ALKERMES INC
Form 10-K
May 28, 2009

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

Form 10-K

þ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the fiscal year ended March 31, 2009

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.)*
88 Sidney Street, Cambridge, MA	**02139-4234**
(Address of principal executive offices)	*(Zip Code)*

(617) 494-0171
(Registrant s telephone number, including area code)

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

Common Stock, par value $.01 per share Series A Junior Participating Preferred Stock Purchase Rights	The NASDAQ Stock Market LLC
Title of each class	**Name of exchange on which registered**

Securities registered pursuant to Section 12(b) of the Act:
None

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

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

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 Exchange Act). Yes o No þ

As of September 30, 2008 (the last business day of the second fiscal quarter) the aggregate market value of the 93,002,448 outstanding shares of voting and non-voting common equity held by non-affiliates of the registrant was $1,236,932,558. Such aggregate value was computed by reference to the closing price of the common stock reported on the NASDAQ Stock Market on September 30, 2008.

As of May 20, 2009, 94,525,706 shares of the Registrant s common stock were issued and outstanding and 382,632 shares of the Registrant s non-voting common stock were issued and outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Definitive Proxy Statement to be filed within 120 days after March 31, 2009 for the Registrant s Annual Shareholders Meeting are incorporated by reference into Part III of this Report on Form 10-K.

ALKERMES, INC. AND SUBSIDIARIES

ANNUAL REPORT ON FORM 10-K
FOR THE FISCAL YEAR ENDED MARCH 31, 2009

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PART I

Item 1. *Business*

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

General

Alkermes, Inc. (as used in this section, together with our subsidiaries, us , we , our or the Company) is a fully integra biotechnology company committed to developing innovative medicines to improve patients lives. We developed, manufacture and commercialize VIVITROL® for alcohol dependence and manufacture RISPERDAL® CONSTA® for schizophrenia and bipolar disorder. Our robust pipeline includes extended-release injectable, pulmonary and oral products for the treatment of prevalent, chronic diseases, such as central nervous system disorders, addiction and diabetes. We have research facilities in Massachusetts and a commercial manufacturing facility in Ohio. We announced in April 2009 that we will move our corporate headquarters from Cambridge, Massachusetts, to Waltham, Massachusetts in early calendar 2010.

Our Strategy

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

Products and Development Programs

RISPERDAL CONSTA

RISPERDAL CONSTA is a long-acting formulation of risperidone, a product of Janssen Pharmaceutica, Inc., a division of Ortho-McNeil-Janssen Pharmaceuticals, Inc., and Janssen Pharmaceutica International, a division of Cilag International (together Janssen), and is the first and only long-acting, atypical antipsychotic approved by the United States (U.S.) Food and Drug Administration (FDA). The medication uses our proprietary Medisorb® technology to deliver and maintain therapeutic medication levels in the body through just one injection every two weeks. RISPERDAL CONSTA is marketed by Janssen and is exclusively manufactured by us. RISPERDAL CONSTA was first approved by regulatory authorities in the United Kingdom (UK) and Germany in August 2002 and by the FDA in October 2003. RISPERDAL CONSTA is approved for the treatment of schizophrenia in approximately 85 countries and marketed in approximately 60 countries, and Janssen continues to launch the product around the world. In the U.S., RISPERDAL CONSTA is also approved for the treatment of bipolar I disorder.

Schizophrenia is a brain disorder characterized by disorganized thinking, delusions and hallucinations. Studies have demonstrated that as many as seventy-five percent of patients with schizophrenia have difficulty taking their oral medication on a regular basis, which can lead to worsening of symptoms. Clinical data has shown that treatment with

RISPERDAL CONSTA may lead to improvements in symptoms, sustained remission and decreases in hospitalization in patients with schizophrenia. 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

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depressive episode. Clinical data has shown that RISPERDAL CONSTA significantly delayed the time to relapse compared to placebo treatment in patients with bipolar disorder.

In April 2008, we announced that our partner, Johnson & Johnson Pharmaceutical Research & Development, L.L.C. (J&JPRD), submitted a supplemental New Drug Application (sNDA) for RISPERDAL CONSTA to the FDA seeking approval for adjunctive therapy to lithium or valproate in the maintenance treatment of bipolar I disorder.

In May 2008, the results of a study sponsored by Janssen were presented at the American Psychiatric Association (APA) 161st Annual Meeting in Washington D.C. The 24-month, open-label, active-controlled, international study compared treatment with RISPERDAL CONSTA to that of SEROQUEL® (quetiapine) among patients with schizophrenia and other related disorders. The results demonstrated that in longer-term maintenance therapy, the average relapse-free time was significantly longer in patients treated with RISPERDAL CONSTA (607 days) compared to quetiapine (533 days) ($p<0.0001$). Furthermore, over the 24-month treatment period, relapse occurred in 16.5 percent of patients treated with RISPERDAL CONSTA and 31.3 percent of patients treated with quetiapine. Both RISPERDAL CONSTA and quetiapine had generally comparable safety profiles.

In July 2008, we announced that J&JPRD submitted a sNDA for RISPERDAL CONSTA to the FDA for approval as monotherapy in the maintenance treatment of bipolar I disorder to delay the time to occurrence of mood episodes in adults.

In October 2008, the FDA approved the deltoid muscle of the arm as a new injection site for RISPERDAL CONSTA. RISPERDAL CONSTA was previously approved as a gluteal injection only.

In January 2009, we announced that J&JPRD initiated a phase 1, single-dose, open-label study of a four-week long-acting injectable formulation of risperidone for the treatment of schizophrenia. The study is designed to assess the pharmacokinetics, safety and tolerability of a gluteal injection of this risperidone formulation in approximately 26 patients diagnosed with chronic, stable schizophrenia.

In April 2009, we announced that Janssen received approval from the Pharmaceuticals and Medical Devices Agency in Japan to market RISPERDAL CONSTA for the treatment of schizophrenia. RISPERAL CONSTA is the first long-acting atypical antipsychotic to be approved in Japan.

In May 2009, the FDA approved RISPERDAL CONSTA for use as both a monotherapy and adjunctive therapy to lithium or valproate in the maintenance treatment of bipolar I disorder. Bipolar disorder is a brain disorder that causes unusual shifts in a person s mood, energy and ability to function. It is often characterized by debilitating mood swings from extreme highs (mania) to extreme lows (depression). Type I bipolar disorder is characterized based on the occurrence of at least one manic episode, with or without the occurrence of a major depressive episode, and affects approximately one percent of the American adult population in any given year.

In May 2009, the results of studies sponsored by Janssen were presented at the APA 162nd Annual Meeting in San Francisco, CA. According to two new studies, the use of RISPERDAL CONSTA) may improve clinical and functional outcomes and reduce rates of rehospitalization among patients with schizophrenia. In an analysis of two prospective, observational two-year studies conducted in the U.S. and three other countries, RISPERDAL CONSTA consistently and significantly improved clinical and functional outcomes for patients with schizophrenia. Data were collected at baseline and at three-month intervals up to 24 months, and included the Clinical Global Impression of Illness Severity (CGI-S), which measures clinical effectiveness outcomes, the Global Assessment of Functioning (GAF), and healthcare resource utilization. Patients were enrolled in the U.S. (N=532), Spain (N=1345), Australia (N=784) and Belgium (N=408). A separate study also showed that maintenance therapy with RISPERDAL CONSTA significantly delayed the time to relapse compared to placebo in patients with bipolar I disorder.

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VIVITROL

VIVITROL is an extended-release Medisorb formulation of naltrexone developed by Alkermes. VIVITROL is the first and only once-monthly injectable medication for the treatment of alcohol dependence. Alcohol dependence is a serious and chronic brain disease characterized by cravings for alcohol, loss of control over drinking, withdrawal symptoms and an increased tolerance for alcohol. Adherence to medication is particularly challenging with this patient population. In clinical trials, when used in combination with psychosocial support, VIVITROL was shown to reduce the number of drinking days and heavy drinking days and to prolong abstinence in patients who abstained from alcohol the week prior to starting treatment. Each injection of VIVITROL provides medication for one month and alleviates the need for patients to make daily medication dosing decisions. VIVITROL was approved by the FDA in April 2006 and was launched in June 2006. In August 2008, the Russian regulatory authorities approved VIVITROL for the treatment of alcohol dependence. Our collaborator, Cilag GmbH International (Cilag), a subsidiary of Johnson & Johnson, launched VIVITROL in Russia in March 2009. The VIVITROL collaboration with Cilag is described in greater detail in the Collaborative Arrangements section of Item 1.

We are also developing VIVITROL for the treatment of opioid dependence, a serious and chronic brain disease characterized by compulsive, prolonged-self administration of opioid substances that are not used for a medical purpose. In June 2008, we initiated a randomized, multi-center registration study of VIVITROL in Russia for the treatment of opioid dependence. The study is designed to assess the efficacy and safety of VIVITROL in more than 250 opioid dependent patients. The clinical data from this study may form the basis of a sNDA to the FDA for VIVITROL for the treatment of opioid dependence. In April 2009, we completed enrollment for this registration study. We expect data from the study to be available in late calendar 2009.

In November 2008, we and Cephalon, Inc. (Cephalon) agreed to end the collaboration for the development, supply and commercialization of certain products, including VIVITROL in the U.S., effective December 1, 2008 (the Termination Date), and we assumed the risks and responsibilities for the marketing and sale of VIVITROL in the U.S. We paid Cephalon $16.0 million for title to two partially completed VIVITROL manufacturing lines, and we received $11.0 million from Cephalon as payment to fund their share of estimated VIVITROL product losses during the one-year period following the Termination Date. As of the Termination Date, Cephalon is no longer responsible for the marketing and sale of VIVITROL in the U.S., and we are responsible for all VIVITROL profits or losses. Cephalon has no rights to royalty payments on future sales of VIVITROL. In order to facilitate the full transfer of all commercialization of VIVITROL to us, Cephalon, at our option and on our behalf, has agreed to perform certain transition services until May 31, 2009 at a full-time equivalent (FTE) rate agreed to by the parties. The VIVITROL collaboration with Cephalon is described in greater detail in the Collaborative Arrangements section of Item 1.

