in an unrealized loss position; the extent to which fair value was less than cost; financial condition and near term prospects of the issuers; and the Company's intent not to sell these securities and the assessment that it is more likely than not that the Company would not be required to sell these securities before the recovery of their amortized cost basis.

The Company's corporate debt securities with unrealized losses at March 31, 2010 primarily consist of investment grade subordinated, medium term, callable step-up floating rate notes ( FRN ) issued by several large European and U.S. banks. At March 31, 2010, the FRN's had a cost of \$34.0 million and a fair value of \$33.0 million with composite ratings by Moody's, Standard & Poor's ( S&P ) and Fitch of between AA- and BBB. Similar securities held by the

Company have been called at par by issuers prior to maturity.

The Company's two investments in auction rate securities consist of taxable student loan revenue bonds issued by the Colorado Student Obligation Bond Authority ( Colorado ), with a cost of \$5.0 million, and Brazos Higher Education Service Corporation ( Brazos ), with a cost of \$5.0 million, which service student loans under the Federal Family Education Loan Program. The bonds 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. The auction processes have repeatedly failed since January 2008. The Colorado and Brazos securities were rated Aaa and Baa3 by Moody's, respectively, at March 31, 2010. The fair value of these securities at March 31, 2010 was \$8.5 million. On May 11, 2010, the Company received a notice that the Colorado securities will be called at their par value on May 27, 2010.

F-17

---

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

The estimated fair value of the Company's securities could change significantly based on future financial market conditions. The Company will continue to monitor the securities and the financial markets, and if there is continued deterioration, the fair value of these securities could decline further which may result in an other-than-temporary impairment charge.

The Company's strategic equity investments include common stock in public companies with which the Company has or had a collaborative arrangement with. For the years ended March 31, 2010, 2009 and 2008, the Company recognized \$0.1 million, \$1.2 million and \$1.6 million, respectively, in charges for other-than-temporary impairment losses on its strategic equity investments due to declines in the fair value of the common stock of certain companies which the Company did not believe would recover in the near term.

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 been written down to zero prior to the time of the sale. This transaction was recorded as a non-operating gain on sale of investment in Reliant of \$174.6 million in the year ended March 31, 2008. In March 2009, the Company received the final \$7.7 million of funds related to the transaction, which were released from escrow subject to the terms of an escrow agreement between GSK and Reliant.

**5. FAIR VALUE MEASUREMENTS**

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

	<b>March 31, 2010</b>	<b>Level 1</b>	<b>Level 2</b>	<b>Level 3</b>
		<b>(In thousands)</b>		
Cash equivalents and money market funds	\$ 1,289	\$ 1,289	\$	\$
U.S. government and agency debt securities	185,768	185,768		
International government agency debt securities	26,799	26,799		
Corporate debt securities	40,404		38,668	1,736
Auction rate securities	8,546			8,546
Asset backed debt securities	959			959
Strategic equity investments	1,335	1,335		
<b>Total</b>	<b>\$ 265,100</b>	<b>\$ 215,191</b>	<b>\$ 38,668</b>	<b>\$ 11,241</b>

	<b>March 31, 2009</b>	<b>Level 1</b>	<b>Level 2</b>	<b>Level 3</b>
--	---------------------------	----------------	----------------	----------------

**(In thousands)**

Cash equivalents	\$ 822	\$ 822	\$	\$
U.S. government and agency debt securities	238,265	238,265		
International government agency debt securities	11,493			11,493
Corporate debt securities	48,237			48,237
Auction rate securities	8,076			8,076
Asset backed debt securities	6,071			6,071
Strategic equity investments	791	791		
Total	\$ 313,755	\$ 239,878	\$	\$ 73,877

F-18

---



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

The following table is a rollforward of the fair value of the Company's investments whose fair value was determined using Level 3 inputs at March 31, 2010:

	<b>Fair Value (In thousands)</b>
Balance, April 1, 2009	\$ 73,877
Investments transferred out of Level 3	(44,960)
Total unrealized gains included in comprehensive income	4,891
Redemptions, at par value	(22,567)
Balance, March 31, 2010	\$ 11,241

During the year ended March 31, 2010, trading resumed for certain of the Company's investments in corporate debt securities and the securities were transferred from a Level 3 classification to a Level 2 classification. The Company did not recognize any gains or losses on Level 3 securities sold during the year ended March 31, 2010 or still held at March 31, 2010 in the consolidated statements of operations.

The Company used a discounted cash flow model to determine the estimated fair value of its Level 3 investments. The Company's most significant Level 3 investment at March 31, 2010 consists of its investment in two auction rate securities, which were not trading at March 31, 2010. The assumptions used in the discounted cash flow models includes estimates for interest rates, timing of cash flows, expected holding periods and risk adjusted discount rates, which include a provision for default and liquidity risk, which the Company believes to be the most critical assumptions utilized within the analysis. The Company's valuation analysis considered, 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. The Company estimated the fair value of the auction rate securities to be \$8.5 million.

**6. INVENTORY**

Inventory consists of the following:

	<b>March 31,</b>	
	<b>2010</b>	<b>2009</b>
	<b>(In thousands)</b>	
Raw materials	\$ 4,130	\$ 5,916
Work in process	7,788	5,397
Finished goods(1)	8,501	7,015
Consigned-out inventory(2)	234	1,969

Inventory	\$ 20,653	\$ 20,297
-----------	-----------	-----------

- (1) At March 31, 2010 and March 31, 2009, the Company had \$0.7 million and none, respectively, of finished goods inventory located at its third party warehouse and shipping service provider.
- (2) At March 31, 2010, consigned-out inventory relates to inventory in the distribution channel for which the Company has not recognized revenue. At March 31, 2009, consigned-out inventory consisted of \$1.8 million of consigned-out inventory to Cephalon and \$0.2 million of inventory in the distribution channel for which the Company had not recognized revenue.

