ALKERMES INC
Form 10-K
May 20, 2011

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

Form 10-K

(Mark One)

þ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the fiscal year ended March 31, 2011

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	**23-2472830**
(State or other jurisdiction of incorporation or organization)	*(I.R.S. Employer Identification No.)*
852 Winter Street, Waltham Massachusetts	**02451-1420**
(Address of principal executive offices)	*(Zip code)*

(781) 609-6000
(Registrant s telephone number, including area code)
Securities registered pursuant to Section 12(g) of the Act:

Common Stock, $0.01 par value Series A Junior Participating Preferred Stock Purchase Rights	The NASDAQ Stock Market LLC
Title of each class	**Name of each 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 þ No o

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 o No þ

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 þ No o

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§ 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 þ No o

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 the 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. þ

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 þ	Accelerated filer o	Non-accelerated filer o (Do not check if a smaller reporting company)	Smaller Reporting company o

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

The aggregate market value of the registrant s common stock held by non-affiliates of the registrant (without admitting that any person whose shares are not included in such calculation is an affiliate) computed by reference to the price at which the common stock was last sold as of the last business day of the registrant s most recently completed second fiscal quarter was $1,372,950,388.

As of May 13, 2011, 95,731,976 shares of common stock were issued and outstanding and 382,632 shares of non-voting common stock were issued and outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the definitive proxy statement for our Annual Shareholders Meeting for the fiscal year ended March 31, 2011 are incorporated by reference into Part III of this report.

ALKERMES INC. AND SUBSIDIARIES

ANNUAL REPORT ON FORM 10-K
FOR THE FISCAL YEAR ENDED MARCH 31, 2011

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EX-101 DEFINITION LINKBASE DOCUMENT

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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; and 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 on Form 10-K 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 expectations regarding the initiation, timing and results of clinical trials, including the thorough QT study, and data reporting;
- our expectation and timeline for regulatory approval of the New Drug Application, or NDA, submission and the Marketing Authorization Application for BYDUREON™ (exenatide extended-release for injectable suspension) and, if approved, the commercialization of BYDUREON by Amylin Pharmaceuticals, Inc., or Amylin, and Eli Lilly & Co., or Lilly;
- 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 health care reform legislation and foreign currency exchange rate fluctuations and valuations;
- the proposed merger transaction with Elan Corporation, plc;
- 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 Item 1A Risk Factors in this Annual Report. The forward looking statements contained and incorporated herein represent our judgment as of the date of this Annual Report, and

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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 Annual Report.

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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.

Overview

Alkermes, Inc. (as used in this section, together with our subsidiaries, us , we , our or the Company) is a fully integra biotechnology company committed to developing innovative medicines to improve patients lives. We are headquartered in Waltham, Massachusetts and have a research facility in Massachusetts and a commercial manufacturing facility in Ohio. We leverage our formulation expertise and proprietary product platforms to develop, both with partners and on our own, innovative and competitively advantaged medications that can enhance patient outcomes in major therapeutic areas. Our robust pipeline includes extended-release injectable and oral products for the treatment of prevalent, chronic diseases, such as central nervous system (CNS) diseases, reward disorders, addiction, diabetes and autoimmune disorders.

On May 9, 2011, we and Elan Corporation, plc, or Elan, a public limited company incorporated in Ireland, announced the signing of a definitive Business Combination Agreement and Plan of Merger, or Merger Agreement, pursuant to which Alkermes and the global drug delivery technologies business of Elan, known as Elan Drug Technologies, or EDT, will be combined under New Alkermes, a new holding company incorporated in Ireland that will be re-registered as a public limited company, and renamed Alkermes, plc, at or prior to the completion of the business combination. At the conclusion of the merger, the former shareholders of Alkermes will own approximately 75% of Alkermes, plc, with the remaining approximately 25% of Alkermes, plc owned by a wholly owned subsidiary of Elan, subject to the terms of a shareholder s agreement to be entered into at the effective time of the merger by and among such Elan subsidiary, Alkermes, and Elan. As an additional payment for EDT, Alkermes will also pay Elan $500 million in cash, subject to certain net cash and working capital adjustments. We have obtained a commitment from Morgan Stanley & Co. Incorporated, or Morgan Stanley, and HSBC Securities (USA) Inc., or HSBC, to provide up to $450 million in term loan financing which, in addition to existing cash and investment balances, will comprise the cash consideration to Elan. Under the terms of the shareholder s agreement and subject to certain conditions, upon the closing of the merger, Elan will have the right to designate one person for election to the Alkermes, plc board of directors, will agree to vote in a manner consistent with the recommendations of the Alkermes, plc s board of directors, and will be subject to a standstill provision and certain other restrictions on its ability to transfer Alkermes, plc shares without the consent of Alkermes plc. This transaction, which has been approved by our board of directors and the board of directors of Elan, is subject to customary closing conditions including approval of our stockholders and customary regulatory approvals. Please reference our filings with the Securities and Exchange Commission, or SEC, including our Current Report on Form 8-K filed with the SEC on May 9, 2011, for more information relating to the merger transaction, including a description of the material terms of the Merger Agreement and Shareholder s Agreement.

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.

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Products and Development Programs

RISPERDAL CONSTA

RISPERDAL CONSTA long-acting injection is a long-acting formulation of risperidone, a product of Janssen, and is the first and only long-acting, atypical antipsychotic approved by the U.S. Food and Drug Administration, or FDA, for the treatment of schizophrenia and for the treatment of bipolar I disorder. The medication uses polymer-based microsphere 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 sold in more than 90 countries, 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. 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.

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. Bipolar disorder is a brain disorder that causes unusual shifts in a person s mood, energy and ability to function. It is often characterized by debilitating mood swings, from extreme highs (mania) to extreme lows (depression). Bipolar I disorder is characterized based on the occurrence of at least one manic episode, with or without the occurrence of a major depressive episode. Bipolar disorder is believed to affect approximately 5.7 million American adults, or about 2.6% of the U.S. population age 18 and older in a given year. The median age of onset for bipolar disorder 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%, 83% and 46% of total net revenues for the fiscal years ended March 31, 2011, 2010 and 2009, respectively. See Collaborative Arrangements below for information about our relationship with Janssen.

VIVITROL

VIVITROL, an extended-release formulation of naltrexone, is the first and only once-monthly injectable medication for the treatment of alcohol dependence and the prevention of relapse to opioid dependence, following opioid detoxification. The medication uses polymer-based microsphere injectable extended-release technology to deliver and maintain therapeutic medication levels in the body through just one injection every four weeks. We developed, and currently market and sell, VIVITROL in the U.S.

VIVITROL was approved by the FDA for the treatment of alcohol dependence in April 2006 and was launched in the U.S. for this indication in June 2006. 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.

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The FDA approved VIVITROL for the prevention of relapse to opioid dependence, following opioid detoxification, in October 2010. Opioid dependence is 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 the pivotal phase 3 clinical trial, when used in combination with psychosocial support, VIVITROL demonstrated statistically significant higher rates of opioid-free urine tests, compared to patients treated with placebo, as measured by the cumulative distribution of opioid-free urine tests. Thirty-six percent of patients on VIVITROL sustained complete abstinence during the evaluation phase of the trial, as compared to 23% of patients on placebo. In addition, a greater percentage of patients in the VIVITROL group remained in the study compared to the placebo group.

In December 2007, we exclusively licensed the right to commercialize VIVITROL for the treatment of alcohol dependence and opioid dependence in Russia and other countries in the Commonwealth of Independent States (CIS), to Cilag. In August 2008, the Russian regulatory authorities approved VIVITROL for the treatment of alcohol dependence and Cilag launched VIVITROL in Russia in March 2009. The Russian regulatory authorities approved VIVITROL for the treatment of opioid dependence in April 2011.

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. 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, two commonly used oral diabetes medications, and in December 2006 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.

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.

In April 2010, 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. In April 2011, we, Lilly and Amylin announced that the Committee for Medicinal Products for Human Use, or CHMP, of the EMA has issued a positive opinion recommending approval of BYDUREON in the European Union, or EU, for the treatment of type 2 diabetes in combination with certain oral therapies. Our application to the European regulatory authorities seeks approval of BYDUREON as a once-weekly 2 mg dose for the treatment of type 2 diabetes in combination with metformin, a sulfonylurea, a thiazolidinedione, metformin plus a sulfonylurea or metformin plus a thiazolidinedione. The CHMP s positive opinion is now referred for final action by the European Commission, which has the authority to approve medicines for the EU. The Commission usually makes a decision on CHMP recommendations within two to three months.

The NDA for BYDUREON was submitted in May 2009. The FDA issued complete response letters to Amylin in March 2010 and in October 2010. In the October 2010 complete response letter the FDA requested a thorough QT, or tQT, study and the submission of the results of the DURATION-5 clinical study to evaluate the efficacy, and the labeling of the safety and effectiveness, of the commercial formulation of BYDUREON.

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In January 2011, Amylin announced that the FDA provided written approval of Amylin s study design for a tQT study for BYDUREON and that, with the approval of the study design, Amylin commenced the study in February 2011 and submit the results of the study to the FDA in the second half of calendar year 2011.

In March 2011, Amylin, Lilly and we announced top-line results from DURATION-6, a head-to-head study designed to compare BYDUREON to daily VICTOZA® (liraglutide (rDNA origin) injection). Both drugs are members of the class of type 2 diabetes medications known as glucagon-like peptide-1, or GLP-1, receptor agonists. This open-label 26-week, multicenter clinical study compared BYDUREON (2 mg weekly) to VICTOZA administered at the maximum approved dose of 1.8 mg daily. The study was designed to measure A1C, an assessment of average blood sugar, and to evaluate safety and tolerability. Results showed that patients receiving BYDUREON experienced a reduction in A1C of 1.3 percentage points from baseline, compared to a reduction of 1.5 percentage points for VICTOZA. BYDUREON did not meet the pre-specified primary endpoint of non-inferiority to VICTOZA. More than 85 percent of patients in both treatment arms completed the study. Gastrointestinal adverse events occurred more frequently among VICTOZA patients (nausea reported among 20% of patients, vomiting 11%, diarrhea 13%) compared with BYDUREON patients (nausea 9%, vomiting 4%, diarrhea 6%). Injection site nodule occurred more frequently among BYDUREON users (10%) compared with VICTOZA users (1%). There were no major hypoglycemia events in either treatment group.

Also, in March 2011, Amylin, Lilly and we announced positive results from a phase 2 study evaluating the effects of a once-monthly injectable suspension formulation of exenatide on glycemic control in patients with type 2 diabetes. The 121-patient, phase 2 study assessed the efficacy, safety and tolerability of three different doses of exenatide once monthly. It also assessed once-weekly BYDUREON. After 20 weeks of treatment (five injections), patients randomized to the exenatide once-monthly treatment arms experienced average reductions in A1C ranging between 1.3 and 1.5 percentage points from baseline. In the once-weekly BYDUREON treatment arm, the reduction was 1.5 percentage points. A1C is a measure of average blood sugar over three months. More than 90% of patients overall completed the study. The most common adverse events among the exenatide once monthly treatment groups were headache and nausea. Headache and diarrhea were most common among the once-weekly BYDUREON group. No major or minor hypoglycemia was reported in the study.

ALKS 33

ALKS 33 is an oral opioid modulator that we are developing for the potential treatment of addictions and other CNS disorders.