Exenatide Once Weekly

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

In June 2008, we, Amylin and Lilly announced positive results from a 52-week, open-label clinical study (DURATION-1 study) that showed the durable efficacy of exenatide once weekly. At 52 weeks, patients taking exenatide once weekly showed an average A1C improvement of 2 percent and an average weight loss

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of 9.5 pounds. The study also showed that patients who switched from BYETTA injection after 30 weeks to exenatide once weekly experienced additional improvements in A1C and fasting plasma glucose. Seventy-four percent of all patients in the study achieved an endpoint of A1C of 7 percent or less at 52 weeks. Exenatide once weekly was generally well tolerated, with no major hypoglycemia events regardless of background therapy and nausea was predominantly mild and transient.

In March 2009, we, Amylin and Lilly reported positive results from a 26-week, double-blind superiority study that compared exenatide once weekly to sitagliptin or pioglitazone (DURATION-2 study). Data from the study showed that after completing 26 weeks of treatment, evaluable patients randomized to exenatide once weekly experienced a statistically significant reduction in A1C of 1.7 percentage points from baseline, compared to a reduction of 1.0 percentage point for sitagliptin and 1.4 percentage points for pioglitazone. Treatment with exenatide once weekly also produced statistically significant differences in weight, with weight loss of 6.2 pounds at 26 weeks, compared with a loss of 1.9 pounds for sitagliptin, and a weight gain of 7.4 pounds for pioglitazone. There was no major hypoglycemia in any treatment group. The most frequently reported adverse events among exenatide once weekly and sitagliptin users were nausea and diarrhea. Upper respiratory tract infection and peripheral edema were the most frequently reported events by patients receiving pioglitazone.

In May 2009, Amylin submitted a New Drug Application (NDA) to the FDA for the treatment of type 2 diabetes. Additional studies designed to demonstrate the superiority of exenatide once weekly are ongoing.

ALKS 33

ALKS 33 is a novel opioid modulator, identified from the library of compounds in-licensed from Rensselaer Polytechnic Institute (RPI). These compounds represent an opportunity for us to develop important therapeutics for a broad range of diseases and medical conditions, including addiction, pain and other nervous system disorders. In July 2008, we announced positive preclinical results for ALKS 33. The study results included efficacy data from an ethanol drinking behavior model in rodents, a well-characterized model for evaluating the effects of potential therapeutics targeting opioid receptors. Results showed that single, oral doses of our novel molecules significantly reduced the ethanol drinking behavior in rodents, with an average reduction from baseline ranging from 35 percent to 50 percent for the proprietary molecules compared to 10 percent for the naltrexone control arm. Details from an evaluation of the *in vivo* pharmacology, pharmacokinetics and *in vitro* metabolism were also presented. Data showed that the molecules have improved metabolic stability compared to the naltrexone control arm when cultured with human hepatocytes (liver cells), suggesting that they are not readily metabolized by the liver, a unique advantage over existing oral therapies for addiction. Pharmacokinetic results showed that the oral bioavailability of ALKS 33 was significantly greater than that of the active control.

In April 2009, we reported positive results from a phase 1 randomized, double-blind, placebo-controlled study for ALKS 33 in healthy volunteers. The study was designed to assess the pharmacokinetics, safety and tolerability of ALKS 33 following single oral administration at escalating dose levels. ALKS 33 demonstrated rapid oral absorption, high plasma concentrations and duration of action that supports once daily dosing. The study results are consistent with previous findings that ALKS 33 is not metabolized by the liver, a unique advantage over existing oral therapies for addiction. ALKS 33 was generally well tolerated during the study. Based on these preliminary results, we expect to initiate a phase 2 study of ALKS 33 in the second half of calendar 2009.

ALKS 29

We are developing ALKS 29, an oral combination therapy for the treatment of alcohol dependence. ALKS 29 is a co-formulation of ALKS 33, a proprietary opioid modulator, and baclofen, an FDA-approved muscle relaxant and antispasmodic therapeutic. Research suggests that baclofen may attenuate the compulsive component of alcohol

dependence. As a co-formulation of ALKS 33 and baclofen, ALKS 29 is designed to address both the compulsive and impulsive components of alcohol dependence.

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In April 2009, we reported positive data from a phase 1, open-label crossover study of a proprietary extended-release formulation of baclofen. The study was designed to assess the pharmacokinetics, safety and tolerability of an extended-release formulation of baclofen compared to the currently marketed formulation of baclofen. Data from the study showed that our baclofen-only formulation demonstrated a favorable pharmacokinetic profile compared to the currently marketed formulation and was generally well tolerated.

ALKS 27

Using our AIR® pulmonary technology, we are developing an inhaled trospium product for the treatment of chronic obstructive pulmonary disease (COPD). COPD is a serious, chronic disease characterized by a gradual loss of lung function. In February 2009, we initiated a phase 2a study of ALKS 27 designed to assess the efficacy, safety, tolerability and pharmacokinetics of ALKS 27 in patients with COPD. In this randomized, double-blind, cross-over, placebo-controlled study, patients will receive single administrations of three doses of ALKS 27 and placebo, each separated by a wash out period. The efficacy of ALKS 27 will be evaluated based on improvements in pulmonary function in patients with COPD, as measured by FEV1, a commonly used measure of lung function. In addition, the phase 2a study will explore the safety, tolerability and effects of ALKS 27 in combination with formoterol fumarate inhalation powder, a long-acting beta agonist (LABA) already approved for the treatment of COPD. All patients will receive the combination dose following the randomized, double-blind, placebo-controlled portion of the study. Research indicates that LABAs and muscarinic receptor antagonists, such as ALKS 27, may have a synergistic effect on improving symptoms in patients with COPD by acting on complementary pathways. We expect to report top-line results from the full study in the second half of calendar 2009.

ALKS 36

We are developing ALKS 36, a co-formulation of an opioid analgesic and RDC-1036, a novel oral, peripherally-acting opioid antagonist, for the treatment of pain. Research indicates that a high percentage of patients receiving opioids are likely to experience side effects affecting gastrointestinal motility. A pain medication that does not inhibit gastrointestinal motility could provide an advantage over current therapies.

In November 2008, we announced positive preclinical data demonstrating that RDC-1036 was effective in reversing opioid effects on gastrointestinal motility. Data also showed that oral administration of RDC-1036 had greater efficacy at a lower dose and for an extended period of time compared to an active comparator, methylnaltrexone. Based on these positive preclinical results, we expect to initiate a phase 1 study of RDC-1036 in the second half of calendar 2009.

Collaborative Arrangements

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

Janssen

Under a product development agreement, we collaborated with Janssen on the development of RISPERDAL CONSTA. Under the development agreement, Janssen provided funding to us for the development of RISPERDAL CONSTA, and Janssen is responsible for securing all necessary regulatory approvals for the product. RISPERDAL CONSTA has been approved in approximately 85 countries. RISPERDAL CONSTA has been launched in approximately 60 countries, including the U.S. and several major international markets. We exclusively manufacture RISPERDAL CONSTA for commercial sale. In addition, we and Janssen entered into an agreement to work to

develop a four week formulation of risperidone.

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 record royalty revenues equal to 2.5 percent of Janssen s net sales of RISPERDAL CONSTA in the quarter when the product is sold by Janssen. Janssen can terminate the license agreements upon 30 days prior written notice to us.

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

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

Cephalon

In June 2005, we entered into a license and collaboration agreement and supply agreement with Cephalon, later amended in October 2006 (together the Agreements) to jointly develop, manufacture and commercialize extended-release forms of naltrexone, including VIVITROL (the product or products), in the U.S. Under the terms of the Agreements, we provided Cephalon with a co-exclusive license to use and sell the product in the U.S. and a non-exclusive license to manufacture the product under certain circumstances, with the ability to sublicense. We were responsible for obtaining marketing approval for VIVITROL in the U.S. for the treatment of alcohol dependence, which we received from the FDA in April 2006, for completing the first VIVITROL manufacturing line and manufacturing the product. The companies shared responsibility for additional development of the products, and also shared responsibility for developing the commercial strategy for the products. Cephalon had primary responsibility for the commercialization, including distribution and marketing, of the products in the U.S., and we supported this effort with a team of managers of market development. Cephalon paid us an aggregate of $274.6 million in nonrefundable milestone payments related to the Agreements and we were responsible to fund the first $124.6 million of cumulative net losses incurred on VIVITROL.

In November 2008, we and Cephalon agreed to end the collaboration for the development, supply and commercialization of certain products, including VIVITROL in the U.S., effective on the Termination Date, and we assumed the risks and responsibilities for the marketing and sale of VIVITROL in the U.S. We paid Cephalon $16.0 million for title to two partially completed VIVITROL manufacturing lines, and we received $11.0 million from Cephalon as payment to fund their share of estimated VIVITROL product losses during the one-year period following the Termination Date. As of the Termination Date, we were responsible for all VIVITROL profits or losses and Cephalon has no rights to royalty payments on future sales of VIVITROL. In order to facilitate the full transfer of all commercialization of VIVITROL to us, Cephalon, at our option and on our behalf, has agreed to perform certain transition services until May 31, 2009 at an FTE rate agreed to by the parties.

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 Commonwealth of Independent States (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.

In August 2008, Cilag paid us a nonrefundable payment of $1.0 million upon achieving regulatory approval of VIVITROL for the treatment of alcohol dependence in Russia. Cilag previously paid us $5.0 million in nonrefundable payments and could pay us up to an additional $33.0 million upon the receipt of regulatory approvals for the product,

the occurrence of certain agreed-upon events and the achievement of certain VIVITROL sales levels.

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

Amylin

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

In October 2005, we amended our existing development and license agreement with Amylin, and reached agreement regarding the construction of a manufacturing facility for exenatide once weekly and certain technology transfer related thereto. In December 2005, Amylin purchased a facility for the manufacture of exenatide once weekly and began construction in early calendar year 2006. Amylin is responsible for all costs and expenses associated with the design, construction and validation of the facility. The parties agreed that we would transfer our technology for the manufacture of exenatide once weekly to Amylin. Amylin agreed to reimburse us for the time, at an agreed-upon FTE rate, and materials we incurred with respect to the transfer of technology. In January 2009, the parties agreed that the technology transfer was complete. Amylin will be responsible for the manufacture of exenatide once weekly and will operate the facility. Amylin will pay us royalties for commercial sales of this product, if approved, in accordance with the development and license agreement.

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

Rensselaer Polytechnic Institute

In September 2006, we and RPI entered into a license agreement granting us exclusive rights to a family of opioid receptor compounds discovered at RPI. These compounds represent an opportunity for us to develop therapeutics for a broad range of diseases and medical conditions, including addiction, pain and other central nervous system disorders.