F-19

---

**Table of Contents****ALKERMES, INC. AND SUBSIDIARIES****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)****7. PROPERTY, PLANT AND EQUIPMENT**

Property, plant and equipment consists of the following:

	<b>March 31,</b>	
	<b>2010</b>	<b>2009</b>
	<b>(In thousands)</b>	
Land	\$ 301	\$ 301
Building and improvements	36,759	36,325
Furniture, fixture and equipment	62,501	67,165
Leasehold improvements	42,660	33,996
Construction in progress	43,695	41,908
Subtotal	185,916	179,695
Less: accumulated depreciation	(89,011)	(73,234)
Total property, plant and equipment, net	\$ 96,905	\$ 106,461

Depreciation expense was \$25.0 million, \$10.3 million and \$12.1 million for the years ended March 31, 2010, 2009 and 2008, respectively. The Company has \$0.5 million of fully depreciated equipment acquired under a capital lease at March 31, 2010 and 2009.

During the year ended March 31, 2010, the Company wrote off or sold furniture, fixtures and equipment that had a carrying value of \$1.3 million at the time of disposition and received proceeds from the sales of furniture, fixtures and equipment of \$0.2 million. During the year ended March 31, 2009, the Company wrote off furniture, fixtures and equipment that had a carrying value of less than \$0.1 million at the time of disposition. During the year ended March 31, 2010, in connection with the Company's relocation of its corporate headquarters from Cambridge, Massachusetts to Waltham, Massachusetts in the fourth quarter of fiscal year 2010, the Company accelerated the depreciation on laboratory related leasehold improvements located at the Company's Cambridge facility, which no longer has any benefit or future use to the Company. The amount of accelerated depreciation recorded was \$14.1 million.

Amounts included as construction in progress in the consolidated balance sheets primarily include costs incurred for the expansion of the Company's manufacturing facilities in Ohio. The Company continues to evaluate its manufacturing capacity based on expectations of demand for its products and will continue to record such amounts within construction in progress until such time as the underlying assets are placed into service, or the Company determines it has sufficient existing capacity and the assets are no longer required, at which time the Company would recognize an impairment charge. The Company continues to periodically evaluate whether facts and circumstances indicate that the carrying value of these long-lived assets to be held and used may not be recoverable.

Table of Contents**ALKERMES, INC. AND SUBSIDIARIES****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)****8. ACCOUNTS PAYABLE AND ACCRUED EXPENSES**

Accounts payable and accrued expenses consists of the following:

	<b>March 31,</b>	
	<b>2010</b>	<b>2009</b>
	<b>(In thousands)</b>	
Accounts payable	\$ 8,197	\$ 8,046
Accrued compensation	15,276	13,817
Accrued interest	898	1,549
Amounts due to Cephalon		1,169
Accrued other	13,510	11,902
Total accounts payable and accrued expenses	\$ 37,881	\$ 36,483

**9. LONG-TERM DEBT**

Long-term debt consists of the following:

	<b>March 31,</b>	
	<b>2010</b>	<b>2009</b>
	<b>(In thousands)</b>	
Non-recourse RISPERDAL CONSTA secured 7% Notes	\$ 51,043	\$ 75,888
Less: current portion	(51,043)	(25,667)
Long-term debt	\$	\$ 50,221

***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 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 non-recourse 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 received only quarterly cash interest payments. Beginning on April 1, 2009, principal payments were made to the holders, subject to certain conditions. Timing of the principal repayment is based on the revenues received by Royalty Sub but occurs 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

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

January 1, 2018. The non-recourse 7% Notes, however, may be redeemed at Royalty Sub's option, subject, in certain circumstances, to the payment of a redemption premium. The non-recourse 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 and the assets of Alkermes are not available to satisfy obligations of Royalty Sub. During the years ended March 31, 2010, 2009 and 2008, amortization of the original issue discount and offering costs, which are being amortized over the expected principal repayment period ending January 1, 2012 totaled \$1.7 million, \$3.7 million and \$4.4 million, respectively.

During the year ended March 31, 2009, the Company purchased, in five separate, privately negotiated transactions, an aggregate of \$93.0 million in principal amount of its outstanding non-recourse 7% Notes for \$89.4 million. The Company recorded a loss on the extinguishment of the purchased non-recourse 7% Notes of \$2.5 million, consisting of \$0.9 million of transaction fees and a \$1.6 million difference between the carrying value and the purchase price of the non-recourse 7% Notes, which was recorded as interest expense.

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 non-recourse 7% Notes. The Company will receive all of the RISPERDAL CONSTA revenues in excess of amounts required to pay interest, principal and redemption premium, if any. The Company's rights to receive such excess revenues will be subject to certain restrictions while the non-recourse 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, 2010, the Company was in compliance with all such covenants.

On May 11, 2010, the Company delivered a notice to the trustee of the non-recourse 7% Notes exercising its option to redeem these notes in full on July 1, 2010, in accordance with the provisions of the purchase and sale agreement. Accordingly, the Company has classified the entire non-recourse 7% Notes balance at March 31, 2010 as a current liability in the accompanying consolidated balance sheets.

**10. 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 March 2008, in connection with the program termination, 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. In connection with the 2008 Restructuring, the Company recorded charges of \$6.9 million during the year ended March 31, 2008. Activity related to the 2008 Restructuring was as follows:

	Facility Closure	Severance	Other Contract Losses	Total
	(In thousands)			
Balance, April 1, 2008	\$ 4,930	\$ 2,881	\$ 37	\$ 7,848
Additions	43	78		121

Edgar Filing: ALKERMES INC - Form 10-K

Payments	(802)	(2,959)	(13)	(3,774)
Other adjustments	22		(24)	(2)
Balance, March 31, 2009	\$ 4,193	\$	\$	\$ 4,193
Payments	(811)			(811)
Other adjustments	214			214
Balance, March 31, 2010	\$ 3,596	\$	\$	\$ 3,596

F-22

---

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

At March 31, 2010 and 2009, the restructuring liability related to the 2008 Restructuring consists of \$0.6 million classified as current and \$3.0 million classified as long-term, respectively, in the accompanying consolidated balance sheets. As of March 31, 2010, the Company had paid in cash, written off, recovered and made restructuring charge adjustments totaling approximately \$0.3 million in facility closure costs, \$2.9 million in employee separation costs and \$0.1 million in other contract termination costs in connection with the 2008 Restructuring. The \$3.6 million remaining in the restructuring accrual at March 31, 2010 is expected to be paid out through fiscal 2016 and relates 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 during the year ended March 31, 2008. Fair value of the impaired assets was based on internally and externally established estimates and selling prices of similar assets.