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 cocaine addiction and mood disorders. Binge-eating disorder is characterized by recurrent binge eating episodes during which a person feels a loss of control over his or her eating. Unlike bulimia, binge-eating episodes are not followed by purging, excessive exercise or fasting. As a result, people with binge-eating disorder often are overweight or obese. It is estimated that approximately 1% to 2% of Americans suffer from binge-eating disorder. We expect to report topline results from a phase 2 study of ALKS 33 for binge eating in mid-calendar year 2011.

In October 2010, we announced positive topline results from a randomized, double-blind, multi-dose, placebo-controlled phase 1 clinical study that assessed the safety, tolerability and pharmacodynamic effects of the combination of ALKS 33 and buprenorphine when administered alone, and in combination, to 12 opioid-experienced users. Data from the study showed that the combination therapy was generally well-tolerated and sublingual administration of ALKS 33 effectively blocked the agonist effects of buprenorphine. Based on these positive results, we expect to initiate a phase 2a study of the combination therapy for the treatment of cocaine addiction in midyear 2011. This phase 2a study is expected to be funded through a grant from the National Institute on Drug Abuse

(NIDA). NIDA has granted us up to $2.4 million to accelerate the clinical

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development of the ALKS 33 and buprenorphine combination therapy. Currently, there are no medications approved for the treatment of cocaine addiction.

In December 2010, we announced preliminary results from a phase 2 study of ALKS 33 designed to assess the safety and efficacy of daily oral administration of three different dose levels of ALKS 33 compared to placebo in 400 alcohol dependent patients. The safety, dose response and efficacy profile demonstrated in the study support the unique pharmacologic properties of ALKS 33 and the further development of ALKS 33 for reward disorders and other central nervous system disorders.

In January 2011, we announced that ALKS 33, in combination with buprenorphrine, is being studied for treatment-resistant depression (TRD). TRD, which is also known as refractory depression, refers to depressive episodes that are not adequately controlled by standard antidepressant therapy. Depression is a serious and chronic disease that affects more than 20 million American adults each year, and finding the right treatment can be difficult for many patients. Approximately half of those patients treated for depression have an inadequate response to monotherapy, and as many as 20% have chronic depression despite multiple interventions. We plan to file an Investigational New Drug application (IND) in the second half of calendar year 2011 and initiate a phase 1/2 trial by the end of calendar year 2011.

ALKS 37

We are developing ALKS 37, an orally active, peripherally-restricted opioid antagonist for the treatment of opioid-induced constipation, or OIC. According to IMS Health, an estimated 266 million prescriptions were written for opioids in the U.S. during calendar year 2010. Many studies indicate that a high percentage of patients receiving opioids are likely to experience side effects affecting gastrointestinal motility. OIC can be severe and adversely impact quality of life, compromising patient compliance with opioid therapy for pain management.

In February 2011, we announced positive preliminary results from a multicenter, randomized, double-blind, placebo-controlled, multi-dose phase 2 study designed to evaluate the efficacy, safety and tolerability of ALKS 37 in 87 patients with OIC. Data from the study showed that ALKS 37 significantly improved gastrointestinal motility and increased the frequency of bowel movements in patients with OIC, while simultaneously preserving the analgesic effects of opioid treatment. The study also demonstrated that ALKS 37 was generally well tolerated with limited systemic exposure and bioavailability. Based on these results, Alkermes plans to advance ALKS 37 into an expanded development program in mid calendar 2011.

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^{tm} product platform discussed below. Aripiprazole is commercially available under the name ABILIFY® for the treatment of a number of CNS disorders. We commenced a phase 1/2 clinical study for ALKS 9070 for the treatment of schizophrenia and expect to report top-line data from the study of ALKS 9070 in the first half of calendar year 2011.

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.

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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 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. Pursuant to the development and license agreement, Amylin has an exclusive, worldwide license to our polymer-based microsphere 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. 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 (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.

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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 terms of the development and license agreement, as amended, filed with our Annual Report on Form 10-K for the fiscal year ended March 31, 2010.

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.

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 (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.

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Acceleron

In December 2009, we entered into a collaboration and license agreement with Acceleron, 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, 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. 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 elect to develop resulting from the platform. Acceleron will retain all rights to the technology for products derived from the TGF-beta superfamily.

Our initial $8.0 million equity investment in Acceleron consisted of shares of Series D-1 convertible, redeemable preferred stock. In July 2010, we invested an additional $0.5 million in exchange for shares of Series E convertible, redeemable preferred stock and common stock warrants. 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.

Other Arrangements

Civitas

In December 2010, we entered into an asset purchase and license agreement and equity investment agreement with Corregidor Therapeutics, Inc. (later renamed Civitas Therapeutics, Inc.) (Civitas). Under the terms of these agreements, we sold, assigned, transferred and licensed to Civitas our right, title and interest in our pulmonary patent portfolio and certain of our pulmonary drug delivery equipment, instruments, contracts and technical and regulatory documentation in exchange for 15% of the issued shares of the Series A Preferred Stock of Civitas and a royalty on future sales of any products developed using this pulmonary drug delivery technology. Civitas also entered into an agreement to sublease our pulmonary manufacturing facility located in Chelsea, Massachusetts and has an option to purchase our pulmonary manufacturing equipment located at this facility. In addition, we have a seat on the Civitas board of directors.

Commencing six months after its effective date, Civitas may terminate the asset purchase and license agreement for any reason upon 90 days written notice to us. We may terminate the asset purchase and license agreement for default in the event Civitas does not meet certain minimum development performance obligations. Either party may terminate the asset purchase and license agreement upon a material default or breach by the other party that is not cured within 45 days after receipt of written notice specifying the default or breach.

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.

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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 (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.

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.

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 (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.

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 (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

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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 for VIVITROL in the U.S. consists of approximately 65 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, 2011, to McKesson Corporation, AmerisourceBergen Drug Corporation, Cardinal Health and ASD Specialty Healthcare Inc., represented approximately 21%, 14%, 14% and 11%, respectively, of total VIVITROL sales.

Effective April 1, 2009, we entered into an agreement with Cardinal Health Specialty Pharmaceutical Services (Cardinal SPS), a division of Cardinal, to provide warehouse, shipping and administrative services for VIVITROL. Our expectation for fiscal year 2012 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.

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 development activities, 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/

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New Zealand, and other products currently in development. RISPERDAL CONSTA may also compete with new oral compounds being developed for the treatment of schizophrenia.

In the treatment of alcohol dependence, 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 developing product candidates that have shown some promise in treating alcohol dependence and that, if approved by the FDA, would compete with VIVITROL.

In the treatment of opioid dependence, VIVITROL competes with methadone, oral naltrexone, and SUBOXONE® (buprenorphone HCI/naloxone HCI dehydrate sublingual tablets), SUBOXONE® (buprenorphone/naloxone) Sublingual Film, and SUBUTEX® (buprenorphine HCI sublingual tablets), each of which is marketed and sold by Reckitt Benckiser Pharmaceuticals, Inc. in the U.S. Other pharmaceutical companies are developing product candidates that have shown promise in treating opioid dependence and that, if approved by the FDA, would compete with VIVITROL.

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 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. 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 85 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 11 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 are responsible for patent expenses, and we pay annual license fees and/or minimum annual royalties. During the year ended March 31, 2011, these fees totaled approximately $0.5 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. The 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

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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, cash flows and financial condition could be materially adversely affected.

Government Regulation

Overview

Our current and contemplated activities, and the products and processes that result from such activities, are subject to substantial government regulation. Before new pharmaceutical products may be sold in the U.S. and other countries, clinical trials of the products must be conducted and the results submitted to appropriate regulatory agencies for approval. The regulatory approval process requires a demonstration of product safety and efficacy and the ability to effectively manufacture such product. Generally, such demonstration of safety and efficacy includes preclinical testing and clinical trials of 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.

United States: FDA Process

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

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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 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.

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 (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 the FDA may extend that deadline in certain

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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 Risk Evaluation and Mitigation Strategy, or 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 the publication and provision to patients of a medication guide or 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. Changes to an approved product, such as 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, legislation enacted in 2007 provides the FDA with expanded authority over drug products after approval. This legislation enhanced 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, or 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 a 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

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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 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 Cosmetic 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.

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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 a 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.

Good Clinical Practices

The FDA, the EMA and other regulatory agencies promulgate regulations and standards, commonly referred to as Good Clinical Practices, or GCP, 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 GCP through periodic inspections of trial sponsors, principal investigators and trial sites. If our study sites fail to comply with applicable GCP, 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

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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 materially harmed. In addition, under certain federal laws and many state laws, there is the 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.

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.

The U.S. and foreign governments regularly consider reforming health care coverage and costs. Such reform may include changes to the coverage and reimbursement of our products which may have a significant impact on our business. In 2010, significant healthcare reform legislation was enacted in the U.S., which has had and will continue to have an impact our business by:

- expanding the coverage of and increasing the rate of rebates on sales of our products, including (1) increasing the Medicaid rebate from 15.1% to 23.1% of the average manufacturer price, or AMP, on branded prescription drugs, (2) extending the Medicaid rebate to Medicaid managed care organizations, and (3) expanding the 340B Public Health Service, or PHS, drug pricing program, which provides outpatient drugs at reduced rates, to include additional hospitals, clinics, and healthcare centers;

- requiring drug manufactures to provide a 50% discount to Medicare beneficiaries whose prescription drug costs cause them to be subject to the Medicare Part D coverage gap (i.e. the donut hole);

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assessing a new fee allocated to all manufacturers and importers of branded prescription drugs paid for pursuant to coverage provided under specified government programs; and

changing the calculation of AMP for injectable drugs not generally dispensed through retail community pharmacies, which is generally expected to increase AMP.

Considerable uncertainty remains surrounding determinations necessary to implement the new legislation. For example, in November 2010 the Centers for Medicare and Medicaid Services, or CMS, amended and then withdrew current regulations governing calculation of AMP; however, no replacement regulations have been proposed.

Medicare is a federal program that is administered by the federal government that covers individuals age 65 and over as well as those with certain disabilities. Medicare Part B pays physicians who administer our products under a payment methodology using average sales price, or ASP, information. Manufacturers, including us, are required to provide ASP information to CMS on a quarterly basis. This information is used to compute Medicare payment rates, which are generally set at ASP plus 6% and are updated quarterly. 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. Effective January 1, 2006, Medicare began to use the same ASP plus 6% payment methodology to determine Medicare rates paid for products furnished by hospital outpatient departments. As of January 1, 2009, the reimbursement rate in the hospital outpatient setting was ASP plus 4%. The reimbursement rate in the hospital outpatient setting was increased to ASP plus 5% effective January 1, 2011. 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.

The Medicare Prescription Drug Improvement and Modernization Act of 2003 established the Medicare Part D program to provide voluntary prescription drug benefit to enrolled Medicare patients. This is a voluntary benefit that is being 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. Medicaid is a joint federal and state program that is administered by the states for low income and disabled beneficiaries. Under the Medicaid rebate program, we are required to pay a rebate for each unit of product reimbursed by the state Medicaid programs. The amount of the rebate for each product is set by law as 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. In addition, the health care reform legislation enacted in March 2010 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, impact the calculation of AMP for certain drugs. 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, is less than the AMP for the current quarter with the upward adjustment equal to the excess amount. 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.

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 PHS as well as hospitals that serve a disproportionate share of poor Medicare beneficiaries.

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We also make our products available for purchase by authorized users of the Federal Supply Schedule (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 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.