Under the terms of the agreement, RPI granted us an exclusive worldwide license to certain patents and patent applications relating to its compounds designed to modulate opioid receptors. We will be responsible for the continued

research and development of any resulting product candidates. We paid RPI a nonrefundable upfront payment of $0.5 million and are obligated to pay annual fees of up to $0.2 million, and tiered royalty payments of between 1% and 4% of annual net sales in the event any products developed under the agreement

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are commercialized. In addition, we are obligated to make milestone payments in the aggregate of up to $9.1 million upon certain agreed-upon development events. All amounts paid to RPI under this license agreement have been expensed and are included in research and development expenses. In 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 $125,000 and slightly increased the annual fees in consideration of this amendment.

Lilly

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

In June 2008, we entered into an agreement with Lilly in connection with the termination of the development and license agreements and supply agreement for the development of AIR Insulin (the AIR Insulin Termination Agreement). Under the AIR Insulin Termination Agreement, we received $40.0 million in cash as payment for all services we had performed through the date of the AIR Insulin Termination Agreement as well as title to all of the assets related to AIR commercial manufacturing and the intellectual property developed under the development and license agreement. We previously recognized $14.5 million of this payment as research and development (R&D) revenue in the year ended March 31, 2008 and recognized $25.5 million of this payment as R&D revenue in the three months ended June 30, 2008.

Drug Delivery Technology

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

Injectable Extended-Release Technology

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

Pulmonary Technology

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

AIR particles can be aerosolized and inhaled efficiently with simple inhaler devices because low forces of cohesion allow the particles to disaggregate easily. We have developed a family of relatively inexpensive, compact, easy-to-use inhalers. The capsule-based AIR inhalers are breath activated and made from injection molded plastic. The powders are designed to disperse easily from the device over a range of inhalation flow rates, which may lead to low patient-to-patient variability and high lung deposition of the inhaled dose. Since

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no carrier particles are required in AIR formulations, high doses can be effectively delivered via a single inhalation. ALKS 27 leverages our pulmonary technology.

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. For information about risks relating to the manufacture of our products and product candidates, see the sections of Item 1A Risk Factors entitled We are subject to risks related to the manufacture of our products , There are risks in the manufacturing and distribution of our products and product candidates , The manufacture of our products is subject to government regulation , and We rely heavily on collaborative partners.

Commercial Products

We manufacture RISPERDAL CONSTA and VIVITROL in our Wilmington, Ohio facility. The facility is periodically inspected by U.S., European and Japanese regulatory authorities to ensure that the facility continues to meet required cGMP standards for continued commercial manufacturing. See Item 2. Properties .

Clinical Products

We have established and are operating clinical facilities with the capability to produce clinical supplies of our pulmonary and injectable extended-release products within our corporate headquarters in Cambridge, Massachusetts and at our Wilmington, Ohio facility. We have also contracted with third-party manufacturers to formulate certain products for clinical use. We require that our contract manufacturers adhere to cGMP, except for products and product candidates for toxicology and animal studies, which we require to be manufactured in accordance with current Good Laboratory Practices (cGLP).

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.

Marketing and Sales

Under our collaboration agreements with Janssen, Cilag, Amylin and Lilly, these companies are responsible for the commercialization of the products developed thereunder if and when regulatory approval is obtained. In December 2008, in connection with the termination of the VIVITROL collaboration with Cephalon, we assumed the risks and responsibilities for the marketing and sale of VIVITROL in the U.S.

We have established a sales force to market VIVITROL in the U.S. consisting of approximately 50 individuals. VIVITROL is sold directly to pharmaceutical wholesalers, specialty pharmacies and a specialty distributor. Product sales of VIVITROL by us and Cephalon during the year ended March 31, 2009, to McKesson Corporation (McKesson), Cardinal Health (Cardinal), AmerisourceBergen Drug Corporation (Amerisource) and Caremark L.L.C. represented approximately 33%, 24%, 21% and 13%, respectively, of total VIVITROL sales. No other customer accounted for more than 10% of VIVITROL product sales in fiscal 2009.

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 at a location outside of Nashville, Tennessee. Our expectation for fiscal 2010 and beyond is to continue to distribute VIVITROL through Cardinal SPS.

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In fiscal 2010, we expect selling and marketing expenses to increase over fiscal 2009 as a result of being solely responsible for all costs relating to the marketing and sale of VIVITROL in the U.S.

Competition

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

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

With respect to our injectable technology, we are aware that there are other companies developing extended-release delivery systems for pharmaceutical products. RISPERDAL CONSTA may compete with a number of other injectable products currently being developed, including two injectable, four-week, long-acting products: paliperidone palmitate, which is being developed by Johnson & Johnson; and olanzapine long-acting injection, which is being developed by Lilly and received marketing authorization for sale in the European Union (E.U.) and New Zealand. RISPERDAL CONSTA may also compete with new oral compounds being developed for the treatment of schizophrenia.

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

If approved, exenatide once weekly 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. Exenatide once weekly would also compete with other long acting GLP-1 agonists 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.

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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 139 issued U.S. patents. The earliest date upon which a U.S. patent issued to us will expire, that is currently material to our business, is 2013. In the future, we plan to file 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 40 issued U.S. patents, a number of U.S. patent applications and corresponding foreign patents and patent applications in many countries, subject in certain instances to the rights of the U.S. government to use the technology covered by such patents and patent applications. Under certain licensing agreements, we currently pay annual license fees and/or minimum annual royalties. During the year ended March 31, 2009, these fees totaled approximately $0.9 million. In addition, under these licensing agreements, we are obligated to pay royalties on future sales of products, if any, covered by the licensed patents.

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

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

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

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

or independently developed by, a competitor, our business, results of operations and financial condition could be materially adversely affected.

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Government Regulation

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

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

Typically, clinical testing involves a three-phase process: phase 1 trials are conducted with a small number of healthy subjects and are designed to determine the early side effect profile and, perhaps, the pattern of drug distribution and metabolism; phase 2 trials are conducted on patients with a specific disease in order to determine appropriate dosages, expand evidence of the safety profile and, perhaps, provide preliminary evidence of product efficacy; and phase 3 trials are large-scale, comparative studies conducted on patients with a target disease in order to generate enough data to provide statistical evidence of efficacy and safety required by national regulatory agencies. The results of the preclinical testing and clinical trials of a pharmaceutical product, as well as the information on the manufacturing of the product and proposed labeling, are then submitted to the FDA in the form of a NDA or, for a biological product, a biologics license application (BLA) for approval to commence commercial sales. Preparing such applications involves considerable data collection, verification, analysis and expense. In responding to an NDA or BLA, the FDA may grant marketing approval, request additional information or deny the application if it determines that the application does not satisfy its regulatory approval criteria. Submission of the application(s) for marketing authorization does not guarantee approval. At the same time, an FDA request for additional information does not mean the product will not be approved or that the FDA s review of the application will be significantly delayed. On occasion, regulatory authorities may require larger or additional studies, leading to unanticipated delay or expense. Even after initial FDA approval has been obtained, further clinical trials may be required to provide additional data on safety and efficacy. It is also possible that the labeling may be more limited than what was originally projected. Each marketing authorization application is unique and should be considered as such.

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

Regulatory authorities track information on side effects and adverse events reported during clinical studies and after marketing approval. Non-compliance with FDA safety reporting requirements may result in FDA regulatory action that may include civil action or criminal penalties. Side effects or adverse events that are reported during clinical trials can delay, impede or prevent marketing approval. Similarly, adverse events that

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are reported after marketing approval can result in additional limitations being placed on the product s use and, potentially, withdrawal or suspension of the product from the market. Furthermore, recently enacted legislation provides the FDA with expanded authority over drug products after approval. This legislation enhances the FDA s authority with respect to post-marketing safety surveillance including, among other things, the authority to require additional post-approval studies or clinical trials and mandate label changes as a result of safety findings.

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

Good Manufacturing Processes (cGMP)

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

If, after receiving clearance from regulatory agencies, a company makes a material change in manufacturing equipment, location, or process, additional regulatory review and approval may be required. We also must adhere to cGMP and product-specific regulations enforced by the FDA following product approval. The FDA, the EMEA and other regulatory agencies also conduct regular, periodic visits to re-inspect equipment, facilities and processes following the initial approval of a product. If, as a result of these inspections, it is determined that our equipment, facilities or processes do not comply with applicable regulations and conditions of product approval, regulatory agencies may seek civil, criminal or administrative sanctions and/or remedies against us, including the suspension of our manufacturing operations.

Advertising and Promotion

The FDA regulates all advertising and promotion activities for products under its jurisdiction both prior to and after approval. A company can make only those claims relating to safety and efficacy that are approved by the FDA. Physicians may prescribe legally available drugs for uses that are not described in the drug s labeling and that differ from those tested by us and approved by the FDA. Such off-label uses are common across medical specialties, and often reflect a physician s belief that the off-label use is the best treatment for his 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.

Regulation Outside the U.S.

In the E.U., regulatory requirements and approval processes are similar in principle to those in the U.S. depending on the type of drug for which approval is sought. There are currently three potential tracks for marketing approval in E.U. countries: mutual recognition; decentralized procedures; and centralized procedures. These review mechanisms may

ultimately lead to approval in all E.U. countries, but each method grants all participating countries some decision-making authority in product approval.

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Sales and Marketing Regulations

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

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

Other Regulations

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

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

Employees

As of May 20, 2009, we had approximately 570 full-time employees. A significant number of our management and professional employees have prior experience with pharmaceutical, biotechnology or medical product companies. We believe that we have been successful in attracting skilled and experienced scientific and senior management personnel, however, competition for such personnel is intense. None of our employees is covered by a collective bargaining agreement. We consider our relations with our employees to be good.

Available Information

We are a Pennsylvania corporation with principal executive offices located at 88 Sidney Street, Cambridge, Massachusetts 02139. Our telephone number is (617) 494-0171 and our website address is

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

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

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

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

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

RISPERDAL CONSTA

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

VIVITROL

In April 2006, the FDA approved VIVITROL for the treatment of alcohol dependence in patients able to refrain from drinking prior to, and not actively drinking at the time of, treatment initiation. In June 2005, we entered into an agreement with Cephalon to develop and commercialize VIVITROL for the treatment of alcohol dependence in the U.S. and its territories. Under this agreement, Cephalon was primarily responsible for the marketing and sale of VIVITROL in the U.S., and we supported their efforts with a team of managers of market development. In November 2008, we and Cephalon agreed to end the collaboration for the development, supply and commercialization of certain products, including VIVITROL in the U.S., effective on the Termination Date, and we assumed the risks and responsibilities for the marketing and sale of VIVITROL in the U.S. We have very little sales and marketing experience. The revenues received or to be received from the sale of VIVITROL may not be significant and will depend on numerous factors, many of which are outside of our control, including but not limited to those specified below.