**11. 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). In June 2008, the board of directors authorized the expansion of this repurchase program by an additional \$40.0 million, bringing the total authorization under this program to \$215.0 million. The objective of the 2007 repurchase program is to improve shareholders' returns. At March 31, 2010, approximately \$101.0 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 years ended March 31, 2010 and 2009, the Company expended approximately \$2.7 million and \$18.0 million, respectively, on open market purchases and repurchased 328,404 shares and 1,569,202 shares, respectively, of outstanding common stock at an average price of \$8.17 and \$11.47 per share, respectively, under the 2007 repurchase program. In addition to the stock repurchases, during the years ended March 31, 2010, 2009 and 2008, the Company acquired, by means of net share settlements, 100,449 shares, 51,891 shares and 77,094 shares of Alkermes common stock, at an average price of \$8.68, \$11.39, and \$17.31 per share, respectively, related to the vesting of employee stock awards to satisfy withholding tax obligations. In addition, during the years ended March 31, 2010, 2009 and 2008, the Company acquired 7,961 shares, 9,176 shares, and 8,675 shares, respectively, of Alkermes common stock, at an average price of \$12.56, \$12.66 and \$16.77 per share, respectively, tendered by former and current employees as payment of the exercise price of stock options granted under our equity compensation plans.

***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 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

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

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.

**12. SHARE-BASED COMPENSATION***Share-based Compensation Expense*

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

	<b>Year Ended March 31,</b>		
	<b>2010</b>	<b>2009</b>	<b>2008</b>
	<b>(In thousands)</b>		
Cost of goods manufactured and sold	\$ 1,506	\$ 1,348	\$ 1,812
Research and development	3,489	4,438	7,010
Selling, general and administrative	8,926	9,024	10,623
Total share-based compensation expense	\$ 13,921	\$ 14,810	\$ 19,445

As of March 31, 2010, 2009 and 2008, \$0.6 million, \$0.4 million and \$0.3 million, respectively, of share-based compensation cost was capitalized and recorded as Inventory in the consolidated balance sheets.

In September 2009, in connection with the resignation of its former President and Chief Executive Officer, the Company entered into a separation agreement that provided for, among other things, the acceleration of vesting of certain stock options and restricted stock awards that were scheduled to vest through June 30, 2010; and the period in which vested stock options are exercisable was extended until the earlier of June 30, 2011 or the stated expiration date of the stock options. As a result of these stock option and award modifications, the Company recorded an expense of \$0.4 million during the year ended March 31, 2010.

*Share-based Compensation Plans*

The Company has one compensation plan pursuant to which awards are currently being made, the 2008 Plan. The Company has six share-based compensation plans pursuant to which outstanding awards have been made, but from which no further awards can or will be made: (i) the 1990 Omnibus Stock Option Plan (the 1990 Plan); (ii) the 1996 Stock Option Plan for Non-Employee Directors (the 1996 Plan); (iii) the 1998 Equity Incentive Plan (the 1998 Plan);

(iv) the 1999 Stock Option Plan (the 1999 Plan ); (v) the 2002 Restricted Stock Award Plan (the 2002 Plan ); and (vi) the 2006 Stock Option Plan for Non-Employee Directors (the 2006 Plan ). The 2008 Plan provides for issuance of non-qualified and incentive stock options, restricted stock, restricted stock units, cash-based awards and performance shares to employees, officers and directors of, and consultants to the Company in such amounts and with such terms and conditions as may be determined by the compensation committee of our board of directors, subject to provisions of the 2008 Plan.

Shares of common stock available for issuance under the 2008 Plan at March 31, 2010 consist of 6.6 million shares. The 2008 Plan provides that awards other than stock options will be counted against the total number of shares available under the plan in a 2-to-1 ratio.

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

A summary of stock option activity is presented in the following table:

	<b>Number of Shares</b>	<b>Weighted Average Exercise Price</b>
Outstanding, April 1, 2009	18,145,589	\$ 16.37
Granted	2,914,000	8.85
Exercised	(495,824)	7.22
Forfeited	(533,758)	11.88
Expired	(2,003,334)	16.53
Outstanding, March 31, 2010	18,026,673	\$ 15.52
Exercisable, March 31, 2010	13,601,229	\$ 17.00

The weighted average grant date fair value of stock options granted during the years ended March 31, 2010, 2009 and 2008 was \$4.46, \$5.41 and \$6.93, respectively. The aggregate intrinsic value of stock options exercised during the years ended March 31, 2010, 2009 and 2008 was \$2.6 million, \$4.9 million and \$7.0 million, respectively.

As of March 31, 2010, there were 4.1 million stock options expected to vest with a weighted average exercise price of \$11.05 per share, a weighted average contractual remaining life of 8.6 years and an aggregate intrinsic value of \$10.3 million. As of March 31, 2010, the aggregate intrinsic value of stock options exercisable was \$12.0 million with a weighted average remaining contractual term of 4.0 years. 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, 2010, there was \$10.8 million of unrecognized compensation cost related to unvested stock options, which is expected to be recognized over a weighted average period of approximately 1.3 years. Cash received from option exercises under the Company's Plans during the years ended March 31, 2010 and 2009 was \$2.6 million and \$7.1 million, respectively. The Company issued new shares upon option exercises during the years ended March 31, 2010 and 2009.