Under the 2008 National Defense Authorization Act, we are required to treat the TRICARE retail pharmacy program, which reimburses military personnel for drug purchases from retail pharmacies, as an element of the Department of Defense to ensure the application of the VHC Act s pricing standards.

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 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.

Employees

As of May 13, 2011, we had approximately 600 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. 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

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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.

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 commercialization 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

We assumed responsibility for the marketing and sale of VIVITROL in the U.S. from Cephalon in December 2008, with Cephalon providing certain transition services to us until May 2009. VIVITROL is our first commercial product for which we have had sole responsibility for commercialization, including but not limited to sales, marketing, distribution and reimbursement-related activities. We have little commercialization experience. 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 their cost effectiveness, our business, results of operations, cash flows and financial condition could be materially adversely affected. In addition, there exist numerous factors, many of which are outside of our control, including but not limited to those specified below, that may materially impact the revenues received or to be received from the sale of VIVITROL.

Cilag has primary responsibility for securing all necessary regulatory approvals for VIVITROL in Russia and other countries of the CIS, and Janssen-Cilag, an affiliate of Cilag, has full responsibility for the commercialization of the product in these countries. We receive manufacturing revenues and royalty revenues based upon product sales. The revenues received or to be received from the sale of VIVITROL in Russia and countries of the CIS 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.

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BYDUREON

Pursuant to our arrangements with Amylin, we are not 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 BYDRUEON. Amylin has an agreement with Lilly for the development and commercialization of exenatide, including BYDUREON. Our revenues will depend on royalties we receive from our partner for BYDUREON, which relate directly to sales of BYDUREON by Amylin and Lilly. On May 16, 2011, Amylin announced that it had filed a lawsuit against Lilly in the United States District Court for the Southern District of California alleging that Lilly is engaging in anti-competitive activity and breaching its strategic alliance agreements with Amylin to maximize commercialization of exenatide. For this and other 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 products 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;

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;

disputes among our collaborators relating to the marketing and sale of partnered products;

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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 partner, or adverse regulatory or legislative developments, would have a material adverse effect on our business, results of operations, cash flows and financial condition. Although we have developed and continue to develop additional products for commercial introduction, we expect to be substantially dependent on sales from this product. A decline in sales from this product would adversely affect our business.

We rely heavily on collaborative partners.

Our arrangements with collaborative partners are critical to bringing our products to the market and successfully commercializing such marketed products. We rely on these parties in various respects, including to conduct preclinical testing and clinical trials; to provide funding for product candidate development programs; to provide 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 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, cash flows 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 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

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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 sickness 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 money, and may not be successful.

Our manufacturing facility requires specialized personnel and is 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 our facility will require us to continue to operate it and retain specialized personnel, which may cause operating losses.

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. If reimbursement for our products changes adversely or if we fail to obtain adequate reimbursement for our current or future products, including the existence of barriers to coverage of our products (such as prior authorization, criteria for use or other requirements), 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.

Further, when a new product, or a new indication for an existing 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 products, and current reimbursement policies for our marketed products may change at any time.

The U.S. Congress recently enacted legislation to reform the health care system. This legislation imposes cost containment measures that have adversely affected the amount of reimbursement for our products. These measures include increasing the minimum rebates we pay to state Medicaid programs for our drugs covered by Medicaid programs; extending such rebates to drugs dispensed to Medicaid beneficiaries enrolled in Medicaid managed care organizations; and expanding the 340B Public Health Service drug discount program under which we are obligated to provide certain discounts on our drugs to certain purchasers. Additional provisions of the health care reform legislation, which became effective in 2011, may negatively affect our revenues and prospects for profitability in the future. Beginning in 2011, a new fee will be payable by all branded prescription drug manufacturers and importers. This fee will be calculated based upon each organization s percentage share of total branded prescription drugs sales to qualifying U.S. government programs, including Medicare and Medicaid. As part of the health care reform

legislation s provisions closing a coverage gap that currently exists in the Medicare Part D prescription drug program (commonly known as the donut hole), we will also be required to provide a 50% discount on brand name prescription drugs sold to beneficiaries who fall within the donut hole.

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Economic pressure on state budgets may result in states increasingly seeking to achieve budget savings through mechanisms that limit coverage or payment for our drugs. 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. Managed care organizations continue to seek price discounts and, in some cases, to impose restrictions on the coverage of particular drugs. 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, including non-governmental managed care organizations, influencing prescription decisions for a larger segment of the population and a corresponding constraint on prices and reimbursement for our products. It is likely that federal and state legislatures and health agencies will continue to focus on additional health care reform in the future. We are unable to predict the nature of such legislation and what effect it would have 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 patients and 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.

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, or 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.

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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.

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.

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 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;

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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 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 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

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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, 2011, our accumulated deficit was $411.2 million, which is primarily the result of net losses incurred from 1987, the year we were founded, through March 31, 2011, 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 commercialize, 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 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 products;
- support the commercialization of RISPERDAL CONSTA by our partner Janssen;
- successfully commercialize VIVITROL in the U.S.;
- support the commercialization 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.

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 our product candidates and for our partnered product candidates, including clinical trials;
- the time and expense that will be required to pursue FDA and/or foreign regulatory approvals for our products 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;

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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 commercialization 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 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 RISPERDAL 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;

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- 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. 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, cash flows 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;

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

changes in the tax laws relating to our operations.

The enactment in the U.S. of health care reform, new legislation or implementation of existing statutory provisions on importation of lower-cost competing drugs from other jurisdictions, and legislation on comparative effectiveness research are examples of previously enacted and possible future changes in laws that could adversely affect our business.

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. Whether or not we have complied with the law, an investigation into alleged unlawful conduct could increase our expenses, damage our reputation, divert management time and attention and adversely affect our business. Recent changes in U.S. fraud and abuse laws have strengthened government regulation, increased the investigative powers of government enforcement agencies, and enhanced penalties for non-compliance.

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,

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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, cash flows and financial condition could be materially adversely affected.

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

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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 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, cash flows 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.

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. Our products or product candidates may cause or contribute to injury or dangerous drug interactions, and we may not learn about or understand those effects until the product or product candidate has been administered to patients for a prolonged period of time. Claims for or from such injuries or interactions, 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 products. We may not be successful in defending ourselves in the litigation and, as a result, our business could be materially harmed. These lawsuits may result in large judgments or settlements against us, any of which could have a negative effect on our financial condition and business if in excess of our insurance coverage. Additionally, lawsuits can be expensive to defend, whether or not they have merit, and the defense of these actions may divert the attention of our management and other resources that would otherwise be engaged in managing our business.

Additionally, product recalls may be issued at our discretion or at the direction of the FDA, other government agencies or other entities 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, cash flows 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.

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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, cash flows 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, cash flows and financial condition.

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

We can provide no assurance that we will be able to compete successfully in commercializing our products.

We face intense competition in the development, manufacture, marketing and commercialization of our products and product candidates from many and varied sources, such as 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, who control the commercialization of products for which we receive manufacturing and royalty revenues. 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

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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 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.

In the treatment of alcohol dependence, 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 developing product candidates that have shown some promise in treating alcohol dependence and that, if approved by the FDA, would compete with VIVITROL.

In the treatment of opioid dependence, VIVITROL competes with methadone, oral naltrexone, and SUBOXONE, SUBOXONE Sublingual Film, and SUBUTEX, each of which is marketed and sold by Reckitt Benckiser Pharmaceuticals, Inc. in the U.S. Other pharmaceutical companies are developing product candidates that have shown promise in treating opioid dependence and that, if approved by the FDA, would compete with VIVITROL.

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 A/S, 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, cash flows 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 RISPERDAL CONSTA, VIVITROL, BYDUREON and our product candidates may not generate significant revenues.

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.

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

If we are unable to successfully integrate the companies, businesses or properties that we acquire, we could experience a material adverse effect on our business, financial condition or results of operations. Merger and acquisition transactions, including the proposed merger with Elan Drug Technologies, or EDT, involve various inherent risks, including:

- uncertainties in assessing the value, strengths, and potential profitability of, and identifying the extent of all weaknesses, risks, contingent and other liabilities of, the respective parties;
- the potential loss of key customers, management and employees of an acquired business;
- the consummation of financing transactions, acquisitions or dispositions and the related effects on our business, including financing related to our proposed transaction with EDT;
- the ability to achieve identified operating and financial synergies from an acquisition in the amounts and on the timeframe;
- problems that could arise from the integration of the respective businesses, including the application of internal control processes to the acquired business; and
- unanticipated changes in business, industry, market, or general economic conditions that differ from the assumptions underlying our rationale for pursuing the transaction.

Any one or more of these factors could cause us not to realize the benefits anticipated from a transaction.

Moreover, any acquisition opportunities we pursue could materially affect our liquidity and capital resources and may require us to incur indebtedness, seek equity capital or both. Future acquisitions could also result in our assuming more long-term liabilities relative to the value of the acquired assets than we have assumed in our previous acquisitions. Further, acquisition accounting rules require changes in certain assumptions made subsequent to the measurement period as defined in current accounting standards, to be recorded in current period earnings, which could affect our results of operations.

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

If additional equity securities or securities convertible into equity securities are issued to raise funds or as part of a merger, acquisition, or other transaction, 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, 2011, we were obligated to issue 18,910,524 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.

We and Elan must obtain required approvals and governmental and regulatory consents to complete the merger, which, if delayed, not granted or granted with unacceptable conditions, may jeopardize or delay the merger, result

in additional expenditures of money and resources and/or reduce the anticipated benefits of the merger.

The merger with EDT is subject to customary closing conditions. These closing conditions include, among others, the receipt of required approvals of our shareholders, the effectiveness of the registration statement and the expiration or termination of all waiting periods under applicable antitrust laws, including the applicable waiting periods under the Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended, (HSR Act) and foreign antitrust laws.

The governmental agencies from which the parties will seek these approvals have broad discretion in administering the governing regulations. As a condition to their approval of the merger, agencies may impose

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requirements, limitations or costs or require divestitures or place restrictions on the conduct of our business after consummation of the merger. These requirements, limitations, costs, divestitures or restrictions could jeopardize or delay the consummation of the merger or may reduce the anticipated benefits of the business combination. Further, no assurance can be given that the required shareholder approval will be obtained, that the related Registration Statement on Form S-4 will be declared effective or that the required closing conditions will be satisfied, and, if all required consents and approvals are obtained and the closing conditions are satisfied, no assurance can be given as to the terms, conditions and timing of the approvals. If we and Elan agree to any material requirements, limitations, costs, divestitures or restrictions in order to obtain any approvals required to consummate the merger, these requirements, limitations, costs, divestitures or restrictions could adversely affect our ability to integrate our operations with EDT operations or reduce the anticipated benefits of the merger. This could result in a failure to consummate the merger or have a material adverse effect on our business and results of operations.

We may fail to realize benefits estimated as a result of the merger.

The success of our merger with Elan Drug Technologies will depend, in part, on our ability to realize the anticipated synergies, business opportunities and growth prospects from combining our business with that of EDT. We may never realize these anticipated synergies, business opportunities and growth prospects. Integrating operations will be complex and will require significant efforts and expenditures. Employees might leave or be terminated because of the merger. Our management might have its attention diverted while trying to integrate operations and corporate and administrative infrastructures. Assumptions underlying estimates of expected cost savings may be inaccurate and general industry and business conditions might deteriorate. If any of these factors limit our ability to integrate our operations with those of EDT successfully or on a timely basis, the expectations of future results of operations, including certain cost savings and synergies expected to result from the merger, might not be met.