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

to those specified below.

There can be no assurance that the phase 3 clinical trial results and other clinical and preclinical data will be sufficient to obtain regulatory approvals for VIVITROL elsewhere in the world. Even if regulatory approvals are received in countries other than the U.S., Russia and countries of the CIS, we will have to

market VIVITROL ourselves in these countries or enter into co-promotion or sales and marketing arrangements with other companies for VIVITROL sales and marketing activities in these countries.

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

- perception of physicians and other members of the health care community of their safety and efficacy relative to that of competing products;
- their cost-effectiveness;
- patient and physician satisfaction with these products;
- the ability to manufacture commercial products successfully and on a timely basis;
- the cost and availability of raw materials;
- the size of the markets for these products;
- reimbursement policies of government and third-party payors;
- unfavorable publicity concerning these products or similar drugs;
- the introduction, availability and acceptance of competing treatments, including those of our collaborators;
- the reaction of companies that market competitive products;
- adverse event information relating to these products;
- changes to product labels to add significant warnings or restrictions on use;
- the continued accessibility of third parties to vial, label and distribute these products on acceptable terms;
- the unfavorable outcome of patent litigation related to any of these products;
- regulatory developments related to the manufacture or continued use of these products, including the issuance of a risk evaluation and mitigation strategy (REMS) by the FDA;
- the extent and effectiveness of the sales and marketing and distribution support these products receive;
- our collaborators decisions as to the timing of product launches, pricing and discounting; and
- any other material adverse developments with respect to the commercialization of these products.

Our revenues will fluctuate from quarter to quarter based on a number of factors, including the acceptance of RISPERDAL CONSTA and VIVITROL in the marketplace, our partners orders, the timing of shipments, our ability to manufacture successfully, our yield and our production schedule. The costs to manufacture RISPERDAL CONSTA

and VIVITROL may be higher than anticipated if certain volume levels are not achieved. In addition, we may not be able to supply the products in a timely manner. If RISPERDAL CONSTA and VIVITROL do not produce significant revenues or if we are unable to supply our partners requirements, our business, results of operations and financial condition would be materially adversely affected.

We are substantially dependent on revenues from our principal product.

Our current and future revenues depend substantially upon continued sales of RISPERDAL CONSTA by our partner, Janssen. Any significant negative developments relating to this product, such as safety or efficacy issues, the introduction or greater acceptance of competing products or adverse regulatory or legislative

developments, would have a material adverse effect on our results of operations. Although we have developed and continue to develop additional products for commercial introduction, we expect to be substantially dependent on sales from this product for the foreseeable future. A decline in sales from this product would adversely affect our business.

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

We currently manufacture RISPERDAL CONSTA, VIVITROL, polymer for exenatide once weekly and some of our product candidates. The manufacture of drugs for clinical trials and for commercial sale is subject to regulation by the FDA under cGMP regulations and by other regulators under other laws and regulations. We may not be able to successfully manufacture our products under cGMP regulations or other laws and regulations in sufficient quantities for commercial sale, or in a timely or economical manner.

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

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

If those product candidates which we will manufacture ourselves progress to mid-to-late-stage development, we may incur significant expenses in the expansion and/or construction of manufacturing facilities and increases in personnel in order to manufacture product candidates. The development of a commercial-scale manufacturing process is complex and expensive. We cannot be certain that we have the necessary funds or that we will be able to develop this manufacturing infrastructure in a timely or economical manner or at all. For product candidates that we will not manufacture ourselves, we will rely on third party manufacturers. We have very little experience managing third party manufacturers.

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

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

personnel, which may cause operating losses.

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

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

In November 2008, we ended our collaboration with Cephalon related to VIVITROL. As part of the termination, we assumed all risks and responsibilities associated with the marketing and sale of VIVITROL. The revenues from the sale of VIVITROL have not been and may not become significant and will depend on numerous factors including but not limited to those specified below.

We have little experience with the commercialization of pharmaceutical products, including the marketing and sale of prescription drugs. We must build an infrastructure to support the sales and marketing of VIVITROL, including integrating former members of the Cephalon sales force with our existing field force to build our own sales force, building a distribution and expanded commercial infrastructure and providing various support services for the sales force. Our ability to realize significant revenues from the marketing and sales activities associated with VIVITROL depends on our ability to retain qualified sales personnel for the sale and marketing of VIVITROL. We must also be able to attract new qualified sales personnel as needed to support potential sales growth and competition for qualified sales personnel is intense. Any failure to attract and retain qualified sales personnel now and in the future, could impair our ability to maintain sales levels and/or support potential future sales growth.

We are responsible for the entire supply chain and distribution network for VIVITROL. We have limited experience in managing a complex, cGMP supply chain and pharmaceutical product distribution network. The manufacture of products and product components, packaging, storage and distribution of our products require successful coordination among ourselves and multiple third party providers. Issues with third parties who are part of our supply chain, including but not limited to suppliers, third party logistics providers, distributors, wholesalers and specialty pharmacies may have a material adverse effect on our business, results of operations and financial condition. Our inability to coordinate these efforts, the lack of capacity available from third parties or any other problems with third party operators could cause a delay in shipment of saleable products, a recall of products previously shipped or an impairment of our ability to supply products at all. These setbacks could increase our costs, cause us to lose revenue or market share and damage our reputation.

Sales of our products are dependent, in part, on the availability of reimbursement from third-party payors such as federal and state government agencies under programs such as Medicare and Medicaid, and private insurance plans and a reduction in payment rate or reimbursement could result in decreased use or sales of our products.

In both domestic and foreign markets, sales of our products are dependent, in part, on the availability of reimbursement from third party payors such as state and federal governments, under programs such as Medicare and Medicaid in the U.S. and private insurance plans. In certain foreign markets, the pricing and profitability of our products, such as RISPERDAL CONSTA, generally are subject to government controls. In the U.S., there have been, there are, and we expect there will continue to be, a number of state and federal proposals that could limit the amount that state or federal governments will pay to reimburse the cost of pharmaceutical products. In addition, we believe that private insurers, such as managed care organizations, may adopt their own reimbursement reductions unilaterally, or in response to any such federal legislation. Reduction in reimbursement for our products could have a material adverse effect on our results of operations and financial condition.

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Also, we believe the increasing emphasis on management of the utilization and cost of healthcare in the U.S. has and will continue to put pressure on the price and usage of our products, which may materially adversely impact product sales. We cannot predict the availability or amount of reimbursement for VIVITROL and current reimbursement policies may change at any time. We may not be able to sell VIVITROL profitably if reimbursement is unavailable or coverage is limited in scope or amount. If reimbursement for VIVITROL changes adversely, health care providers may limit how much or under what circumstances they will prescribe or administer VIVITROL, which could reduce use of VIVITROL or cause us to reduce the price of our product.

Additionally, we have assumed all of the risks and responsibilities associated with the additional development of VIVITROL, including regulatory approval and costs. We are currently conducting a randomized, multi-center registration study of VIVITROL in Russia for the treatment of opioid dependence. Clinical data from this study may form the basis of a sNDA to the FDA for VIVITROL for the treatment of opioid dependence. However, there is no assurance that the data from this study or any clinical or preclinical data will be sufficient to gain regulatory approval of VIVITROL for opioid dependence in the U.S. or other countries. Approval of VIVITROL for alcohol dependence in countries outside of the U.S., except for Russia and other countries in the CIS, and approval of VIVITROL for other indications in the U.S. and countries outside of the U.S. will depend on our sponsoring such efforts ourselves, including conducting additional clinical studies, which can be very costly, or entering into co-development, co-promotion or sales and marketing agreements with collaborators.

Further, when a new therapeutic product is approved, the availability of governmental and/or private reimbursement for that product is uncertain, as is the amount for which that product will be reimbursed. We cannot predict the availability or amount of reimbursement for our approved products or product candidates, including those at any stage of development, and current reimbursement policies for marketed products may change at any time.

If federal or state legislation is adopted substantially changing the way health insurance is provided to individuals in the U.S., if reimbursement for our products changes adversely or if we fail to obtain adequate reimbursement for our current or future products, healthcare providers may limit how much or under what circumstances they will prescribe or administer them, or patients may be unwilling to pay any required co-payments, which could reduce the use of our products or cause us to reduce the price of our products, either or both of which could have a material adverse effect on our business, results of operations and financial condition.

Our customer base who 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, McKesson and Amerisource, control a significant share of this network. Fluctuations in the buying patterns of these customers, which may result from seasonality, wholesaler buying decisions 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.

In an effort to combat the fluctuations in the buying patterns and the potential harm to our financial condition, we have entered into wholesaler distribution service agreements, (DSAs), with our three largest wholesale drug distributors. Under the DSAs, we will pay the wholesalers a fee. We believe it is beneficial to enter into DSAs to establish specified levels of product inventory to be maintained by our wholesalers and to 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

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inventory level data provided through DSAs is inaccurate, our business, financial condition, cash flows and results of operations may be adversely affected.

There are risks in the manufacturing and distribution of our products and product candidates.

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

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

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

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, results of operations and financial condition.

The manufacture of our products is subject to government regulation.

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

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Our business involves environmental risks.

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

We rely heavily on collaborative partners.

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

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

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

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

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

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

We currently have very little marketing experience and limited sales capabilities. Therefore, in order to commercialize our product candidates, we must either develop our own marketing and distribution sales capabilities or collaborate with a third party to perform these functions. We may, in some instances, rely significantly on sales, marketing and distribution arrangements with our collaborative partners and other third parties. For example, we rely completely on Janssen to market, sell and distribute RISPERDAL CONSTA, and will rely upon Lilly and Amylin to market and distribute exenatide once weekly. In these instances, our future revenues will be materially dependent upon the success of the efforts of these third parties.

In November 2008, we and Cephalon agreed to end the collaboration for the development, supply and commercialization of certain products, including VIVITROL in the U.S., effective on the Termination Date, and we assumed the risks and responsibilities for the marketing and sale of VIVITROL in the U.S. As of the Termination Date, Cephalon is no longer responsible for the marketing and sale of VIVITROL in the U.S., and we are responsible for all VIVITROL profits or losses. In order to facilitate the full transfer of all commercialization of VIVITROL to us, Cephalon, at our option, is performing certain transition services on our behalf until May 31, 2009 at an FTE rate agreed to by the parties. We have limited experience in the commercialization of pharmaceutical products. We may not be able to attract and retain qualified personnel to

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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 and financial condition would be materially adversely affected.