During the year ended March 31, 2010, as a result of the carryback of its 2010 U.S. Alternative Minimum Tax ( AMT ) net operating loss ( NOL ) to prior fiscal years as discussed in Note 14 Income Taxes, the Company recorded a \$0.2 million benefit to additional paid-in capital related to excess tax benefits from stock option exercises.

**Table of Contents****ALKERMES, INC. AND SUBSIDIARIES****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)*****Time-Vested Restricted Stock Units***

A summary of time-vested RSU activity is presented in the following table:

	<b>Number of Shares</b>	<b>Weighted Average Grant Date Fair Value</b>
Outstanding, April 1, 2009	801,940	\$ 13.52
Granted	1,030,750	8.83
Vested	(276,818)	14.72
Forfeited	(90,375)	11.78
Outstanding, March 31, 2010	1,465,497	\$ 10.14

The weighted average grant date fair value of time-vested restricted stock units granted during the years ended March 31, 2010, 2009 and 2008 was \$8.83, \$12.29 and \$14.84, respectively. The total fair value of time-vested restricted stock units that vested during the years ended March 31, 2010, 2009 and 2008 was \$2.4 million, \$1.7 million and \$2.1 million, respectively.

At March 31, 2010, there was \$8.4 million of total unrecognized compensation cost related to time-vested unvested RSUs, which will be recognized over a weighted average remaining contractual term of 1.7 years.

***Performance-Based Restricted Stock Units***

In May 2009, the board of directors awarded 45,000 RSUs to certain of the Company's executive officers under the 2006 Plan that vest upon the approval of BYDUREON by the U.S. Food and Drug Administration ( FDA ) provided the approval by the FDA occurs at least one year after the date of grant. During the year ended March 31, 2010, 20,000 RSUs were forfeited upon the resignation of an executive officer. The grant date fair value of the award was \$8.55 per share, which was the market value of the Company's stock on the date of grant. As of March 31, 2010, the performance condition had not been met and the award had not vested. At March 31, 2010, there was \$0.1 million of unrecognized compensation cost related to these RSUs.

In May 2008, the board of directors awarded 40,000 RSUs to certain of the Company's executive officers under the 2002 Plan that vests upon the achievement of a market condition specified in the award terms. During the year ended March 31, 2010, 10,000 RSUs were forfeited upon the resignation of an executive officer. As of March 31, 2010, the market condition had not been met and the award had not vested. The grant date fair value of \$9.48 per share was determined through the use of a Monte Carlo simulation model. The compensation cost for the award's grant date fair value of \$0.4 million was recognized over a derived service period of 1.4 years. At March 31, 2010, there was no unrecognized compensation cost related to these RSUs.

**13. 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.

**Table of Contents**

**ALKERMES, INC. AND SUBSIDIARIES**

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

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 receives royalties 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.

The Company exclusively manufactures RISPERDAL CONSTA for commercial sale. Under the manufacturing and supply agreement with Janssen, the Company records manufacturing revenue 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 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, 2010, 2009 and 2008, the Company recognized \$148.8 million, \$150.2 million and \$124.7 million, respectively, of revenue from its arrangements with Janssen.

***Amylin***

In May 2000, the Company entered into a development and license agreement with Amylin for the development of BYDUREON, 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 MEDISORB<sup>®</sup> 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 BYDUREON. The Company receives funding for R&D 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. In October 2005 and in July 2006, the Company amended the development and license agreement. Pursuant to the 2006 amendment, 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 conjunction with the 2005 amendment of the development and license agreement with Amylin, the parties reached an agreement regarding the construction of a manufacturing facility for BYDUREON and certain technology transfer related thereto. In December 2005, Amylin purchased a facility for the manufacture of BYDUREON 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 BYDUREON to Amylin. Amylin agreed to reimburse the Company for any time, at an agreed-upon FTE rate, and materials the Company incurred with respect to the transfer of technology. In January 2009, the parties agreed that the technology transfer was complete. Amylin will be responsible for the manufacture of

BYDUREON and will operate the facility. Until the end of the first ten full calendar years following the year in which the first commercial sale of BYDUREON takes place, the Company will receive royalties equal to 8% of net sales from the first 40 million units of BYDUREON sold in any particular year and 5.5% of net sales from units sold beyond the first



**Table of Contents**

**ALKERMES, INC. AND SUBSIDIARIES**

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

40 million for that year. After this period, royalties will be paid at the rate of 5.5% of net sales. Notwithstanding the aforementioned, in countries in which there is no patent coverage for the product, royalties will be payable at the rate of 25% of 5.5% for ten years from the first commercial sale in such country. Amylin's obligation to pay royalties on BYDUREON shall cease on a country by country basis upon the later of (i) ten years after the date of the first commercial sale of the product in such country or (ii) the expiration of the last patent covering BYDUREON in such country. In addition, the Company will receive a \$7.0 million milestone payment upon the first commercial sale of BYDUREON in the U.S. and an additional \$7.0 million milestone payment upon the first commercial sale in Europe.

Amylin may terminate the development and license agreement for any reason upon 180 days written notice to the Company. 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, 2010, 2009 and 2008, the Company recognized \$4.1 million, \$9.5 million and \$32.9 million, respectively, of revenue from its arrangements with Amylin.

***Cilag***

In December 2007, the Company 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 has primary responsibility for securing all necessary regulatory approvals for VIVITROL and Janssen-Cilag, an affiliate of Cilag, commercializes the product. The Company is responsible for the manufacture of VIVITROL and receives manufacturing revenue upon shipment of VIVITROL to Cilag and royalty revenues based upon Cilag product sales.