Our merger agreement with Elan requires payment of a termination fee of up to $25 million in certain instances, which could deter a third party from proposing an alternative transaction to the merger.

Under the terms of our merger agreement with Elan, we may be required to pay to Elan a termination fee of up to $25 million if the Merger Agreement is terminated in specified circumstances. The effect of this termination fee may discourage competing bidders from presenting proposals to acquire or merge with us that, from a financial perspective, might be superior to the terms of the merger. Our financial position and results of operations would be adversely affected if we were required to pay the termination fee to Elan.

Our level of indebtedness following consummation of the merger transaction could adversely affect our business and limit our ability to plan for or respond to changes in our business.

Pursuant to our merger agreement with Elan, we will pay Elan $500 million in cash, subject to certain net cash and working capital adjustments. We have obtained a commitment, subject to customary conditions, from Morgan Stanley and HSBC to provide up to $450 million in term loan financing. Our level of indebtedness following consummation of the merger transaction with Elan could adversely affect our business by, among other things:

- requiring us to dedicate a substantial portion of our cash flow from operations to payments on our indebtedness, thereby reducing the availability of our cash flow for other purposes, including business development efforts and research and development;

- limiting our flexibility in planning for, or reacting to, changes in our business and the industry in which we operate, thereby placing us at a competitive disadvantage compared to our competitors that may have less debt; and

increasing our vulnerability to adverse economic and industry conditions.

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

The successful commercialization of our products is dependent, in large part, on reimbursement from government health administration authorities and private health insurers. 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.

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;

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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 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 shareholders.

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.

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

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which could have a material adverse effect on our business, results of operations, cash flows and financial condition.

Item 1B. ***Unresolved Staff Comments***

None.

Item 2. ***Properties***

We lease approximately 115,000 square feet of space in Waltham, Massachusetts, which houses our principal executive offices, administrative areas and laboratories. This lease expires in 2020 and has an option to extend the term for up to two five-year periods.

We own a 15-acre manufacturing, office and laboratory site in Wilmington, Ohio. The site produces RISPERDAL CONSTA, VIVITROL and polymer for BYDUREON. 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.

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. We also have a sublease agreement in place for a commercial manufacturing facility we lease 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. As we are not currently utilizing these facilities, we have no plans to extend the Cambridge or Chelsea leases beyond their 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, cash flows and financial condition.

Item 4. ***[Removed and Reserved]***

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PART II

Item 5. ***Market for Registrant s Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities***

Market and Shareholder 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:

	Fiscal 2011		Fiscal 2010	
	High	Low	High	Low
1st Quarter	$ 13.87	$ 9.81	$ 12.33	$ 7.41
2nd Quarter	15.10	11.90	11.77	8.64
3rd Quarter	16.10	9.85	10.08	7.54
4th Quarter	14.75	11.86	14.19	9.47

There were 306 shareholders of record for our common stock and one shareholder of record for our non-voting common stock on May 13, 2011. In addition, the last reported sale price of our common stock as reported on the NASDAQ Global Select Stock Market on May 13, 2011 was $17.76.

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.

Securities authorized for issuance under equity compensation plans

For information regarding securities authorized for issuance under equity compensation plans, see Part III, Item 12. Security Ownership of Certain Beneficial Owners and Management, which incorporates by reference to the Proxy Statement relating to our 2011 Annual Meeting of Shareholders (the 2011 Proxy Statement).

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. The repurchase program has no set expiration date and may be suspended or discontinued at any time. We did not purchase any shares during the quarter or year ended March 31, 2011. As of March 31, 2011, we have purchased a

total of 8,866,342 shares under this program at a cost of approximately $114.0 million.

In addition, during the quarter ended March 31, 2011, we acquired, by means of net share settlements, 2,393 shares of our common stock at an average price of $12.77 per share, related to the vesting of employee stock awards to satisfy withholding tax obligations.

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Stock 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 (U.S.) Index and the Nasdaq Biotechnology Index. The comparison assumes $100 was invested on March 31, 2006 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

	2006	2007	2008	2009	2010	2011
Alkermes, Inc.	100	70	54	55	59	59
NASDAQ Stock Market (U.S.) Index	100	104	97	52	82	97
NASDAQ Biotechnology Index	100	92	93	81	112	124

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Item 6. ***Selected Financial Data***

The selected historical financial data set forth below at March 31, 2011 and 2010 and for the years ended March 31, 2011, 2010 and 2009 are derived from our audited consolidated financial statements, which are included elsewhere in this Annual Report. The selected historical financial data set forth below at March 31, 2008, 2007 and 2006 and for the years ended March 31, 2008 and 2007 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.

	Year Ended March 31,				
	2011	2010	2009	2008	2007
	(In thousands, except per share data)				
Consolidated Statements of Operations Data:					
REVENUES:					
Manufacturing revenues	$ 118,521	$ 112,938	$ 116,844	$ 101,700	$ 105,416
Royalty revenues	38,319	36,979	33,247	29,457	23,151
Product sales, net	28,920	20,245	4,467		
Research and development revenue under collaborative arrangements	880	3,117	42,087	89,510	74,483
Net collaborative profit(1)		5,002	130,194	20,050	36,915
Total revenues	186,640	178,281	326,839	240,717	239,965
EXPENSES:					
Cost of goods manufactured and sold	52,185	49,438	43,396	40,677	45,209
Research and development	97,239	95,363	89,478	125,268	117,315
Selling, general and administrative	82,847	76,514	59,008	59,508	66,399
Impairment of long-lived assets(2)				11,630	
Restructuring(2)				6,423	
Total expenses	232,271	221,315	191,882	243,506	228,923
OPERATING (LOSS) INCOME	(45,631)	(43,034)	134,957	(2,789)	11,042
OTHER (EXPENSE) INCOME(3)	(860)	(1,667)	(3,945)	175,619	(499)
(LOSS) INCOME BEFORE INCOME TAXES	(46,491)	(44,701)	131,012	172,830	10,543
(BENEFIT) PROVISION FOR INCOME TAXES	(951)	(5,075)	507	5,851	1,098

NET (LOSS) INCOME	$ (45,540)	$ (39,626)	$ 130,505	$ 166,979	$ 9,445
(LOSS) EARNINGS PER COMMON SHARE:					
BASIC	$ (0.48)	$ (0.42)	$ 1.37	$ 1.66	$ 0.10
DILUTED	$ (0.48)	$ (0.42)	$ 1.36	$ 1.62	$ 0.09
WEIGHTED AVERAGE NUMBER OF COMMON SHARES OUTSTANDING:					
BASIC	95,610	94,839	95,161	100,742	99,242
DILUTED	95,610	94,839	96,252	102,923	103,351
Consolidated Balance Sheet Data:					
Cash, cash equivalents and investments	$ 294,730	$ 350,193	$ 404,482	$ 460,361	$ 357,466
Total assets	452,448	515,600	566,486	656,311	568,621
Long-term debt(4)			75,888	160,371	156,898
Unearned milestone revenue current and long-term				117,657	128,750
Shareholders equity	392,018	412,616	434,888	305,314	203,461

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(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) 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.

(3) Includes a gain on the sale of our Series C convertible, redeemable preferred stock of Reliant Pharmaceuticals, Inc. (Reliant) during the year ended March 31, 2008 of $174.6 million. This gain was recorded upon the acquisition of Reliant by GlaxoSmithKline in November 2007. 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.

(4) Includes the Non-Recourse RISPERDAL CONSTA secured 7% Notes (the non-recourse 7% Notes), which were issued by RC Royalty Sub LLC, a wholly-owned subsidiary of Alkermes, Inc. (Royalty Sub) and are non-recourse to Alkermes. These notes were fully redeemed on July 1, 2010 in advance of the previously scheduled maturity date of January 1, 2012.

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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.

Executive Summary

Alkermes is a fully integrated biotechnology company committed to developing innovative medicines to improve patients lives. We are headquartered in Waltham, Massachusetts and have a research facility in Massachusetts and a commercial manufacturing facility in Ohio. We leverage our formulation expertise and proprietary product platforms to develop, both with partners and on our own, innovative and competitively advantaged medications that can enhance patient outcomes in major therapeutic areas. Our robust pipeline includes extended-release injectable and oral products for the treatment of prevalent, chronic diseases, such as CNS disorders, reward disorders, addiction, diabetes and autoimmune disorders.

In the near term, our current and future revenues are dependent upon the continued sales of our two principal products, RISPERDAL CONSTA, which we manufacture for the treatment of schizophrenia and bipolar I disorder, and VIVITROL, which we developed, manufacture and commercialize for alcohol dependence and for the prevention of relapse to opioid dependence, following opioid detoxification. RISPERDAL CONSTA and VIVITROL revenues comprised 83% and 16%, respectively, of our consolidated revenues for the year ended March 31, 2011. In the longer term, our revenue growth will be dependent upon the successful pursuit of clinical development, regulatory approval and launch of new commercial products. As part of our ongoing research and development efforts, we have devoted significant resources to conducting clinical studies to advance the development of new pharmaceutical products and to explore the utility of our existing products in treating disorders beyond those currently approved in their labels.

Net loss for the year ended March 31, 2011 was $45.5 million, or $0.48 per common share basic and diluted, as compared to a net loss of $39.6 million, or $0.42 per common share basic and diluted for the year ended March 31, 2010 and 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. As described below under Results of Operations, our operating results for the year ended March 31, 2011 reflect the following:

Manufacturing and royalty revenues from RISPERDAL CONSTA totaled $154.3 million, representing an increase of 6% over the year ended March 31, 2010. RISPERDAL CONSTA is marketed by Janssen and sold in more than 90 countries, and is exclusively manufactured by us.

Product sales, net, manufacturing and royalty revenues from VIVITROL totaled $29.2 million, representing an increase of 41% over the year ended March 31, 2010. We market VIVITROL in the U.S. and we exclusively manufacture VIVITROL and licensed the right to commercialize VIVITROL for the treatment of alcohol dependence and opioid dependence in Russia and other countries in the CIS to Cilag. In October 2010, the FDA approved VIVITROL for the prevention of relapse to opioid dependence, following opioid detoxification. In April 2011, the Russian regulatory authorities approved VIVITROL for the treatment of opioid dependence.

Total expenses increased by $11.0 million, as compared to the year ended March 31, 2010, due primarily to an increase in the number of ongoing studies and clinical trials, marketing expenses due to the start-up costs related to the commercialization of VIVITROL and employee related expenses, partially offset by savings in depreciation, relocation and occupancy savings as a result of the relocation of our corporate headquarters from

Cambridge, Massachusetts to Waltham, Massachusetts in fiscal year 2010.

In July 2010, in addition to a scheduled principal payment of $6.4 million, we redeemed the balance of our non-recourse 7% Notes in full in exchange for $39.2 million, representing 101.75% of the outstanding principal balance in accordance with the terms of the Indenture for the non-recourse

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

As previously discussed, we entered into the Merger Agreement with Elan pursuant to which we and EDT will be combined under a new holding company incorporated in Ireland that will be re-registered as a public limited company and renamed Alkermes, plc, at or prior to the completion of the business combination. At the conclusion of the merger, our former shareholders will own approximately 75% of Alkermes, plc, with the remaining 25% of Alkermes, plc, owned by a wholly owned subsidiary of Elan, subject to the terms of a shareholder s agreement to be entered into at the effective time of the merger by and among such Elan subsidiary, Alkermes and Elan. Upon closing, as an additional payment for EDT, we will also pay Elan $500 million in cash, subject to certain net cash and working capital adjustments. We have obtained a commitment from Morgan Stanley and HSBC to provide up to $450 million in term loan financing which, in addition to existing cash and investment balances, will comprise the cash consideration to Elan. This transaction, which was been approved by our board of directors and the board of directors of Elan is subject to customary closing conditions including approval of our shareholders and customary regulatory approvals.