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

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

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

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

be difficult to manufacture on a large scale;

be uneconomical; or

infringe on proprietary rights of another party.

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

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

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

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

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

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

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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.

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, results of operations and financial condition may be materially adversely affected by any delays in, or termination of, our clinical trials.

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

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

We may not become profitable on a sustained basis.

At March 31, 2009, our accumulated deficit was $326.1 million, which is primarily the result of net losses incurred from 1987, the year we were founded, to date, partially offset by net income over the past four fiscal years. There can be no assurance we will achieve sustained profitability.

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

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

obtain and maintain regulatory approval for our products and product candidates, and for our partnered products, including exenatide once weekly, both in the U.S. and in foreign countries;

efficiently manufacture our commercial products;

support the marketing and sale of RISPERDAL CONSTA by our partner Janssen;

successfully commercialize VIVITROL in the U.S.;

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

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

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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 proprietary and collaborative product candidates, including clinical trials;

the time and expense that will be required to pursue FDA and/or foreign regulatory approvals for our product candidates and whether such approvals are obtained;

the time and expense required to prosecute, enforce and/or challenge patent and other intellectual property rights;

the cost of building, operating and maintaining manufacturing and research facilities;

the cost of third party manufacture;

the number of product candidates we pursue, particularly proprietary product candidates;

how competing technological and market developments affect our product candidates;

the cost of possible acquisitions of technologies, compounds, product rights or companies;

the cost of obtaining licenses to use technology owned by others for proprietary products and otherwise;

the costs of potential litigation; and

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

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

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

We may require additional funds to complete any of our programs, and we may seek funds through various sources, including debt and equity offerings, corporate collaborations, bank borrowings, arrangements relating to assets, sale of

royalty streams we receive on our products or other financing methods or structures. The source, timing and availability of any financings will depend on market conditions, interest rates and other factors. If we are unable to raise additional funds on terms that are favorable to us, we may have to cut back significantly on one or more of our programs or give up some of our rights to our technologies, 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.

Approval from the FDA is required to manufacture and market pharmaceutical products in the U.S. Regulatory agencies in foreign countries have similar requirements. The process that pharmaceutical products must undergo to obtain this approval is extensive and includes preclinical testing and clinical trials to demonstrate

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safety and efficacy and a review of the manufacturing process to ensure compliance with cGMP regulations. The FDA or foreign regulatory agencies may choose not to communicate with or update us during clinical testing and regulatory review periods. The ultimate decision by the FDA or foreign regulatory agencies regarding drug approval may not be consistent with prior communications. See risk factor RISPERDAL CONSTA, VIVITROL and our product candidates may not generate significant revenues.

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

- a product candidate may not be safe or effective;
- data from preclinical testing and clinical trials may be interpreted by the FDA or foreign regulatory agencies in different ways than we or our partners interpret it;
- the FDA or foreign regulatory agencies might not approve our or our partners manufacturing processes or facilities;
- the FDA or foreign regulatory agencies may change their approval policies or adopt new regulations;
- a product candidate may not be approved for all the indications we or our partners request; 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.

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

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

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

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

- new laws, regulations or judicial decisions, or new interpretations of existing laws, regulations or decisions, related to patent protection and enforcement, health care availability, method of delivery and payment for health care products and services or our business operations generally;
- changes in the FDA and foreign regulatory approval processes that may delay or prevent the approval of new products and result in lost market opportunity;

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

changes in the tax laws relating to our operations.

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

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

Our activities, including the sale and marketing of our products, are subject to extensive government regulation and oversight, including regulation under the federal Food, Drug and Cosmetic Act and other

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

Pharmaceutical and biotechnology companies have been the target of lawsuits and investigations alleging violations of government regulation, including claims asserting antitrust violations, violations of the Federal False Claim Act, the Anti-Kickback Statute, the Prescription Drug Marketing Act and other violations in connection with off-label promotion of products and Medicare and/or Medicaid reimbursement or related to environmental matters and claims under state laws, including state anti-kickback and fraud laws.

While we continually strive to comply with these complex requirements, interpretations of the applicability of these laws to marketing practices are ever evolving. If any such actions are instituted against us or our collaboration partners and we are not successful in defending ourselves or asserting our rights, those actions could have a significant and material impact on our business, including the imposition of significant fines or other sanctions. Even an unsuccessful challenge could cause adverse publicity and be costly to respond to, and thus could have a material adverse effect on our business, results of operations and financial condition.

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

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

Patent protection for our products is important and uncertain.

The following factors are important to our success:

- receiving and maintaining patent protection for our products and product candidates, including those which are the subject of collaborations with our collaborative partners;
- maintaining our trade secrets;
- not infringing the proprietary rights of others; and
- preventing others from infringing our proprietary rights.

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

We know of several U.S. patents issued to third parties that may relate to our product candidates. We also know of patent applications filed by other parties in the U.S. and various foreign countries that may relate to some of our product candidates if such patents are issued in their present form. If patents are issued that cover our product candidates, we may not be able to manufacture, use, offer for sale, import or sell some of them without first getting a license from the patent holder. The patent holder may not grant us a license on

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reasonable terms or it may refuse to grant us a license at all. This could delay or prevent us from developing, manufacturing or selling those of our product candidates that would require the license. A patent holder might also file an infringement action against us claiming that the manufacture, use, offer for sale, import or sale of our product candidates infringed one or more of its patents. Our cost of defending such an action is likely to be high and we might not receive a favorable ruling.

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

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

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

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

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

There has been, and we expect that there may continue to be, significant litigation in the industry regarding patents and other intellectual property rights. Litigation and administrative proceedings concerning patents and other intellectual property rights may be protracted, expensive and distracting to management. Competitors may sue us as a way of delaying the introduction of our products. Any litigation, including any interference proceedings to determine

priority of inventions, oppositions to patents in foreign countries or litigation against our partners may be costly and time consuming and could harm our business. We expect that litigation may be necessary in some instances to determine the validity and scope of certain of our proprietary rights. Litigation may be necessary in other instances to determine the validity, scope and/or noninfringement

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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, conversely, hinder our ability to manufacture and market our products.

We may be exposed to product liability claims and recalls.

We may be exposed to product liability claims arising from the testing, manufacture and commercial sale of RISPERDAL CONSTA and VIVITROL, or the use of our product candidates in clinical trials or commercially, once approved. These claims may be brought by consumers, clinical trial participants, our collaborative partners or third parties selling the products. We currently carry product liability insurance coverage in such amounts as we believe are sufficient for our business. However, we cannot provide any assurance that this coverage will be sufficient to satisfy any liabilities that may arise. As our development activities progress and we continue to have commercial sales, this coverage may be inadequate, we may be unable to obtain adequate coverage at an acceptable cost or we may be unable to get adequate coverage at all or our insurer may disclaim coverage as to a future claim. This could prevent or limit our commercialization of our product candidates or commercial sales of our products. Even if we are able to maintain insurance that we believe is adequate, our results of operations and financial condition may be materially adversely affected by a product liability claim. Uncertainties resulting from the initiation and continuation of products liability litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace. Products liability litigation and other related proceedings may also absorb significant management time.

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

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

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

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

We compete with other biotechnology and pharmaceutical companies with financial resources and capabilities substantially greater than our resources and capabilities, in the development of new products. We cannot 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 platform technologies or to the product candidates we have in development. Because there is rapid technological change in the industry and because other companies have

more resources than we do, other companies may:

develop their products more rapidly than we can;

complete any applicable regulatory approval process sooner than we can; or

offer their newly developed products at prices lower than our prices.

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

Foreign currency exchange rates may affect revenue.

We conduct a large portion of our business in international markets. We derive a majority of our RISPERDAL CONSTA revenues from sales in foreign countries and these sales are denominated in foreign currencies. Such revenues fluctuate when translated to U.S. dollars as a result of changes in foreign currency exchange rates. We currently do not hedge this exposure. An increase in the U.S. dollar relative to other currencies in which we have revenues will cause our foreign revenues to be lower than with a stable exchange rate. A large increase in the value of the U.S. dollar relative to such foreign currencies could have a material adverse affect on our revenues, results of operations and financial condition.

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

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

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

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

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

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

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

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

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

Our product candidates, if successfully developed and approved for commercial sale, will compete with a number of drugs and therapies currently manufactured and marketed by major pharmaceutical and other biotechnology companies. Our product candidates may also compete with new products currently under development by others or with products which may cost less than our product candidates. Physicians, patients, third party payors and the medical community may not accept or utilize any of our product candidates that may be approved. If our product candidates, if and when approved, do not achieve significant market acceptance, our business, results of operations and financial condition may be materially adversely affected. For more information on other factors that would impact the market acceptance of our product candidates, if and when approved, see the risk factor RISPERDAL CONSTA, VIVITROL and our product candidates may not generate significant revenues.

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

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

We may not be able to retain our key personnel.

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

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

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

mergers;

acquisitions;

strategic alliances;

licensing agreements; and

co-promotion agreements.

We may choose to enter into one or more of these transactions at any time, which may cause substantial fluctuations in the market price of our stock. Moreover, depending upon the nature of any transaction, we may

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experience a charge to earnings, which could also materially adversely affect our results of operations and could harm the market price of our stock.

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

As discussed above under the risk factor We may require additional funds to complete our programs and such funding may not be available on commercially favorable terms and may cause dilution to our existing shareholders, we may issue additional equity securities or securities convertible into equity securities to raise funds, thus reducing the ownership share of the current holders of our common stock, which may adversely affect the market price of the common stock. As of March 31, 2009, we were obligated to issue 18,987,529 shares of common stock upon the vesting and exercise of stock options and vesting of stock awards. In addition, any of our shareholders could sell all or a large number of their shares, which could adversely affect the market price of our common stock.

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

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

In addition, we rely on third parties for several important aspects of our business. For example, we depend upon collaborators for both manufacturing and royalty revenue 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 continued deterioration 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 investment portfolio may become impaired by further deterioration of the capital markets.