In December 2007, Cilag made a nonrefundable payment of \$5.0 million to the Company upon signing the agreement and in August 2008, paid the Company an additional \$1.0 million upon achieving regulatory approval of VIVITROL for the treatment of alcohol dependence in Russia. Under the agreement, Cilag could pay the Company up to an additional \$33.0 million in milestone payments upon the receipt of additional 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 90 days advance written notice of material breach or, in certain circumstances, a 30 day extension of that period.

During the year ended March 31, 2010 and 2009, the Company recognized \$0.8 million and \$1.4 million of revenue from its arrangement with Cilag, respectively. There was no revenue recognized from this arrangement in the year ended March 31, 2008.

***Cephalon***

In June 2005 and October 2006, the Company entered into the Agreements and Amendments, respectively, with Cephalon 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

F-28

---

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

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 was received from the FDA in April 2006, for completing the first VIVITROL manufacturing line and manufacturing the product. The companies shared responsibility for additional development of the products, and also shared responsibility for developing the commercial strategy for the products. Cephalon had primary responsibility for the commercialization, including distribution and marketing, of the products in the U.S. and the Company supported this effort with a team of managers of market development. Cephalon paid the Company an aggregate of \$274.6 million in nonrefundable milestone payments related to the Agreements and Amendments and the Company was responsible to fund the first \$124.6 million of cumulative net losses incurred on the product.

In November 2008, the Company and Cephalon agreed to end the collaboration for the development, supply and commercialization of certain products, including VIVITROL in the U.S., effective on the Termination Date, and the Company assumed the risks and responsibilities for the marketing and sale of VIVITROL in the U.S. The Company paid Cephalon \$16.0 million for title to two partially completed VIVITROL manufacturing lines, and the Company received \$11.0 million from Cephalon as payment to fund their share of estimated VIVITROL product losses during the one-year period following the Termination Date.

As of the Termination Date, the Company was responsible for all VIVITROL profits or losses, net of \$11.0 million. Cephalon paid the Company to fund its share of estimated VIVITROL product losses during the one-year period following the Termination Date, and Cephalon has no rights to royalty payments on future sales of VIVITROL. In order to facilitate the full transfer of all commercialization of VIVITROL to the Company, Cephalon, at the Company's option, and on its behalf, agreed to perform certain transition services until May 31, 2009 at an FTE rate agreed to by the parties.

During the years ended March 31, 2010, 2009 and 2008, the Company recognized \$5.0 million, \$134.0 million, and \$27.7 million, respectively, of revenue from its arrangements with Cephalon. During the years ended March 31, 2010 and 2009, the Company recorded expense of \$0.6 million and \$1.8 million, respectively, related to certain transition services performed by Cephalon on its behalf. There was no transition expense incurred from this arrangement in the year ended March 31, 2008.

***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. In June 2008, the Company entered into an agreement (the AIR Insulin Termination Agreement) with Lilly whereby the Company received \$40.0 million in cash as payment for all services we had performed through the date of the AIR Insulin Termination Agreement and title to the Lilly-owned manufacturing equipment located at the Company's AIR manufacturing facility. Upon entering into the AIR Insulin Termination Agreement, the license the Company granted to Lilly under the development and license agreement reverted to the Company.

*AIR Parathyroid Hormone*

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

F-29

---

**Table of Contents**

**ALKERMES, INC. AND SUBSIDIARIES**

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

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, 2010, 2009 and 2008, the Company recognized none, \$26.8 million and \$54.6 million, respectively, of revenue from its arrangements with Lilly.

***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. In July 2008, the parties amended the agreement to expand the license to include certain additional patent applications. The Company paid RPI an additional nonrefundable payment of \$0.1 million and slightly increased the annual fees in consideration of this amendment. During the years ended March 31, 2010, 2009 and 2008, the Company recorded R&D expense of \$0.3 million, \$0.6 million and \$0.2 million related to its agreements with RPI.

***Acceleron***

In December 2009, the Company entered into a collaboration and license agreement with Acceleron Pharma, Inc. ( Acceleron ). In exchange for a nonrefundable upfront payment of \$2.0 million, an equity investment in Acceleron of \$8.0 million and certain potential milestone payments and royalties, the Company has obtained an exclusive license to Acceleron s proprietary long-acting Fc fusion technology platform, called the MEDIFUSION<sup>®</sup> technology, which is designed to extend the circulating half-life of proteins and peptides. The first drug candidate being developed with this technology is a long-acting form of a TNF receptor-Fc fusion protein for the treatment of rheumatoid arthritis and related autoimmune diseases.

The Company and Acceleron have agreed to collaborate on the development of product candidates from the MEDIFUSION technology platform. Pursuant to the terms of the agreement, Acceleron will develop up to two selected drug compounds using the MEDIFUSION technology through preclinical studies, at which point the Company will assume responsibility for all clinical development and commercialization of these two compounds and any other compounds the Company elects to develop resulting from the platform. Acceleron will retain all rights to the technology for products derived from the TGF-beta superfamily.

The Company s \$8.0 million investment in Acceleron consists of shares of Series D-1 convertible, redeemable preferred stock, which represents a 3% ownership position in Acceleron. The Company s Chairman, President and

Chief Executive Officer is one of nine members of Acceleron's board of directors. The Company is accounting for its investment in Acceleron under the cost method as Acceleron is a privately-held company over which the Company does not exercise significant influence. Accordingly, the Company does not record any share of Acceleron's net income or losses, but would record dividends, if received. The carrying value of the investment is \$8.0 million at March 31, 2010, and is recorded within Other assets in the accompanying consolidated balance sheets. The Company will monitor this investment to evaluate whether

F-30

---

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

any decline in its value has occurred that would be other than temporary, based on the implied value from any recent rounds of financing completed by the investee, market prices of comparable public companies, and general market conditions.

In addition to the upfront payment and equity investment, the Company will reimburse Acceleron for any time, at an agreed-upon FTE rate, and materials Acceleron incurs during development. The Company is obligated to make developmental and sales milestone payments in the aggregate of up to \$110.0 million per product in the event that certain development and sales goals are achieved. The Company is also obligated to make tiered royalty payments in the mid-single digits on annual net sales in the event any products developed under the agreement are commercialized.