Results of Operations

Manufacturing Revenues

	Years Ended March 31,			Change Favorable/(Unfavorable)	
	2011	2010	2009	2011-2010	2010-2009
	(In millions)				
Manufacturing revenues:					
Risperdal Consta	$ 116.1	$ 109.0	$ 112.4	$ 7.1	$ (3.4)
Polymer	2.3	3.4		(1.1)	3.4
Vivitrol	0.1	0.5	4.4	(0.4)	(3.9)
Manufacturing revenues	$ 118.5	$ 112.9	$ 116.8	$ 5.6	$ (3.9)

The increase in RISPERDAL CONSTA manufacturing revenues for the year ended March 31, 2011, as compared to the year ended March 31, 2010, was primarily due to a 16% increase in the number of units shipped to Janssen, partially offset by a 5% decrease in the net unit sales price due to foreign currency fluctuations and a 1% decrease in the net unit sales price due in part to the effect from the recently-enacted U.S. health care reform law. 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. 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.

The decrease in polymer manufacturing revenues for the year ended March 31, 2011, as compared to the year ended March 31, 2010, was due to a 33% decrease in the amount of polymer shipped to Amylin. We did not make any shipments of polymer to Amylin during the year ended March 31, 2009.

The decrease in VIVITROL manufacturing revenues for the year ended March 31, 2011, as compared to the year ended March 31, 2010, was due to a 71% decrease in the amount of VIVITROL shipped to Cilag for resale in Russia. The decrease in VIVITROL manufacturing revenues for the year ended March 31, 2010, as compared to the year ended March 31, 2009, is due to the inclusion of manufacturing revenues on product sold to Cephalon during the first eight months of the year ended March 31, 2009 under our VIVITROL collaboration with Cephalon. 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

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U.S. and began reporting sales of VIVITROL in the U.S. as Product Sales. From December 1, 2008 through March 31, 2011, VIVITROL manufacturing revenues consist solely of VIVITROL shipments to Cilag for resale in Russia.

Royalty Revenues

	Years Ended March 31,			Change Favorable/(Unfavorable)	
	2011	2010	2009	2011-2010	2010-2009
	(In millions)				
Royalty revenues	$ 38.3	$ 37.0	$ 33.2	$ 1.3	$ 3.8

Substantially all of our royalty revenues for the years ended March 31, 2011, 2010 and 2009 were related to sales of RISPERDAL CONSTA. Under our license agreements with Janssen, we record royalty revenues equal to 2.5% of Janssen s net sales of RISPERDAL CONSTA in the period that the product is sold by Janssen. Royalty revenues for the years ended March 31, 2011, 2010 and 2009 were based on RISPERDAL CONSTA sales of $1,525.6 million, $1,477.6 million and $1,324.9 million, respectively. Units sold in foreign countries by Janssen in the year ended March 31, 2011, 2010 and 2009 accounted for 83%, 79% and 77% of the total units sold, respectively.

Product Sales, net

In December 2008, upon termination of the VIVITROL collaboration with Cephalon, we assumed responsibility 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 years ended March 31, 2011 and 2010 and the period from December 1, 2008 through March 31, 2009:

	Year Ended March 31, 2011		Year Ended March 31, 2010		December 1, 2008 Through March 31, 2009	
	Amount	% of Sales	Amount	% of Sales	Amount	% of Sales
	(In millions)					
Product sales, gross	$ 39.3	100.0%	$ 24.7	100.0%	$ 6.3	100.0%
Adjustments to product sales, gross:						
Medicaid rebates	(3.1)	(8.0)%	(0.9)	(3.6)%	(0.2)	(3.2)%
Chargebacks	(2.4)	(6.1)%	(1.2)	(4.9)%	(0.1)	(1.6)%
Wholesaler fees	(1.3)	(3.3)%	(0.9)	(3.6)%		0.0%
Reserve for inventory in the channel(1)	(0.8)	(2.0)%	(0.5)	(2.0)%	(1.3)	(20.6)%
Other	(2.8)	(7.1)%	(1.0)	(4.1)%	(0.2)	(3.2)%
Total adjustments	(10.4)	(26.5)%	(4.5)	(18.2)%	(1.8)	(28.6)%

Product sales, net	$ 28.9	73.5%	$ 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.

The increase in product sales, gross for the year ended March 31, 2011, as compared to the year ended March 31, 2010, was primarily due to a 36% increase in the number of units sold into the distribution channel and a 17% increase in the sales price. The increase in Medicaid rebates as a percentage of gross sales for the year ended March 31, 2011, as compared to the year ended March 31, 2010, was primarily due to higher rebates resulting from a price increase in October 2010 and the effect from the recently-enacted U.S. health care reform law, which increased Medicaid rebates and extended Medicaid rebates to managed care

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organizations. The increase in chargebacks as a percentage of gross sales for the year ended March 31, 2011, as compared to the year ended March 31, 2010, is primarily due to VIVITROL price increases and increased Public Health Service pricing discounts.

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. 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 the sales price and a 7% increase in the number of units sold.

Research and Development Revenue Under Collaborative Arrangements

	Years Ended March 31,			Change Favorable/(Unfavorable)	
	2011	2010	2009	2011-2010	2010-2009
	(In millions)				
Research and development programs:					
BYDUREON	$ 0.6	$ 0.7	$ 9.5	(0.1)	$ (8.8)
Four-week RISPERDAL CONSTA		2.0	4.6	(2.0)	(2.6)
AIR® Insulin			26.8		(26.8)
Other	0.3	0.4	1.2	(0.1)	(0.8)
Research and development revenue under collaborative arrangements	$ 0.9	$ 3.1	$ 42.1	(2.2)	$ (39.0)

The decrease in research and development (R&D) revenues in the year ended March 31, 2011, as compared to the year ended March 31, 2010, was primarily due to the decision made by our collaborative partner, Johnson & Johnson Pharmaceutical Research and Development, L.L.C. (J&JPRD) in August 2009 not to pursue further development of a four-week formulation of RISPERDAL CONSTA. The decrease in R&D revenues in the year ended March 31, 2010, as compared to the year ended March 31, 2009, was primarily due to termination of the AIR Insulin development program in March 2008, the final revenue from which was recognized in the three months ended June 30, 2009. In addition, there was a decrease in revenues generated from the BYDUREON development program due to reduced activity as the program neared the submission of the NDA to the FDA, which occurred in May 2009.

Net Collaborative Profit

Upon the termination of the VIVITROL collaboration with Cephalon, we received $11.0 million from Cephalon to fund their share of estimated VIVITROL losses during the one-year period following December 1, 2008 (the Termination Date). We recorded the $11.0 million as deferred revenue and recognized $5.0 million and $6.0 million as revenue though the application of a proportional performance model based on net VIVITROL losses in the years ended March 31, 2010 and 2009, respectively. On the Termination Date, we also recognized $120.7 million of net collaborative profit which consisted of $113.9 million of unearned milestone revenue and $6.8 million of deferred revenue, as we had no remaining performance obligations to Cephalon and the amounts were nonrefundable.

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Cost of Goods Manufactured and Sold

	Years Ended March 31,			Change Favorable/(Unfavorable)	
	2011	2010	2009	2011-2010	2010-2009
	(In millions)				
Cost of goods manufactured and sold:					
Risperdal Consta	$ 41.0	$ 40.2	$ 31.3	$ (0.8)	$ (8.9)
Vivitrol	8.8	6.9	11.8	(1.9)	4.9
Polymer	2.4	2.3	0.3	(0.1)	(2.0)
Cost of goods manufactured and sold	$ 52.2	$ 49.4	$ 43.4	$ (2.8)	$ (6.0)

The increase in cost of goods manufactured for RISPERDAL CONSTA in the year ended March 31, 2011, as compared to the year ended March 31, 2010, was primarily due to a 16% increase in the number of units shipped to Janssen, partially offset by an 11% decrease in the unit cost of RISPERDAL CONSTA. The decrease in the unit cost of RISPERDAL CONSTA is partially due to a $1.7 million decrease in costs incurred for scrap. 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 costs incurred for scrap. 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 the increased focus on manufacturing activities, as compared to development activities, at our Ohio manufacturing facility.

The increase in cost of goods manufactured and sold for VIVITROL in the year ended March 31, 2011, as compared to the year ended March 31, 2010, was primarily due to a 19% increase in the number of units sold out of the distribution channel and $1.8 million of idle capacity charges that are the result of managing VIVITROL inventory levels by reducing manufacturing output. These increases to cost of goods manufactured and sold for VIVITROL were partially offset by a $1.8 million decrease in costs incurred for scrap in the year ended March 31, 2011, as compared to the year ended March 31, 2010. 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 scrap and reduced costs related to the restart of our manufacturing line following scheduled shutdowns.

We also began to manufacture polymer for Amylin for use in the formulation of BYDUREON during the fourth quarter of the year ended March 31, 2009. The increase in cost of goods manufactured for polymer in the year ended March 31, 2011, as compared to the year ended March 31, 2010, was primarily due to $0.8 million of idle capacity charges, partially offset by a 33% decrease in the amount of polymer shipped to Amylin.

Research and Development Expense

	Years Ended March 31,			Change Favorable/(Unfavorable)	
	2011	2010	2009	2011-2010	2010-2009
	(In millions)				

Research and development	$ 97.2	$ 95.4	$ 89.5	$ (1.8)	$ (5.9)

The increase in R&D expenses for the year ended March 31, 2011, as compared to the year ended March 31, 2010, was primarily due to an increase of $11.7 million in internal clinical and preclinical study, laboratory and license and collaboration expenses, a $7.3 million increase in professional service expense and a $7.0 million increase in employee related expenses. The increase in internal clinical and preclinical study, laboratory and license and collaboration expenses is due to an increase in the number of and composition of ongoing clinical and preclinical studies. The increase in professional service expense is primarily due to activities related to the approval of VIVITROL for opioid dependence and the increase in employee related expenses is primarily due to an increase in share-based compensation expense due to recent equity grants

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awarded with a higher grant-date fair value than older grants, as well as the exclusion of certain prior grants that have vested and are no longer included in share-based compensation expense. These increases were partially offset by $24.0 million in savings in depreciation, relocation and occupancy savings as a result of the relocation of our corporate headquarters from Cambridge, Massachusetts to Waltham, Massachusetts in fiscal year 2010.

The increase in 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 expenses under the collaboration and license agreement we signed with Acceleron. These increased 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.

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 Favorable/(Unfavorable)	
	2011	2010	2009	2011-2010	2010-2009
	(In millions)				
Selling, general and administrative	$ 82.8	$ 76.5	$ 59.0	$ (6.3)	$ (17.5)

The increase in selling, general and administrative (SG&A) expense for the year ended March 31, 2011, as compared to the year ended March 31, 2010, was primarily due to an increase in employee related expenses of $5.2 million and marketing expenses of $4.1 million, partially offset by a reduction in professional services of $3.9 million. The increase in employee related expenses is primarily due to an increase in share-based compensation as recent equity grants have been awarded with a higher grant-date fair value than older grants. The increase in marketing expenses is primarily due to costs incurred leading up to the launch of VIVITROL for opioid dependence and the decrease in professional services is primarily due to start-up costs related to the commercialization of VIVITROL for the alcohol indication during the year ended March 31, 2010, that were not incurred during the year ended March 31, 2011.