As a result of current adverse financial market conditions, investments in some financial instruments, such as auction rate securities and asset backed debt securities, may pose risks arising from liquidity and credit concerns. We have limited holdings of these investments in our portfolio, however, the current disruptions in the credit and financial markets have negatively affected investments in many industries, including those in which we invest. The current global economic crisis has had, and may continue to have, a negative impact on the market values of the investments in our investment portfolio. We cannot predict future market conditions or market liquidity and there can be no assurance that the markets for these securities will not deteriorate further or that the institutions that these investments are with will be able to meet their debt obligations at the time we may need to liquidate such investments or until such time as the investments mature. Although we currently have no plans to access the equity or debt markets to meet capital or liquidity needs, constriction and volatility in these markets may restrict future flexibility to do so if unforeseen capital or liquidity needs were to arise.

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

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reasons that were unrelated to the operating performance of any one company. In particular, and in addition to circumstances described elsewhere under these risk factors, the following risk factors can adversely affect the market price of our common stock:

- non-approval, set-backs or delays in the development or manufacture of our product candidates and success of our research and development programs;
- public concern as to the safety of drugs developed by us or others;
- announcements of issuances of common stock or acquisitions by us;
- the announcement and timing of new product introductions by us or others;
- material public announcements;
- events related to our products or those of our competitors, including the withdrawal or suspension of products from the market;
- availability and level of third party reimbursement;
- political developments or proposed legislation in the pharmaceutical or healthcare industry;
- economic or other external factors, disaster or crisis;
- developments of our corporate partners;
- termination or delay of development program(s) by our corporate partners;
- announcements of technological innovations or new therapeutic products or methods by us or others;
- changes in government regulations or policies or patent decisions;
- changes in patent legislation or adverse changes to patent law;
- changes in key members of management;
- failure to meet our financial expectations or changes in opinions of analysts who follow our stock; or
- general market conditions.

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

Although we have limited experience in acquiring businesses, we may acquire additional businesses that complement or augment our existing business. If we acquire businesses with promising drug candidates or technologies, we may not be able to realize the benefit of acquiring such businesses if we are unable to move one or more drug candidates through preclinical and/or clinical development to regulatory approval and commercialization. Integrating any newly acquired businesses or technologies could be expensive and time-consuming, resulting in the diversion of resources from our current business. We may not be able to integrate any acquired business successfully. We cannot assure you

that, following an acquisition, we will achieve revenues, specific net income or loss levels that justify the acquisition or that the acquisition will result in increased earnings, or reduced losses, for the combined company in any future period. Moreover, we may need to raise additional funds through public or private debt or equity financing to acquire any businesses, which would result in dilution for shareholders or the incurrence of indebtedness. We may not be able to operate acquired businesses profitably or otherwise implement our growth strategy successfully.

Anti-takeover provisions may not benefit shareholders.

We are a Pennsylvania corporation and Pennsylvania law contains strong anti-takeover provisions. In February 2003, our board of directors adopted a shareholder rights plan. The shareholder rights plan is designed to cause substantial dilution to a person who attempts to acquire us on terms not approved by our board of directors. The shareholder rights plan and Pennsylvania law could make it more difficult for a person

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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 stockholders.

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

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

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

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

We may incur financial and operational risk in connection with the move of our headquarters from Cambridge, Massachusetts to Waltham, Massachusetts.

In April 2009, we announced plans to move our corporate headquarters to Waltham, Massachusetts from Cambridge, Massachusetts. In connection with the move, we have signed a lease agreement and are building out a 100,000 square foot facility in Waltham. We anticipate that the move will be completed in early calendar year 2010 and expect the relocation to result in annual cash savings in fiscal year 2011 and beyond of approximately $8 million, however, expected savings from relocating a facility can be highly variable and uncertain. In addition, we subleased

substantially all of our current headquarters for the balance of that lease term. This sublease transaction substantially offsets our ongoing expenses associated with our current headquarters, however, to the extent the build-out of the Waltham facility is delayed, the terms of the sublease may be adversely affected, which may result in increased costs and risks. In addition, relocation of our

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corporate headquarters could adversely affect employee retention and focus, and it may be difficult to manage operations during the overlapping period that the Waltham and Cambridge facilities are both open.

The risk factors discussed within Item 1A and other similar matters could divert our management s attention from other business concerns. Such matters could also result in harm to our reputation and significant monetary liability for us, and require that we take other actions not presently contemplated, any or all of which could have a material adverse effect on our business, results of operations and financial condition.

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

None.

Item 2. ***Properties***

We lease space 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. Our corporate headquarters, administration areas and laboratories are located in this space. We have established and are operating clinical facilities, with the capability to produce clinical supplies of our pulmonary and injectable extended-release products, at this location. In April 2009, we announced that we will move our corporate headquarters from Cambridge, Massachusetts to Waltham, Massachusetts in early calendar 2010.

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

We lease a commercial manufacturing facility in Chelsea, Massachusetts designed for clinical and commercial manufacturing of inhaled products based on our AIR pulmonary technology that we are not currently utilizing. The lease term is for fifteen years, expiring in 2015, with an option to extend the term for up to two five-year periods. We exited this facility in fiscal 2008 and have no plans to extend the lease beyond its expiration date.

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

Item 3. ***Legal Proceedings***

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

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

No matters were submitted to a vote of our security holders, through the solicitation of proxies or otherwise, during the last quarter of the fiscal year ended March 31, 2009.

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PART II

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

(a) Market Information

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

	Fiscal 2009		Fiscal 2008	
	High	Low	High	Low
1st Quarter	$ 13.94	$ 10.81	$ 17.85	$ 14.38
2nd Quarter	17.05	11.79	18.51	14.00
3rd Quarter	13.54	5.55	18.78	12.30
4th Quarter	13.16	8.26	16.00	10.32

The last reported sale price of our common stock as reported on the NASDAQ Stock Market on May 20, 2009 was $8.81

(b) Stockholders

There were 340 shareholders of record for our common stock and one shareholder of record for our non-voting common stock on May 20, 2009.

(c) Dividends

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

(d) Securities authorized for issuance under equity compensation plans

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

(e) Repurchase of equity securities

A summary of our stock repurchase activity for the fourth quarter of the fiscal year ended March 31, 2009 is as follows:

	Total

Period	Total Number of Shares Purchased(a)	Average Price Paid per Share	Number of Shares Purchased as Part of a Publicly Announced Program(a)	Approximate Dollar Value of Shares That May Yet be Purchased Under the Program (In millions)
January 1 through January 31	4,747	9.99	4,747	$ 103.7
February 1 through February 28				$ 103.7
March 1 through March 31				$ 103.7
Total	4,747	$ 9.99	4,747	

(a) In November 2007, our board of directors authorized a program to repurchase up to $175.0 million of our common stock to be repurchased at the discretion of management from time to time in the open market or

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through privately negotiated transactions. The repurchase program has no set expiration date and may be suspended or discontinued at any time. We publicly announced the share repurchase program in our press release dated November 21, 2007. In June 2008, the board of directors authorized the expansion of this repurchase program by an additional $40.0 million, bringing the total authorization under this program to $215.0 million. We purchased 1,569,202 shares at a cost of approximately $18.0 million under this program during the year ended March 31, 2009 by means of open market purchases. As of March 31, 2009, we have purchased a total of 8,537,938 shares under this program at a cost of approximately $111.3 million.

In addition to the stock repurchases above, during the year ended March 31, 2009, we acquired, by means of net share settlements, 51,891 shares of Alkermes common stock, at an average price of $11.39 per share, related to the vesting of employee stock awards to satisfy withholding tax obligations. In addition, during the year ended March 31, 2009, we acquired 9,176 shares of Alkermes common stock, at an average price of $12.66 per share, tendered by employees as payment of the exercise price of stock options granted under our equity compensation plans.

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Performance Graph

The following graph compares the yearly percentage change in the cumulative total shareholder return on our common stock for the last five fiscal years, with the cumulative total return on the Nasdaq Stock Market Index and the Nasdaq Biotechnology Index. The comparison assumes $100 was invested on March 31, 2004 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

	2004	2005	2006	2007	2008	2009
Alkermes, Inc.	100	65	138	97	74	76
NASDAQ Stock Market Index	100	101	119	123	115	62
NASDAQ Biotechnology Index	100	84	108	100	100	88

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

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

Alkermes, Inc. and Subsidiaries

	Year Ended March 31,				
	2009	**2008**	**2007**	**2006**	**2005**
	(In thousands, except per share data)				
Consolidated Statements of Operations Data:					
REVENUES:					
Manufacturing revenues	$ 116,844	$ 101,700	$ 105,416	$ 64,901	$ 40,488
Royalty revenues	33,247	29,457	23,151	16,532	9,636
Product sales, net	4,467				
Research and development revenue under collaborative arrangements	42,087	89,510	74,483	45,883	26,002
Net collaborative profit(1)	130,194	20,050	36,915	39,285	
Total revenues	326,839	240,717	239,965	166,601	76,126
EXPENSES:					
Cost of goods manufactured and sold(2)	43,396	40,677	45,209	23,489	16,834
Research and development(2)	89,478	125,268	117,315	89,068	91,641
Selling, general and administrative(2)	59,008	59,508	66,399	40,383	29,499
Impairment of long-lived assets		11,630			
Restructuring(3)		6,423			11,527
Total expenses	191,882	243,506	228,923	152,940	149,501
OPERATING INCOME (LOSS)	134,957	(2,789)	11,042	13,661	(73,375)
OTHER (EXPENSE) INCOME:					
Gain on sale of investment in Reliant Pharmaceuticals, Inc.		174,631			
Interest income	11,400	17,834	17,707	11,569	3,005
Interest expense	(13,756)	(16,370)	(17,725)	(20,661)	(7,394)
Derivative (loss) income related to convertible subordinated notes(4)				(1,084)	4,385
Other (expense) income, net(5)	(1,589)	(476)	(481)	333	(1,789)
Total other (expense) income	(3,945)	175,619	(499)	(9,843)	(1,793)
INCOME (LOSS) BEFORE INCOME TAXES	131,012	172,830	10,543	3,818	(75,168)
INCOME TAXES	507	5,851	1,098		

NET INCOME (LOSS)	$ 130,505	$ 166,979	$ 9,445	$ 3,818	$ (75,168)
EARNINGS (LOSS) PER COMMON SHARE:					
BASIC	$ 1.37	$ 1.66	$ 0.10	$ 0.04	$ (0.83)
DILUTED	$ 1.36	$ 1.62	$ 0.09	$ 0.04	$ (0.83)
WEIGHTED AVERAGE NUMBER OF COMMON SHARES OUTSTANDING:					
BASIC	95,161	100,742	99,242	91,022	90,094
DILUTED	96,252	102,923	103,351	97,377	90,094

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	Year Ended March 31,				
	2009	2008	2007	2006	2005
	(In thousands, except per share data)				
Consolidated Balance Sheet Data:					
Cash, cash equivalents and investments	$ 404,482	$ 460,361	$ 357,466	$ 303,112	$ 202,567
Total assets	566,486	656,311	568,621	477,163	338,874
Long-term debt(6)	75,888	160,371	156,898	279,518	276,485
Unearned milestone revenue current and long-term		117,657	128,750	99,536	
Redeemable convertible preferred stock				15,000	30,000
Shareholders equity	434,888	305,314	203,461	33,216	4,112

(1) Includes $120.7 million recognized as revenue upon the termination of the VIVITROL collaboration with Cephalon during the year ended March 31, 2009.