During the year ended March 31, 2010, the Company incurred expenses of \$0.9 million in connection with its arrangement with Acceleron, which is recorded within Research and development expense in the accompanying consolidated statement of operations. Additionally, the \$2.0 million upfront payment was charged to research and development expense as technological feasibility of the acquired technology has not been established.

**14. INCOME TAXES**

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

	<b>March 31,</b>	
	<b>2010</b>	<b>2009</b>
	<b>(In thousands)</b>	
NOL carryforwards - federal and state	\$ 39,603	\$ 36,403
Tax benefit from the exercise of stock options	38,776	38,776
Tax credit carryforwards	16,961	19,274
Alkermes Europe, Ltd. NOL carryforward	5,236	5,531
Deferred revenue	2,070	1,772
Share-based compensation	14,133	12,256
Property, plant and equipment	(4,412)	(9,915)
Other	6,176	7,641
Less: valuation allowance	(118,543)	(111,738)
	\$	\$

As of March 31, 2010, the Company had approximately \$236.5 million of Federal domestic operating loss carryforwards, \$57.8 million of state operating loss carryforwards, and \$18.7 million of foreign net operating loss and foreign capital loss carryforwards, which either expire on various dates through 2030 or can be carried forward indefinitely. These loss carryforwards are available to reduce future federal, state and foreign taxable income, if any. These loss carryforwards are subject to review and possible adjustment by the appropriate taxing authorities. These loss carryforwards, which 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. net operating losses 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



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

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, 2010, 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 \$5.8 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 \$44.6 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.

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

	<b>Year Ended March 31,</b>		
	<b>2010</b>	<b>2009</b>	<b>2008</b>
	<b>(In thousands)</b>		
Current income tax (benefit) expense:			
Federal	\$ (3,318)	\$ 483	\$ 5,770
State	75	24	81
Deferred income tax (benefit) expense:			
Federal	(1,674)		
State	(158)		
Total tax (benefit) provision	\$ (5,075)	\$ 507	\$ 5,851

The current federal income tax benefit of \$3.3 million for the year ended March 31, 2010 is primarily the result of a carryback of the Company's 2010 AMT NOL pursuant to the *Worker, Homeownership and Business Act of 2009*. This law increased the carryback period for certain net operating losses from two years to five years. Prior to the adoption of this law, the Company had recorded a full valuation allowance against the credits that were established in prior periods when the Company was subject to AMT provisions. The deferred federal and state tax benefit of \$1.8 million for the year ended March 31, 2010 is primarily due to the Company's recognition of a \$1.8 million income tax expense associated with the increase in the value of certain securities that it carried at fair market value during the year ended March 31, 2010. This income tax expense was recorded in other comprehensive income. There were no similar income tax benefits or provisions for the years ended March 31, 2009 and 2008. The provision for income taxes in the amount of \$0.5 million and \$5.9 million for the years ended March 31, 2009 and 2008 primarily represents 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;

F-32

---

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

however, unrecognized foreign tax credit carryforwards may be available to reduce some portion of the U.S. tax liability, if any.

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

	<b>Year Ended March 31,</b>		
	<b>2010</b>	<b>2009</b>	<b>2008</b>
Statutory federal rate	34.0%	34.0%	34.0%
State income taxes, net of federal benefit	(0.1)%		
Research and development benefit	0.8%	(0.5)%	
Share-based compensation	(2.9)%	1.0%	1.5%
Other permanent items	(0.5)%	0.5%	0.4%
Other	0.0%	0.1%	0.1%
Change in valuation allowance	(19.9)%	(34.7)%	(32.6)%
Effective tax rate	11.4%	0.4%	3.4%

A reconciliation of the beginning and ending amount of unrecognized tax benefits is as follows:

	<b>Unrecognized Tax Benefits (In thousands)</b>
Balance, April 1, 2008	\$ 1,796
Additions based on tax positions related to prior periods	30
Balance, March 31, 2009	1,826
Additions based on tax positions related to prior periods	9
Balance, March 31, 2010	\$ 1,835

Included in unrecognized tax benefits at March 31, 2010 is \$1.8 million of tax benefits that, if recognized, would affect the Company's annual effective tax rate. Of this balance, \$1.7 million relates to deferred tax assets for which a full valuation allowance would be recorded, offsetting any tax benefits that would be realized. The Company does not expect a significant increase in unrecognized tax benefits within the next twelve months.

The tax years 1993 through 2009 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, 2010, the Company's accrued interest and penalties related to uncertain tax positions was not significant.

## 15. 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 2020. 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 facility in Massachusetts. As of March 31, 2010, the

F-33

---

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

total future annual minimum lease payments under the Company's non-cancelable operating leases are as follows:

	<b>Payment Amount (In thousands)</b>
Fiscal Years:	
2011	\$ 12,581
2012	13,210
2013	6,009
2014	3,686
2015	3,840
Thereafter	17,582
	56,908
Less: estimated sublease income	(17,868)
Total future minimum lease payments	\$ 39,040

Rent expense related to operating leases charged to operations was approximately \$11.2 million, \$11.7 million, and \$11.9 million for the years ended March 31, 2010, 2009 and 2008, respectively. These amounts are net of sublease income of \$3.5 million, \$1.7 million and \$2.0 million earned in the years ended March 31, 2010, 2009 and 2008, respectively. In addition to its lease commitments, the Company has open purchase orders totaling \$31.9 million at March 31, 2010.

***License and Royalty Commitments***

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 \$0.6 million, \$0.9 million and \$0.2 million for the years ended March 31, 2010, 2009 and 2008, respectively, and were recorded as Research and development expense in the consolidated statements of operations and comprehensive (loss) income.