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 assumed responsibility for the marketing and sale of VIVITROL in the U.S. beginning in December 2008. Our employee related expenses 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 employee related expenses for the year ended March 31,

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2010 are $1.5 million of severance and share-based compensation expense in connection with the resignation of our former President and Chief Executive Officer in September 2009.

Other (Expense) Income

	Years Ended March 31,			Change Favorable/(Unfavorable)	
	2011	2010	2009	2011-2010	2010-2009
	(In millions)				
Interest income	$ 2.7	$ 4.7	$ 11.4	$ (2.0)	$ (6.7)
Interest expense	(3.3)	(6.0)	(13.7)	2.7	7.7
Other expense, net	(0.3)	(0.4)	(1.6)	0.1	1.2
Total other expense	$ (0.9)	$ (1.7)	$ (3.9)	$ 0.8	$ 2.2

The decrease in interest income for the year ended March 31, 2011, as compared to the year ended March 31, 2010, was due to a lower average balance of cash and investments and lower interest rates earned during the year ended March 31, 2011, as compared to the year ended March 31, 2010. 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 the year ended March 31, 2009.

The decrease in interest expense for the year ended March 31, 2011, as compared to the year ended March 31, 2010, was due to the early redemption of our non-recourse 7% Notes on July 1, 2010. As a result of this transaction, we recorded charges of $1.4 million relating to the write-off of the unamortized portion of deferred financing costs and $0.8 million primarily related to the premium paid on the redemption of the non-recourse 7% Notes. We expect to save $3.2 million in interest and accretion expense through the previously scheduled maturity date of January 1, 2012 as a result of redeeming the non-recourse 7% Notes on July 1, 2010. 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 of quarterly scheduled principal payments on the notes made during the year ended March 31, 2010 and repurchases of the notes made 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.

In the years ended March 31, 2011, 2010 and 2009, we recorded other-than-temporary impairments on our investments in the common stock of our collaborators of none, $0.1 million and $1.2 million, respectively, in other expense, net.

Provision for Income Taxes

	Years Ended March 31,			Change Favorable/(Unfavorable)	
	2011	2010	2009	2011-2010	2010-2009
	(In millions)				

(Benefit) provision for income taxes	$ (1.0)	$ (5.1)	$ 0.5	$ (4.1)	$ 5.6

The income tax benefit of $1.0 million for the year ended March 31, 2011 is primarily related to a $0.8 million current tax benefit for bonus depreciation pursuant to the *Small Business Jobs Act of 2010*. Bonus depreciation increased our 2010 alternative minimum tax (AMT) net operating loss (NOL) carryback and allowed us to recover AMT paid in the carryback period. 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 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, we had recorded a full valuation allowance against the credits that were established in prior periods when

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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 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 (loss) income. Our provision for income taxes in the amount of $0.5 million for the year ended March 31, 2009 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, 2011, we had approximately $274.2 million of federal NOL carryforwards, $38.5 million of state operating loss carryforwards, and $18.7 million of foreign NOL and foreign capital loss carryforwards, which expire on various dates through the year 2031 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 $133.2 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:

	March 31, 2011	March 31, 2010
	(In millions)	
Cash and cash equivalents	$ 38.4	$ 79.3
Investments short-term	162.9	202.1
Investments long-term	93.4	68.8
Total cash, cash equivalents and investments	$ 294.7	$ 350.2
Working capital	$ 204.9	$ 247.1
Outstanding borrowings current and long-term	$	$ 51.0

Our cash flows for the years ended March 31, 2011, 2010 and 2009 were as follows:

	Years Ended March 31,		
	2011	2010	2009
	(In millions)		
Cash and cash equivalents, beginning of period	$ 79.3	$ 86.9	$ 101.2
Cash (used in) provided by operating activities	(5.9)	(12.3)	34.6
Cash provided by investing activities	5.6	28.0	45.4
Cash used in financing activities	(40.6)	(23.3)	(94.3)
Cash and cash equivalents, end of period	$ 38.4	$ 79.3	$ 86.9

The decrease in cash used in operating activities during the year ended March 31, 2011, as compared to the year ended March 31, 2010, was primarily due to an increase in the amount of cash received from our customers, partially offset by an increase in cash paid to our employees and suppliers and the early redemption of our non-recourse 7% Notes on July 1, 2010. In addition to a scheduled principal payment of $6.4 million, we redeemed the balance of our non-recourse 7% Notes in full in exchange for $39.2 million, representing 101.75% of the outstanding principal balance in accordance with the terms of the Indenture for the non-recourse 7% Notes. We allocated $6.6 million of the principal payments made during the year ended March 31, 2011 to operating activities to account for the original issue discount on the non-recourse 7% Notes, and the remaining $45.4 million of principal payments was allocated to financing activities in the consolidated statement of cash flows. The increase in cash used in operating activities during the year ended March 31, 2010, as compared to the year ended March 31, 2009, was primarily due to the termination of the VIVITROL collaboration with Cephalon, which resulted in the addition of approximately $16.2 million in payments for

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sales and marketing costs as we hired employees to market and sell VIVITROL in the year ended March 31, 2010. 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 the year ended March 31, 2009.

The decrease in cash provided by investing activities during the year ended March 31, 2011, as compared to the year ended March 31, 2010, is primarily due to a decrease in the net sales of investments, partially offset by a decrease in property, plant and equipment purchases and our investment in Acceleron. During the year ended March 31, 2010, we moved our corporate headquarters from Cambridge, Massachusetts, to Waltham, Massachusetts and increased cash expenditures for property, plant and equipment to furnish and equip our new headquarters. During the year ended March 31, 2010, we also entered into a collaborative arrangement with Acceleron and made an $8.0 million investment in Acceleron. The decrease in cash provided by investing activities during the year ended March 31, 2010, as compared to the year ended March 31, 2009, is primarily due to increased cash expenditures for property, plant and equipment to furnish and equip our new corporate headquarters and our investment in Acceleron, partially offset by an increase in net sales of investments during the year ended March 31, 2010 and cash received from the sale of fixed assets to Amylin in the year ended March 31, 2009.

The increase in cash used in financing activities during the year ended March 31, 2011, as compared to the year ended March 31, 2010, is primarily due to the early redemption of our non-recourse 7% Notes, as discussed above. The decrease in cash used in financing activities during the year ended March 31, 2010, as compared to the year ended March 31, 2009, is primarily due to our purchase of an aggregate total of $93.0 million principal amount of our non-recourse 7% Notes for $89.4 million and the purchase of $18.0 million of treasury stock under our stock repurchase program during the year ended March 31, 2009.

At March 31, 2011, our investments consist of the following:

		Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
			(In millions)		
Investments	short-term	$ 162.5	$ 0.4	$	$ 162.9
Investments	long-term available-for-sale	88.8		(1.3)	87.5
Investments	long-term held-to-maturity	5.9			5.9
Total		$ 257.2	$ 0.4	$ (1.3)	$ 256.3

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 and strategic equity investments, which include the common stock of public companies we have or had 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.

Our primary sources of liquidity are cash provided by past operating activities, payments we have received under R&D arrangements and other arrangements with collaborators and private placements of debt securities. As discussed in Part I, we will pay Elan $500 million in cash, subject to certain net cash and working capital adjustments. We have obtained a commitment, subject to customary conditions, from Morgan Stanley and HSBC to provide up to

$450 million in term loan financing which, in addition to existing cash and investment balances, will comprise the cash consideration to Elan.

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, 2011, we performed an analysis of our investments with unrealized losses for impairment and determined that they are temporarily impaired.

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At March 31, 2011, less than 1% 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. The illiquidity of our Level 3 investments does 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 $6.0 million during the year ended March 31, 2012 for capital expenditures. This estimate does not include any impact of the proposed merger with EDT, as previously discussed. Our capital expenditures were higher in the year ended March 31, 2010, as compared to the years ended March 31, 2011 and 2009, due to the relocation of our corporate headquarters from Cambridge, Massachusetts to Waltham, Massachusetts, which occurred during the fourth quarter of the year ended March 31, 2010.

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

We did not have any outstanding borrowings at March 31, 2011. On July 1, 2010, in addition to a scheduled principal payment of $6.4 million, we redeemed the balance of our non-recourse 7% Notes in full in exchange for $39.2 million, representing 101.75% of the outstanding principal balance in accordance with the terms of the Indenture for the non-recourse 7% Notes. We expect to save $3.2 million in interest and accretion expense through the previously scheduled maturity date of January 1, 2012 as a result of redeeming these notes on July 1, 2010.

Contractual Obligations

The following table summarizes our obligations to make future payments under our current contracts at March 31, 2011:

Contractual Obligations	Total	Less Than One Year (Fiscal 2012)	One to Three Years (Fiscal 2013-2014)	Three to Five Years (Fiscal 2015-2016)	More than Five Years (After Fiscal 2016)
			(In thousands)		

Operating lease obligations	$ 44,563	$ 13,258	$ 9,791	$ 7,592	$ 13,922
Purchase obligations	44,002	44,002			
Capital expansion programs	894	894			
Total contractual cash obligations	$ 89,459	$ 58,154	$ 9,791	$ 7,592	$ 13,922

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 $0.2 million of long term liabilities associated with uncertain tax positions at March 31, 2011.

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

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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 expense 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. In July 2010, we invested an additional $0.5 million in Acceleron. 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 $8.5 million equity investment we made which is included in other assets in our consolidated balance sheet at March 31, 2011.

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.

Off-Balance Sheet Arrangements

At March 31, 2011, 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, 2011, 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 when polymer is shipped to them, at an agreed upon price. We sell VIVITROL to Cilag for resale in Russia and the CIS. Under our arrangement with Cilag, we record

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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 pharmaceutical wholesalers, specialty distributors and specialty pharmacies.

VIVITROL product sales are recorded net of sales reserves and allowances. Sales of many pharmaceutical products in the U.S. are subject to increased pricing pressure from managed care groups, institutions, government agencies and other groups seeking discounts. We and other biotechnology companies in the U.S. market are required to provide statutorily defined rebates and discounts to various U.S. government agencies in order to participate in the Medicaid program and other government-funded programs. The sensitivity of our estimates can vary by program and type of customer. Estimates associated with Medicaid and other government allowances may become subject to adjustment in a subsequent periods. We record VIVITROL product sales net of the following significant categories of product sales allowances:

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;

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 actual and expected utilization of these programs. Wholesaler chargebacks 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.

Wholesaler Fees cash consideration, including sales incentives, given by us under distribution service agreements with a number of wholesaler, distributor and specialty pharmacy customers that provide them with the opportunity to earn discounts in exchange for the performance of certain services;

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.