(2) Includes share-based compensation expense as a result of the adoption of the Financial Accounting Standards Board s (FASB) Statement of Financial Accounting Standard (SFAS) No. 123(R), *Share-Based Payment* on April 1, 2006 (see Note 12 in the notes to the consolidated financial statements included in this Annual Report on Form 10-K).

(3) Represents charges in connection with our March 2008 and June 2004 restructurings of operations. The March 2008 and June 2004 restructuring programs were substantially completed during fiscal 2009 and fiscal 2005, respectively. Certain closure costs related to the leased facilities exited in connection with the March 2008 restructuring of operations will continue to be paid through December 2015.

(4) Represents noncash (loss) income in connection with derivative liabilities associated with the two-year interest make-whole payment provision of our 6.52% convertible senior subordinated notes and the three-year interest make-whole (Three-Year Interest Make-Whole) payment provision of our 2.5% convertible subordinated notes (2.5% Subordinated Notes). The derivative liability is recorded at fair value in the consolidated balance sheets.

(5) Primarily represents (expense) income recognized on the changes in the fair value of warrants of public companies held by us in connection with collaboration and licensing arrangements, which are recorded as derivatives under Other assets in the consolidated balance sheets. The recorded value of such warrants can fluctuate significantly based on fluctuations in the market value of the underlying securities of the issuer of the warrants. Also includes charges for other-than-temporary impairments attributed to certain strategic investments in the common stock of our collaborative partners.

(6) Includes the 7% Notes which were issued by Royalty Sub and are non-recourse to Alkermes.

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

Forward-Looking Statements

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

Although we believe that our expectations are based on reasonable assumptions within the bounds of our knowledge of our business and operations, the forward-looking statements contained in this document are neither promises nor guarantees, and our business is subject to significant risk and uncertainties and there can be no assurance that our actual results will not differ materially from our expectations. These forward looking statements include, but are not limited to, statements concerning: the achievement of certain business and operating milestones and future operating results and profitability; continued growth of RISPERDAL CONSTA sales; the commercialization of VIVITROL in the U.S. by us and in Russia and the CIS by Cilag; recognition of milestone payments from Cilag related to the future sales of VIVITROL; the successful continuation of development activities for our programs, including exenatide once weekly, a four-week formulation of RISPERDAL CONSTA, VIVITROL for opiate dependence, ALKS 27, ALKS 29, ALKS 33 and ALKS 36; the expectation and timeline for regulatory approval of the NDA submission for exenatide once weekly; the successful manufacture of our products and product candidates, including RISPERDAL CONSTA and VIVITROL, by us at a commercial scale, and the successful manufacture of exenatide once weekly by Amylin; and our building a successful commercial infrastructure for VIVITROL. Factors which could cause actual results to differ materially from our expectations set forth in our forward-looking statements include, among others: (i) manufacturing and royalty revenues from RISPERDAL CONSTA may not continue to grow, particularly because we rely on our partner, Janssen, to forecast and market this product; (ii) we may be unable to manufacture RISPERDAL CONSTA and VIVITROL in sufficient quantities and with sufficient yields to meet our partners requirements or to add additional production capacity for RISPERDAL CONSTA and VIVITROL, or unexpected events could interrupt manufacturing operations at our RISPERDAL CONSTA and VIVITROL manufacturing facility, which is the sole source of supply for these products; (iii) we may be unable to develop the commercial capabilities, and/or infrastructure, necessary to successfully commercialize VIVITROL; (iv) Cilag may be unable to receive approval for VIVITROL for the treatment of opioid dependence in Russia and for the treatment of alcohol and opioid dependence in the other countries in the CIS; (v) Cilag may be unable to successfully commercialize VIVITROL; (vi) third party payors may not cover or reimburse our products; (vii) if approved, Lilly and Amylin may be unable to successfully commercialize exenatide once weekly; (viii) we may be unable to scale-up and manufacture our product candidates commercially or economically; (ix) we may not be able to source raw materials for our production processes from third parties; (x) Amylin may not be able to successfully operate the manufacturing facility for exenatide once weekly and the FDA may not find the product produced in the Amylin facility comparable to the product used in the pivotal clinical study which was produced in our facility; (xi) our product candidates, if approved for marketing, may not be launched successfully in one or all indications for which marketing is approved and, if launched, may not produce significant revenues; (xii) we rely on our partners to determine the regulatory and marketing strategies for RISPERDAL CONSTA, including the four-week formulation of RISPERDAL CONSTA currently being developed by us, and our other partnered, non-proprietary programs; (xiii) RISPERDAL CONSTA, VIVITROL and our product candidates in commercial use may have unintended side effects, adverse reactions or incidents of misuse and the FDA or other health authorities could require post approval studies or require removal of

our products from the market; (xiv) our collaborators could elect to terminate or delay programs at any time and disputes with collaborators or failure to negotiate acceptable new

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collaborative arrangements for our technologies could occur; (xv) clinical trials may take more time or consume more resources than initially envisioned; (xvi) results of earlier clinical trials may not necessarily be predictive of the safety and efficacy results in larger clinical trials; (xvii) our product candidates could be ineffective or unsafe during preclinical studies and clinical trials, and we and our collaborators may not be permitted by regulatory authorities to undertake new or additional clinical trials for product candidates incorporating our technologies, or clinical trials could be delayed or terminated; (xviii) after the completion of clinical trials for our product candidates, including exenatide once weekly, or after the submission for marketing approval of such product candidates, the FDA or other health authorities could refuse to accept such filings, could request additional preclinical or clinical studies be conducted or request a safety monitoring program, any of which could result in significant delays or the failure of such products to receive marketing approval; (xix) even if our product candidates appear promising at an early stage of development, product candidates could fail to receive necessary regulatory approvals, be difficult to manufacture on a large scale, be uneconomical, fail to achieve market acceptance, be precluded from commercialization by proprietary rights of third parties or experience substantial competition in the marketplace; (xx) technological change in the biotechnology or pharmaceutical industries could render our products and/or product candidates obsolete or non-competitive; (xxi) difficulties or set-backs in obtaining and enforcing our patents and difficulties with the patent rights of others could occur; (xxii) we may incur losses in the future; (xxiii) we may need to raise substantial additional funding to continue research and development programs and clinical trials and other operations and could incur difficulties or setbacks in raising such funds, which may be further impacted by current economic conditions and the lack of available credit sources; (xxiv) we may not be able to liquidate or otherwise recoup our investments in corporate debt securities, asset backed debt securities and auction rate securities.

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

Executive Summary

Net income for the year ended March 31, 2009 was $130.5 million, or $1.37 per common share basic and $1.36 per common share diluted, as compared to net income of $167.0 million, or $1.66 per common share basic and $1.62 per common share diluted, for the year ended March 31, 2008 and $9.4 million, or $0.10 per common share basic and $0.09 per common share diluted, for the year ended March 31, 2007.

Net income for the year ended March 31, 2009 reflects continued growth in unit sales of RISPERDAL CONSTA and the recognition of $120.7 million of previously deferred and unearned milestone revenue related to the termination of the VIVITROL collaboration with Cephalon. As of the Termination Date, we assumed the risks and responsibilities for the marketing and sale of VIVITROL in the U.S. and we were responsible for all VIVITROL profits or losses, except for $11.0 million Cephalon paid us to fund its share of estimated VIVITROL product losses during the one-year period following the Termination Date.

During the year ended March 31, 2009, we purchased $93.0 million in principal amount of our 7% Notes for $89.4 million and repurchased 1,569,202 shares of our common stock for $18.0 million.

Results of Operations

Manufacturing Revenues

	Years Ended March 31,	Change Favorable/(Unfavorable)

	2009	2008	2007	2009-2008	2008-2007
			(In millions)		
Manufacturing revenues:					
Risperdal Consta	$ 112.4	$ 95.2	$ 88.6	$ 17.2	$ 6.6
Vivitrol	4.4	6.5	16.8	(2.1)	(10.3)
Manufacturing revenues	$ 116.8	$ 101.7	$ 105.4	$ 15.1	$ (3.7)

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The increase in RISPERDAL CONSTA manufacturing revenues for the year ended March 31, 2009, as compared to the year ended March 31, 2008, was due to a 19% increase in the number of units shipped to Janssen due to increased customer demand. The number of RISPERDAL CONSTA units shipped for sale in foreign countries comprised 76%, 80% and 73% of the total units shipped during the years ended March 31, 2009, 2008 and 2007, respectively. 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 increase in RISPERDAL CONSTA manufacturing revenues for the year ended March 31, 2008, as compared to the year ended March 31, 2007, was due to an 11% increase in the per unit net sales price, partially offset by a 3% decrease in the number of units shipped to Janssen. The increase in the per unit net sales price was primarily due to the weakening of the U.S. dollar in relation to the foreign countries in which the product was sold and the decrease in the number of units shipped was due to Janssen managing its product inventory due in part to increased efficiencies and reliability in our RISPERDAL CONSTA manufacturing process.

Under our manufacturing and supply agreement with Janssen, we earn manufacturing revenues when product is shipped to Janssen, based on a percentage of Janssen s estimated unit net sales price. Revenues include a quarterly adjustment from Janssen s estimated unit net sales price to Janssen s actual unit net sales price for product shipped. In the years ended March 31, 2009, 2008 and 2007, our RISPERDAL CONSTA manufacturing revenues were based on an average of 7.5% of Janssen s unit net sales price of RISPERDAL CONSTA. We anticipate that we will earn manufacturing revenues at 7.5% of Janssen s unit net sales price of RISPERDAL CONSTA for product shipped in the fiscal year ending March 31, 2010 and beyond.