***Litigation***

From time to time, the Company may be subject to various legal proceedings and claims in the ordinary course of business. Although the outcome of litigation cannot be predicted with certainty and some legal proceedings and claims may be disposed of unfavorably to the Company, the Company does not believe that it is currently a party to any material legal proceedings.

**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 our Annual 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 our 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 our 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 our 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 our 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 our Annual 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 our 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 our 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 our 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 our Annual 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 our 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 our Quarterly 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 our Quarterly Report on Form 10-Q for the quarter ended December 31, 2000 (File No. 001-14131).)
- 10.5 Lease Agreement, dated as of April 22, 2009 between PDM Unit 850, LLC, and Alkermes, Inc. (Incorporated by reference to Exhibit 10.5 to our Annual Report on Form 10-K for the fiscal year ended March 31, 2009.)
- 10.5(a) First Amendment to Lease Agreement between Alkermes, Inc. and PDM Unit 850, LLC, dated as of June 18, 2009 (Incorporated by reference to Exhibit 10.2 to our Quarterly Report on Form 10-Q for the quarter ended June 30, 2009.)

Edgar Filing: ALKERMES INC - Form 10-K

- 10.6 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 our Annual Report on Form 10-K for the fiscal year ended March 31, 1996 (File No. 000-19267).)\*
  - 10.7 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 our Annual Report on Form 10-K for the fiscal year ended March 31, 1996 (File No. 000-19267).)\*
-

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

- 10.8 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 our Annual Report on Form 10-K for the fiscal year ended March 31, 2002 (File No. 001-14131).)\*\*\*
- 10.8(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 our Quarterly Report on Form 10-Q for the quarter ended December 31, 2004.)\*\*\*\*
- 10.8(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 our Quarterly Report on Form 10-Q for the quarter ended December 31, 2004.)\*\*\*\*
- 10.8(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 our Annual Report on Form 10-K for the fiscal year ended March 31, 2002 (File No. 001-14131).)\*\*\*
- 10.8(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 our Annual Report on Form 10-K for the fiscal year ended March 31, 2002.)\*\*\*
- 10.8(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 our Quarterly Report on Form 10-Q for the quarter ended December 31, 2004.)\*\*\*\*
- 10.8(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 our Quarterly Report on Form 10-Q for the quarter ended December 31, 2004.)\*\*\*\*
- 10.9 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 our Quarterly Report on Form 10-Q for the quarter ended December 31, 2004.)\*\*\*\*
- 10.9(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 our Quarterly Report on Form 10-Q for the quarter ended December 31, 2004.)\*\*\*\*
- 10.10 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 our Annual Report on Form 10-K for the fiscal year ended March 31, 1999 (File No. 001-14131).)\*\*



Edgar Filing: ALKERMES INC - Form 10-K

- 10.11 Employment agreement, dated as of December 12, 2007, by and between Richard F. Pops and Alkermes, Inc. (Incorporated by reference to Exhibit 10.1 to our Quarterly Report on Form 10-Q for the quarter ended December 31, 2007.)+
  - 10.11(a) Amendment to Employment Agreement by and between Alkermes, Inc. and Richard F. Pops. (Incorporated by reference to Exhibit 10.5 to our Current Report on Form 8-K filed on October 7, 2008.)+
  - 10.11(b) Amendment No. 2 to Employment Agreement by and between Alkermes, Inc. and Richard F. Pops, dated September 10, 2009. (Incorporated by reference to Exhibit 10.2 to our Current Report on Form 8-K filed on September 11, 2009.)+
-

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

- 10.12 Employment agreement, dated as of December 12, 2007, by and between David A. Broecker and Alkermes, Inc. (Incorporated by reference to Exhibit 10.2 to our Quarterly Report on Form 10-Q for the quarter ended December 31, 2007.)+
- 10.12(a) Amendment to Employment Agreement by and between Alkermes, Inc. and David A. Broecker. (Incorporated by reference to Exhibit 10.6 to our Current Report on Form 8-K filed on October 7, 2008.)+
- 10.13 Separation Agreement by and between Alkermes, Inc. and David A. Broecker, dated September 10, 2009. (Incorporated by reference to Exhibit 10.1 to our Current Report on Form 8-K filed on September 11, 2009.)+
- 10.14 Form of Employment Agreement, dated as of December 12, 2007, by and between Alkermes, Inc. 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 our Quarterly Report on Form 10-Q for the quarter ended December 31, 2007.)+
- 10.14(a) Form of Amendment to Employment Agreement by and between Alkermes, Inc. and each of each of Kathryn L. Biberstein, Elliot W. Ehrich, M.D., James M. Frates, Michael J. Landine, Gordon G. Pugh. (Incorporated by reference to Exhibit 10.7 to our Current Report on Form 8-K filed on October 7, 2008.)+
- 10.15 Form of Covenant Not to Compete, of various dates, by and between Alkermes, Inc. and each of Kathryn L. Biberstein and James M. Frates. (Incorporated by reference to Exhibit 10.15 to our Annual Report on Form 10-K for the year ended March 31, 2007.)+
- 10.15(a) Form of Covenant Not to Compete, of various dates, by and between Alkermes, Inc. and each of Elliot W. Ehrich, M.D., Michael J. Landine, and Gordon G. Pugh. (Incorporated by reference to Exhibit 10.15(a) to our Annual Report on Form 10-K for the year ended March 31, 2007.)+
- 10.16 Form of Indemnification Agreement by and between Alkermes, Inc. and each of its directors and executive officers (Incorporated by reference to Exhibit 10.1 to our Current Report on Form 8-K filed on March 25, 2010.)+
- 10.17 License and Collaboration Agreement between Alkermes, Inc. and Cephalon, Inc. dated as of June 23, 2005. (Incorporated by reference to Exhibit 10.1 to our Quarterly Report on Form 10-Q for the quarter ended June 30, 2005.)\*\*\*\*\*
- 10.17(a) Supply Agreement between Alkermes, Inc. and Cephalon, Inc. dated as of June 23, 2005. (Incorporated by reference to Exhibit 10.2 to our Quarterly Report on Form 10-Q for the quarter ended June 30, 2005.)\*\*\*\*\*
- 10.17(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 our Annual Report on Form 10-K for the year ended March 31, 2007.)\*\*\*\*\*
- 10.17(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 our Annual Report on Form 10-K for the year ended March 31, 2007.)\*\*\*\*\*
- 10.18 Accelerated Share Repurchase Agreement, dated as of February 7, 2008, between Morgan Stanley & Co. Incorporated and Alkermes, Inc. (Incorporated by reference to Exhibit 10.17 to our Annual Report on Form 10-K for the year ended March 31, 2008.)
- 10.19 Alkermes, Inc. 1998 Equity Incentive Plan as Amended and Approved on November 2, 2006. (Incorporated by reference to Exhibit 10.1 to our Quarterly Report on Form 10-Q for the fiscal quarter ended December 31, 2006.)+
- 10.19(a)