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Our provisions for VIVITROL sales and allowances reduced gross VIVITROL sales as follows:

	Medicaid Rebates	Chargebacks	Wholesaler Fees	Inventory Reserve	Other	Total
			(In millions)			
Balance, April 1, 2009	$ 0.2	$ 0.1	$	$ 1.3	$ 0.2	$ 1.8
Provision:						
Current Period	0.8	1.1	1.2	1.8	0.7	5.6
Prior Period					0.1	0.1
Total	0.8	1.1	1.2	1.8	0.8	5.7
Actual:						
Current Period	(0.4)	(1.0)	(1.0)		(0.8)	(3.2)
Prior Period	(0.2)	(0.1)		(1.3)	(0.1)	(1.7)
Total	(0.6)	(1.1)	(1.0)	(1.3)	(0.9)	(4.9)
Balance, March 31, 2010	$ 0.4	$ 0.1	$ 0.2	$ 1.8	$ 0.1	2.6
Provision:						
Current Period	3.2	2.4	2.2	2.5	1.9	12.2
Prior Period	(0.1)					(0.1)
Total	3.1	2.4	2.2	2.5	1.9	12.1
Actual:						
Current Period	(1.9)	(2.3)	(1.8)		(1.1)	(7.1)
Prior Period	(0.3)	(0.1)	(0.2)	(1.8)	(0.1)	(2.5)
Total	(2.2)	(2.4)	(2.0)	(1.8)	(1.2)	(9.6)
Balance, March 31, 2011	$ 1.3	$ 0.1	$ 0.4	$ 2.5	$ 0.8	$ 5.1

Investments

At March 31, 2011, we held investments in U.S. government and agency obligations, debt securities issued by foreign agencies and backed by foreign governments and corporate debt securities. In addition, we hold strategic equity investments, which include the common stock of public companies we have or had 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

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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 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 that include assumptions such as 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. 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. 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.

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, 2011, the ranges in weighted-average assumptions were as follows:

Expected option term	5 - 7 years
Expected stock volatility	46% - 51%
Risk-free interest rate	1.11% - 3.42%
Expected annual dividend yield	

In addition to the above, we apply judgment in developing estimates of award forfeitures. For the year ended March 31, 2011, we used an estimated forfeiture rate of zero 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

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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. 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. At March 31, 2011, 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.

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

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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 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 $0.3 million over an annual period. Due to the conservative nature of our short-term and long-term investments and our investment policy, we do not believe that we have a material exposure to interest rate risk as our investment policies specify credit quality standards for our investments and limit the amount of credit exposure from any single issue, issuer or type of investment.

We do not believe that inflation and changing prices have had a material impact on our results of operations, and as over 81% of our investments are in debt securities issued by the U.S. government and/or agencies of developed countries, our exposure to liquidity and credit risk does not appear significant.

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, 2011, 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 CONTSTA manufacturing and royalty revenues being reduced by approximately $5.4 million and $2.7 million, respectively.

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Item 8. ***Financial Statements and Supplementary Data***

Selected Quarterly Financial Data

	First Quarter	Second Quarter	Third Quarter	Fourth Quarter
	(In thousands, except per share data)			
Year Ended March 31, 2011				
REVENUES:				
Manufacturing revenues	$ 26,891	$ 33,163	$ 26,155	$ 32,312
Royalty revenues	8,917	9,460	9,777	10,165
Product sales, net	6,204	6,469	7,729	8,518
Research and development revenue under collaborative arrangements	268	155	314	143
Total revenues	42,280	49,247	43,975	51,138
EXPENSES:				
Cost of goods manufactured and sold	12,665	13,911	12,860	12,749
Research and development	22,977	23,932	22,503	27,827
Selling, general and administrative	19,726	18,436	20,521	24,164
Total expenses	55,368	56,279	55,884	64,740
OPERATING LOSS	(13,088)	(7,032)	(11,909)	(13,602)
OTHER (EXPENSE) INCOME	(379)	(1,577)	567	529
LOSS BEFORE INCOME TAXES	(13,467)	(8,609)	(11,342)	(13,073)
INCOME TAX (BENEFIT) PROVISION	(58)	(943)	41	9
NET LOSS	$ (13,409)	$ (7,666)	$ (11,383)	$ (13,082)
BASIC AND DILUTED NET LOSS PER SHARE	$ (0.14)	$ (0.08)	$ (0.12)	$ (0.14)
Year Ended March 31, 2010				
REVENUES:				
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	4,315	687		
Total revenues	47,496	48,157	44,152	38,476
EXPENSES:				

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
Total expenses	57,520	56,381	50,388	57,026
OPERATING LOSS	(10,024)	(8,224)	(6,236)	(18,550)
OTHER EXPENSE	(211)	(545)	(566)	(345)
LOSS BEFORE INCOME TAXES	(10,235)	(8,769)	(6,802)	(18,895)
INCOME TAX (BENEFIT) PROVISION	(70)	(60)	15	(4,960)
NET LOSS	$ (10,165)	$ (8,709)	$ (6,817)	$ (13,935)
BASIC AND DILUTED NET LOSS PER SHARE	$ (0.11)	$ (0.09)	$ (0.07)	$ (0.15)

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.

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

Not applicable.

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

Disclosure Controls and Procedures and Internal Control over Financial Reporting

Controls and Procedures

Our management has evaluated, with the participation of our principal executive officer and principal financial officer, 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), as of March 31, 2011. Based upon that evaluation, our principal executive officer and principal financial officer concluded that, as of the end of the period covered by this report, our disclosure controls and procedures were effective to provide reasonable assurance that (a) the information required to be disclosed by us in the reports that we file or submit under the Securities Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC s rules and forms, and (b) such information is accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate to allow timely decisions regarding required disclosure. In designing and evaluating our disclosure controls and procedures, our management recognized that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives, and our management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting during the quarter ended March 31, 2011 that have materially affected, or are reasonably likely to materially affect, our 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 as defined in Rules 13a-15(f) and 15d-15(f). Internal control over financial reporting is defined in Rules 13a-15(f) and 15d-15(f) under the Securities Exchange Act as a process designed by, or under the supervision of, the issuer s principal executive and principal financial officers, or persons performing similar functions, and effected by the issuer s board of directors, management and other personnel to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with GAAP and includes those policies and procedures that:

pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect our transactions and dispositions of the assets of the issuer;

provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with GAAP, and that receipts and expenditures of the issuer are being made only in accordance with authorizations of management and directors of the issuer; and

provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of the issuer 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. 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.

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Our management assessed the effectiveness of our internal control over financial reporting as of March 31, 2011. In making this assessment, management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in Internal Control Integrated Framework.

Based on this assessment, our management has concluded that, as of March 31, 2011, our internal control over financial reporting was effective.

The effectiveness of our internal control over financial reporting as of March 31, 2011 has been audited by PricewaterhouseCoopers LLP, an independent registered public accounting firm, as stated in their report, which is included herein.

Item 9B. ***Other Information***

None.

PART III

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

The information required by this item is incorporated herein by reference to the 2011 Proxy Statement.

Item 11. ***Executive Compensation***

The information required by this item is incorporated herein by reference to the 2011 Proxy Statement.

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

The information required by this item is incorporated herein by reference to the 2011 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 2011 Proxy Statement.

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

The information required by this item is incorporated herein by reference to the 2011 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.

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EXHIBIT INDEX

Exhibit No.	
2.1	Business Combination Agreement and Plan of Merger, dated as of May 9, 2011, by and among Elan Corporation, plc, Antler Science Two Limited, Elan Science Four Limited, EDT Pharma Holdings Limited, EDT US Holdco, Inc., Antler Acquisition Corp., and Alkermes, Inc. (Incorporated by reference to Exhibit 2.1 to our Current Report on Form 8-K filed on May 9, 2011.)
2.2	Form of Shareholder s Agreement by and among Alkermes, plc, Elan Corporation, plc, and Elan Science Three Limited. (Incorporated by reference to Exhibit 2.2 to our Current Report on Form 8-K filed on May 9, 2011.)
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).)
10.1	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).)+
10.2	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).)
10.3	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).)
10.4	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	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.)
10.5(a)	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).)*

10.6 License Agreement, dated as of February 21, 1996, between Medisorb Technologies International L.P. and Janssen Pharmaceutica International (worldwide except U.S.) (assigned to Alkermes Inc. in July 2006). (Incorporated by reference to Exhibit 10.20 to our Annual Report on Form 10-K for the fiscal year ended March 31, 1996 (File No. 000-19267).)*

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Exhibit No.	
10.7	Manufacturing and Supply Agreement, dated August 6, 1997, by and among Alkermes Controlled Therapeutics Inc. II, Janssen Pharmaceutica International and Janssen Pharmaceutica, Inc. (assigned to Alkermes Inc. in July 2006). (Incorporated by reference to Exhibit 10.19 to our Annual Report on Form 10-K for the fiscal year ended March 31, 2002 (File No. 001-14131).)***
10.8	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(a)	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(b)	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(c)	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(d)	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(e)	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	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.)+
10.10(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.)+
10.10(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.)+
10.11	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.)+

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Exhibit No.	
10.11(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.)+
10.11(b)	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.)+
10.12	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.)+
10.12(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.)+
10.13	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.)+
10.14	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.)+
10.15	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.)+
10.16	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.)
10.17	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.)+
10.17(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.)+
10.18	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.)+
10.18(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.)+
10.18(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.)+
10.19	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.)+
10.19(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.)+

10.20	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.)+
10.20(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.)+
10.21	Alkermes Fiscal 2012 Reporting Officer Performance Pay Plan. (Incorporated by reference to Exhibit 10.1 to our Current Report on Form 8-K filed on March 24, 2011.)+
10.21(a)	Amended and Restated Alkermes Fiscal 2012 Reporting Officer Performance Pay Plan. (Incorporated by reference to Exhibit 10.1 to our Current Report on Form 8-K filed on May 19, 2011.)+

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Exhibit No.	
10.22	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.)+
10.23	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.)+
10.23(a)	Alkermes, Inc. 2008 Stock Option and Incentive Plan, Stock Option Award Certificate (Incentive Stock Option), as amended (Incorporated by reference to Exhibit 10.27(a) to our Annual Report on Form 10-K for the fiscal year ended March 31, 2010.)+
10.23(b)	Alkermes, Inc. 2008 Stock Option and Incentive Plan, Stock Option Award Certificate (Non-Qualified Option), as amended (Incorporated by reference to Exhibit 10.27(b) to our Annual Report on Form 10-K for the fiscal year ended March 31, 2010.)+
10.23(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.)+
10.23(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.)+
10.23(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.)+
10.24	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). (Incorporated by reference to Exhibit 10.28 to our Annual Report on Form 10-K for the fiscal year ended March 31, 2010.) *******
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.#
101	The following materials from Alkermes, Inc. s Annual Report on Form 10-K for the year ended March 31, 2011, formatted in XBRL (Extensible Business Reporting Language): (i) the Consolidated Balance Sheets, (ii) the Consolidated Statements of Operations and Comprehensive (Loss) Income, (iii) the Consolidated Statements of Shareholders Equity, (iv) the Consolidated Statements of Cash Flows, and (v) the Notes to the Consolidated Financial Statements, tagged as blocks of text (furnished herewith).

* 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 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 June 35, 2010. Such provisions have been filed separately with the Commission.

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

Filed herewith.

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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 20, 2011

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.

Signature	Title	Date
/s/ Richard F. Pops Richard F. Pops	Chairman, President and Chief Executive Officer (Principal Executive Officer)	May 20, 2011
/s/ James M. Frates James M. Frates	Senior Vice President, Chief Financial Officer and Treasurer (Principal Financial and Accounting Officer)	May 20, 2011
/s/ David W. Anstice David W. Anstice	Director	May 20, 2011
/s/ Floyd E. Bloom Floyd E. Bloom	Director	May 20, 2011
/s/ Robert A. Breyer Robert A. Breyer	Director	May 20, 2011

/s/ Geraldine Henwood	Director	May 20, 2011
Geraldine Henwood		
/s/ Paul J. Mitchell	Director	May 20, 2011
Paul J. Mitchell		

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Signature	Title	Date
/s/ Wendy L. Dixon	Director	May 20, 2011
Wendy L. Dixon		
/s/ Alexander Rich	Director	May 20, 2011
Alexander Rich		
/s/ Mark B. Skaletsky	Director	May 20, 2011
Mark B. Skaletsky		
/s/ Michael A. Wall	Director and Chairman Emeritus	May 20, 2011
Michael A. Wall		

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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, of shareholders equity and of cash flows present fairly, in all material respects, the financial position of Alkermes, Inc. and its subsidiaries at March 31, 2011 and 2010, and the results of their operations and their cash flows for each of the three years in the period ended March 31, 2011 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, 2011, 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.

Boston, Massachusetts
May 20, 2011

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ALKERMES INC. AND SUBSIDIARIES

CONSOLIDATED BALANCE SHEETS
March 31, 2011 and 2010

	2011	2010
	(In thousands, except share and per share amounts)	
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 38,394	$ 79,324
Investments short-term	162,928	202,053
Receivables	22,969	25,316
Inventory	20,425	20,653
Prepaid expenses and other current assets	8,244	10,936
Total current assets	252,960	338,282
PROPERTY, PLANT AND EQUIPMENT, NET	95,020	96,905
INVESTMENTS LONG-TERM	93,408	68,816
OTHER ASSETS	11,060	11,597
TOTAL ASSETS	$ 452,448	$ 515,600
LIABILITIES AND SHAREHOLDERS EQUITY		
CURRENT LIABILITIES:		
Accounts payable and accrued expenses	$ 44,934	$ 37,881
Deferred revenue current	3,123	2,220
Non-recourse RISPERDAL CONSTA secured 7% notes current		51,043
Total current liabilities	48,057	91,144
DEFERRED REVENUE LONG-TERM	4,837	5,105
OTHER LONG-TERM LIABILITIES	7,536	6,735
TOTAL LIABILITIES	60,430	102,984
COMMITMENTS AND CONTINGENCIES (Note 15)		
SHAREHOLDERS EQUITY:		
Common stock, par value, $0.01 per share; 160,000,000 shares authorized; 105,771,507 and 104,815,328 shares issued; 95,702,299 and 94,870,063 shares outstanding at March 31, 2011 and 2010, respectively	1,055	1,047
Non-voting common stock, par value, $0.01 per share; 450,000 shares authorized; 382,632 shares issued and outstanding at March 31, 2011 and 2010	4	4
	(131,095)	(129,681)

Treasury stock, at cost (10,069,208 and 9,945,265 shares at March 31, 2011 and 2010, respectively)		
Additional paid-in capital	936,295	910,326
Accumulated other comprehensive loss	(3,013)	(3,392)
Accumulated deficit	(411,228)	(365,688)
Total shareholders equity	392,018	412,616
TOTAL LIABILITIES AND SHAREHOLDERS EQUITY	$ 452,448	$ 515,600

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

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ALKERMES INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE (LOSS) INCOME
Years Ended March 31, 2011, 2010 and 2009

	2011	2010	2009
	(In thousands, except per share amounts)		
REVENUES:			
Manufacturing revenues	$ 118,521	$ 112,938	$ 116,844
Royalty revenues	38,319	36,979	33,247
Product sales, net	28,920	20,245	4,467
Research and development revenue under collaborative arrangements	880	3,117	42,087
Net collaborative profit		5,002	130,194
Total revenues	186,640	178,281	326,839
EXPENSES:			
Cost of goods manufactured and sold	52,185	49,438	43,396
Research and development	97,239	95,363	89,478
Selling, general and administrative	82,847	76,514	59,008
Total expenses	232,271	221,315	191,882
OPERATING (LOSS) INCOME	(45,631)	(43,034)	134,957
OTHER (EXPENSE) INCOME:			
Interest income	2,728	4,667	11,400
Interest expense	(3,298)	(5,974)	(13,756)
Other expense, net	(290)	(360)	(1,589)
Total other expense, net	(860)	(1,667)	(3,945)
(LOSS) INCOME BEFORE INCOME TAXES	(46,491)	(44,701)	131,012
(BENEFIT) PROVISION FOR INCOME TAXES	(951)	(5,075)	507
NET (LOSS) INCOME	$ (45,540)	$ (39,626)	$ 130,505
(LOSS) EARNINGS PER COMMON SHARE:			
BASIC	$ (0.48)	$ (0.42)	$ 1.37
DILUTED	$ (0.48)	$ (0.42)	$ 1.36
WEIGHTED AVERAGE NUMBER OF COMMON SHARES OUTSTANDING:			
BASIC	95,610	94,839	95,161

DILUTED	95,610	94,839	96,252
COMPREHENSIVE (LOSS) INCOME:			
Net (loss) income	$ (45,540)	$ (39,626)	$ 130,505
Unrealized losses on marketable securities:			
Holding gains (losses), net of tax	379	2,998	(6,153)
Less: Reclassification adjustment for losses included in net (loss) income		94	1,195
Unrealized gains (losses) on marketable securities	379	3,092	(4,958)
COMPREHENSIVE (LOSS) INCOME	$ (45,161)	$ (36,534)	$ 125,547

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

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ALKERMES INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF SHAREHOLDERS EQUITY
Years Ended March 31, 2011, 2010 and 2009

	Common Stock		Non-Voting Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive (Loss) Income		Accumulated Deficit	Treasury Stock	
	Shares	Amount	Shares	Amount		Foreign Currency Translation Adjustments	Unrealized Gain/(Loss) on Marketable Securities		Shares	Amou
					(In thousands, except share data)					
1, 2008	102,977,348	$ 1,030	382,632	$ 4	$ 869,695	$ (142)	$ (1,384)	$ (456,567)	(7,878,182)	$ (107
stock k	1,067,315	10			7,049					
stock tock										
lding stock					707				(61,067)	
non cost sation om sation					14,884 80				(1,569,202)	(17
s							(4,958)	130,505		
31,	104,044,663	$ 1,040	382,632	$ 4	$ 892,415	$ (142)	$ (6,342)	$ (326,062)	(9,508,451)	$ (126
stock k	770,665	7			2,586					
stock tock					972				(108,410)	
lding stock										

non											
cost										(328,404)	(2
sation					14,107						
om											
sation					246						
s, net											
							3,092				
								(39,626)			
31,											
	104,815,328	$ 1,047	382,632	$ 4	$ 910,326	$ (142)	$ (3,250)	$ (365,688)		(9,945,265)	$ (129
stock											
k											
	956,179	8			4,736						
stock											
tock											
lding											
stock											
					1,414					(123,943)	(1
sation					19,819						
s, net											
							379				
								(45,540)			
31,											
	105,771,507	$ 1,055	382,632	$ 4	$ 936,295	$ (142)	$ (2,871)	$ (411,228)		(10,069,208)	$ (131

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

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ALKERMES INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF CASH FLOWS
Years Ended March 31, 2011, 2010 and 2009

	2011	2010	2009
		(In thousands)	
CASH FLOWS FROM OPERATING ACTIVITIES:			
Net (loss) income	$ (45,540)	$ (39,626)	$ 130,505
Adjustments to reconcile net income to cash flows from operating activities:			
Share-based compensation expense	19,832	13,921	14,810
Depreciation	8,652	25,026	10,265
Realized losses on investments		94	1,195
Loss on purchase of non-recourse RISPERDAL CONSTA secured 7% Notes	841		2,512
Other non-cash charges	1,861	3,739	4,283
Changes in assets and liabilities:			
Receivables	2,347	(728)	13,710
Inventory, prepaid expenses and other assets	5,211	(4,037)	(5,140)
Accounts payable and accrued expenses	6,954	(2,064)	2,014
Unearned milestone revenue			(117,657)
Deferred revenue	635	(4,753)	(14,525)
Other long-term liabilities	(88)	(1,638)	(1,366)
Payment or purchase of non-recourse RISPERDAL CONSTA secured 7% notes attributable to original issue discount	(6,611)	(2,181)	(6,016)
Cash flows (used in) provided by operating activities	(5,906)	(12,247)	34,590
CASH FLOWS FROM INVESTING ACTIVITIES:			
Additions to property, plant and equipment	(9,401)	(15,787)	(5,502)
Proceeds from the sale of equipment	395	248	7,717
Investment in Acceleron Pharmaceuticals, Inc.	(501)	(8,000)	
Proceeds from the sale of investment in Reliant Pharmaceuticals, Inc.			7,766
Purchases of investments	(370,375)	(465,387)	(609,741)
Sales and maturities of investments	385,511	516,935	645,120
Cash flows provided by investing activities	5,629	28,009	45,360
CASH FLOWS FROM FINANCING ACTIVITIES:			
Proceeds from the issuance of common stock for share-based compensation arrangements	4,744	2,593	7,059
Excess tax benefit from share-based compensation		246	80
Payment of debt and capital leases			(47)
Payment or purchase of non-recourse RISPERDAL CONSTA secured 7% notes	(45,397)	(23,486)	(83,394)

Purchase of common stock for treasury		(2,684)	(17,996)
Cash flows used in financing activities	(40,653)	(23,331)	(94,298)
NET DECREASE IN CASH AND CASH EQUIVALENTS	(40,930)	(7,569)	(14,348)
CASH AND CASH EQUIVALENTS Beginning of period	79,324	86,893	101,241
CASH AND CASH EQUIVALENTS End of period	$ 38,394	$ 79,324	$ 86,893
SUPPLEMENTAL CASH FLOW DISCLOSURE:			
Cash paid for interest	$ 1,684	$ 4,918	$ 15,342
Cash paid for taxes	$ 60	$ 114	$ 860
Non-cash investing and financing activities:			
Purchased capital expenditures included in accounts payable and accrued expenses	$ 424	$ 2,798	$ 1,774
Investment in Civitas Therapeutics, Inc.	$ 1,320	$	$

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

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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 is headquartered in Waltham, Massachusetts and has a research facility in Massachusetts and a commercial manufacturing facility in Ohio. The Company developed, manufactures and commercializes VIVITROL® (naltrexone for extended-release injectable suspension) for alcohol dependence and for the prevention of relapse to opioid dependence, following opioid detoxification. The Company also 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.

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, 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) requires management to make estimates and assumptions that affect the reported amounts of assets, liabilities, revenues, expenses and related disclosure of contingent assets and liabilities. On an ongoing basis, the Company evaluates its estimates and judgments and methodologies, including those related to revenue recognition and related allowances, its collaborative relationships, clinical trial expenses, the valuation of inventory, impairment and amortization of long-lived assets, share-based compensation, income taxes including the valuation allowance for deferred tax assets, valuation of investments, contingencies, litigation, and restructuring charges. The Company bases its estimates on historical experience and on various other assumptions that are believed to be reasonable, the results of which form the basis for making judgments about the carrying values of assets and liabilities. Actual results may differ from these estimates under different assumptions or conditions.

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 and corporate debt securities. The Company

also has strategic equity investments which includes 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

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ALKERMES INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

March 31, 2011, 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. The Company uses the specific identification method for reclassifying unrealized gains and losses into earnings when investments are sold. Certain of the Company s money market funds and held-to-maturity investments are restricted investments held as collateral under 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.

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. If 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 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

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ALKERMES INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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.

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 product