Edgar Filing: ALKERMES INC - Form 10-K

Form of Stock Option Certificate pursuant to Alkermes, Inc. 1998 Equity Incentive Plan.  
(Incorporated by reference to Exhibit 10.37 to our Annual Report on Form 10-K for the fiscal year  
ended March 31, 2006.)+

10.20 Alkermes, Inc. Amended and Restated 1999 Stock Option Plan. (Incorporated by reference to  
Appendix A to our Definitive Proxy Statement on Form DEF 14/A filed on July 27, 2007.)+

10.20(a) Form of Incentive Stock Option Certificate pursuant to the 1999 Stock Option Plan, as amended.  
(Incorporated by reference to Exhibit 10.35 to our Annual Report on Form 10-K for the fiscal year  
ended March 31, 2006.)+

---

**Table of Contents**

**Exhibit  
No.**

- 10.20(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 our Annual Report on Form 10-K for the fiscal year ended March 31, 2006.)+
- 10.21 Alkermes, Inc. 2002 Restricted Stock Award Plan as Amended and Approved on November 2, 2006. (Incorporated by reference to Exhibit 10.3 to our Quarterly Report on Form 10-Q for the fiscal quarter ended December 31, 2006.)+
- 10.21(a) Amendment to Alkermes, Inc. 2002 Restricted Stock Award Plan. (Incorporated by reference to Appendix B to our Definitive Proxy Statement on Form DEF 14/A filed on July 27, 2007.)+
- 10.22 2006 Stock Option Plan for Non-Employee Directors. (Incorporated by reference to Exhibit 10.4 to our Quarterly Report on Form 10-Q for the fiscal quarter ended September 30, 2006.)+
- 10.22(a) Amendment to 2006 Stock Option Plan for Non-Employee Directors. (Incorporated by reference to Appendix C to our Definitive Proxy Statement on Form DEF 14/A filed on July 27, 2007.)+
- 10.23 Alkermes Fiscal 2008 Named-Executive Bonus Plan. (Incorporated by reference to Exhibit 10.1 to our Current Report on Form 8-K filed on April 26, 2007.)+
- 10.24 Alkermes Fiscal Year 2009 Reporting Officer Performance Pay Plan. (Incorporated by reference to Exhibit 10.1 to our Current Report on Form 8-K filed on May 16, 2008.)+
- 10.25 Alkermes Fiscal Year 2010 Reporting Officer Performance Pay Plan. (Incorporated by reference to Exhibit 10.1 to our Current Report on Form 8-K filed on July 15, 2009.)+
- 10.26 Alkermes Fiscal 2011 Reporting Officer Performance Pay Plan. (Incorporated by reference to Exhibit 10.2 to our Current Report on Form 8-K filed on March 25, 2010.)+
- 10.27 Alkermes, Inc., 2008 Stock Option and Incentive Plan (Incorporated by reference to Exhibit 10.1 to our Current Report on Form 8-K filed on October 7, 2008.)+
- 10.27(a) Alkermes, Inc. 2008 Stock Option and Incentive Plan, Stock Option Award Certificate (Incentive Stock Option) , as amended #
- 10.27(b) Alkermes, Inc. 2008 Stock Option and Incentive Plan, Stock Option Award Certificate (Non-Qualified Option) , as amended #
- 10.27(c) Alkermes, Inc. 2008 Stock Option and Incentive Plan, Stock Option Award Certificate (Non-Employee Director) (Incorporated by reference to Exhibit 10.4 to our Current Report on Form 8-K filed on October 7, 2008.)+
- 10.27(d) Alkermes, Inc. 2008 Stock Option and Incentive Plan, Restricted Stock Unit Award Certificate (Time Vesting Only). (Incorporated by reference to Exhibit 10.1 to our Current Report on Form 8-K filed on May 22, 2009.)+
- 10.27(e) Alkermes, Inc. 2008 Stock Option and Incentive Plan, Restricted Stock Unit Award Certificate (Performance Vesting Only). (Incorporated by reference to Exhibit 10.2 to our Current Report on Form 8-K filed on May 22, 2009.)+
- 10.28 Development and License Agreement, dated as of May 15, 2000, by and between Alkermes Controlled Therapeutics Inc. II and Amylin Pharmaceuticals, Inc., as amended on October 24, 2005 and July 17, 2006 (assigned, as amended, to Alkermes, Inc. in July 2006). #\*\*\*\*\*
- 21.1 Subsidiaries of Alkermes, Inc..#
- 23.1 Consent of Independent Registered Public Accounting Firm PricewaterhouseCoopers 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.

---

**Table of Contents**

- \*\*\* 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.
  - \*\*\*\*\* Confidential treatment status has been requested as to certain portions thereof, which portions are omitted and filed separately with the Securities and Exchange Commission.
- + Indicates a management contract or any compensatory plan, contract or arrangement.
- # Filed herewith.