VIVITROL manufacturing revenues consist of the following:

	Years Ended March 31,		
	2009	2008	2007
	(In millions)		
VIVITROL manufacturing revenues:			
VIVITROL sold to Cephalon(1)	$ 3.8	$ 6.5	$ 16.8
VIVITROL sold to Cilag for resale in Russia	0.6		
VIVITROL manufacturing revenues	$ 4.4	$ 6.5	$ 16.8

(1) Prior to the termination of the VIVITROL collaboration with Cephalon, Cephalon was responsible for the marketing and sale of VIVITROL in the U.S. and we were responsible for the manufacturing, for which we billed Cephalon at cost upon shipment of product. VIVITROL manufacturing revenues includes a 10% markup on cost of goods manufactured which is described in greater detail below.

VIVITROL manufacturing revenues on product sold to Cephalon for the years ended March 31, 2009, 2008 and 2007 included $0.3 million, $0.6 million and $1.5 million, respectively, of milestone revenue related to manufacturing profit earned on VIVITROL, which equaled a 10% markup on VIVITROL cost of goods manufactured and drew down from unearned milestone revenue. VIVITROL manufacturing revenues on product sold to Cephalon for the years ended March 31, 2008 and 2007 included $2.2 million and $3.7 million, respectively, of billings for idle capacity costs. VIVITROL was approved for sale in Russia for the treatment of alcohol dependence in August 2008 and was launched by Cilag in March 2009.

As a result of the termination of the collaboration with Cephalon, we assumed title to certain VIVITROL inventory which we had previously sold to Cephalon, and in December 2008 we reduced VIVITROL manufacturing revenues earned on product sold to Cephalon by $0.7 million and manufacturing profit by $0.1 million to reverse the previous sale of this product inventory to Cephalon.

The decrease in VIVITROL manufacturing revenues for the year ended March 31, 2008, as compared to March 31, 2007, was due to the management of manufacturing volumes to avoid excess inventory. During the year ended March 31, 2007, we shipped large quantities of VIVITROL to Cephalon to build sufficient inventory to support the commercial launch of VIVITROL.

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Royalty Revenues

	Years Ended March 31,			Change Favorable/(Unfavorable)	
	2009	2008	2007	2009-2008	2008-2007
	(In millions)				
Royalty revenues	$ 33.2	$ 29.5	$ 23.2	$ 3.7	$ 6.3

Substantially all of our royalty revenues for the years ended March 31, 2009, 2008 and 2007 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, 2009, 2008 and 2007 were based on RISPERDAL CONSTA sales of $1,324.9 million, $1,176.5 million and $924.2 million, respectively. Units sold in foreign countries by Janssen in the year ended March 31, 2009, 2008 and 2007 accounted for 77%, 77% and 76% of the total units sold, respectively. The increase in royalty revenues in the year ended March 31, 2009, as compared to the year ended March 31, 2008, was due to a 16% increase in the number of units sold by Janssen, partially offset by a 4% decrease in the selling price of the product in foreign countries primarily due to an overall strengthening of the U.S. dollar in relation to the foreign currencies of the countries in which the product was sold. The increase in royalty revenues in the year ended March 31, 2008, as compared to the year ended March 31, 2007, was due to a 15% increase in the number of units sold by Janssen and a 12% increase in the average selling price of the product primarily due to an overall weakening of the U.S. dollar in relation to the foreign currencies of the countries in which the product was sold. 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.

Product Sales, net

Upon termination of the VIVITROL collaboration with Cephalon, we assumed the risks and responsibilities for the marketing and sale of VIVITROL in the U.S., effective on the Termination Date. The following table presents the adjustments deducted from gross VIVITROL product sales to arrive at VIVITROL product sales, net, during the period from December 1, 2008 through March 31, 2009:

	Year Ended March 31,	
	2009	% of Sales
	(In millions)	
Product sales, gross	$ 6.3	100.0%
Adjustments to product sales, gross:		
Product returns(1)	(1.3)	(20.6)%
Medicaid rebates	(0.2)	(3.2)%
Prompt-pay discounts	(0.1)	(1.6)%
Other	(0.2)	(3.2)%
Total adjustments	(1.8)	(28.6)%
Product sales, net	$ 4.5	71.4%

(1) Following the introduction of a return policy for VIVITROL, our estimate for product returns 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 sales history to reasonably estimate returns related to these shipments. We estimate 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.

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During the year ended March 31, 2009, gross sales of VIVITROL 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 Date. Gross sales of VIVITROL by Cephalon during the years ended March 31, 2008 and 2007 were $18.0 million and $6.5 million, respectively.

Research and Development Revenue Under Collaborative Arrangements

	Years Ended March 31,			Change Favorable/(Unfavorable)	
	2009	2008	2007	2009-2008	2008-2007
	(In millions)				
Research and development programs:					
AIR Insulin	$ 26.8	$ 49.5	$ 40.1	$ (22.7)	$ 9.4
Exenatide once weekly	9.5	32.9	19.3	(23.4)	13.6
Four-week RISPERDAL CONSTA	4.6			4.6	
AIR PTH		5.1	6.5	(5.1)	(1.4)
VIVITROL		1.2	4.6	(1.2)	(3.4)
Other	1.2	0.8	4.0	0.4	(3.2)
Research and development revenue under collaborative arrangements	$ 42.1	$ 89.5	$ 74.5	$ (47.4)	$ 15.0

The decrease in revenue from the AIR Insulin program in the year ended March 31, 2009, as compared to the year ended March 31, 2008, was due to the termination of the AIR Insulin development program in March 2008. Under the AIR Insulin Termination Agreement, we recognized $25.5 million of R&D revenue in the three months ended June 30, 2008. We do not expect to record any material amounts of revenue from the AIR Insulin development program in the future. The decrease in the revenues earned under the exenatide once weekly development program in the year ended March 31, 2009, as compared to the year ended March 31, 2008, was due to reduced activity as the program neared the submission of the NDA to the FDA, which occurred in May 2009. In January 2009, we announced that J&JPRD initiated a phase 1, single-dose, open-label study of a four-week formulation of RISPERDAL CONSTA for the treatment of schizophrenia. RISPERDAL CONSTA is currently marketed as a two-week formulation.

The increase in the revenues earned under the AIR Insulin and exenatide once weekly development programs in the year ended March 31, 2008, as compared to the year ended March 31, 2007, were due to increased activity as the programs progressed through their clinical trials. Included in the exenatide once weekly development program revenue for the year ended March 31, 2008 was a $5.0 million payment we received from Amylin in December 2007 related to the achievement of a phase 3 milestone. Upon achievement of the phase 3 milestone, we recalculated the amounts due under the proportional performance model, and based on the proportional performance to date adjusted revenues to the lesser of the amount due under the contract or the amount based on the proportional performance to date. Based on the amount of effort that had been expended when the phase 3 milestone was achieved and the payments we expect to receive under the program, we were able to recognize the full amount as revenue in the period received.

The AIR parathyroid hormone (PTH) program was terminated in August 2007. We do not expect to record any material amounts of revenue from the AIR PTH development program in the future. During the years ended

March 31, 2008 and 2007, we recorded VIVITROL research and development revenue related to the work we performed on the construction and validation of two additional VIVITROL manufacturing lines at our Ohio manufacturing facilities, which were constructed under the VIVITROL collaboration with Cephalon. We stopped construction on the lines during the year ended March 31, 2008.

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Net Collaborative Profit

	Years Ended March 31,			Change Favorable/(Unfavorable)	
	2009	2008	2007	2009-2008	2008-2007
	(In millions)				
Net collaborative profit:					
Milestone revenue cost recovery	$	$ 5.3	$ 78.8	$ (5.3)	$ (73.5)
Milestone revenue license	3.5	5.2	5.1	(1.7)	0.1
Recognition of deferred and unearned milestone revenue due to termination of VIVITROL collaboration	120.7			120.7	
Total milestone revenue	124.2	10.5	83.9	113.7	(73.4)
Net payments from (to) Cephalon		9.6	(47.0)	(9.6)	56.6
VIVITROL losses funded by Cephalon, post termination	6.0			6.0	
Net collaborative profit	$ 130.2	$ 20.1	$ 36.9	$ 110.1	$ (16.8)

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

Upon the termination of the VIVITROL collaboration with Cephalon, we recognized $120.7 million of net collaborative profit which consisted of $113.9 million of unearned milestone revenue that existed at the Termination Date and $6.8 million of deferred revenue. At the Termination Date, we had $22.8 million of deferred revenue related to the original sale of the two partially completed VIVITROL manufacturing lines to Cephalon. We paid Cephalon $16.0 million to acquire the title to these manufacturing lines and accounted for the payment as a reduction to deferred revenue. The remaining $6.8 million of deferred revenue and the $113.9 million of unearned milestone revenue were recognized as revenue in the three months ended December 31, 2008, as we had no remaining performance obligations to Cephalon and the amounts were nonrefundable. Net payments from (to) Cephalon were received based upon the sharing of VIVITROL costs and losses incurred during the reporting periods.

Upon termination of the VIVITROL collaboration, we received $11.0 million from Cephalon to fund their share of estimated VIVITROL losses during the one-year period following the Termination Date. We recorded the $11.0 million as deferred revenue and are recognizing it as revenue though the application of a proportional performance model based on net VIVITROL losses. We do not expect to recognize any further net collaborative profit after the $11.0 million payment has been fully recognized as revenue, which we expect to occur in fiscal year 2010.

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Cost of Goods Manufactured and Sold

	Years Ended March 31,			Change Favorable/(Unfavorable)	
	2009	2008	2007	2009-2008	2008-2007
	(In millions)				
Cost of goods manufactured and sold:					
Risperdal Consta	$ 31.3	$ 34.8	$ 29.9	$ 3.5	$ (4.9)
Vivitrol	11.8	5.9	15.3	(5.9)	9.4
Other	0.3			(0.3)	
Cost of goods manufactured and sold	$ 43.4	$ 40.7	$ 45.2	$ (2.7)	$ 4.5

The decrease in cost of goods manufactured for RISPERDAL CONSTA in the year ended March 31, 2009, as compared to the year ended March 31, 2008, was due to a 24% decrease in the unit cost of RISPERDAL CONSTA, primarily due to increased operating efficiencies, partially offset by a 19% increase in the number of units of RISPERDAL CONSTA shipped to Janssen to meet customer demand. The increase in cost of goods manufactured for RISPERDAL CONSTA in the year ended March 31, 2008, as compared to the year ended March 31, 2007, was due to a 19% increase in unit cost of RISPERDAL CONSTA, partially offset by a 3% decrease in the number of units of RISPERDAL CONSTA shipped to Janssen. Shipments of RISPERDAL CONSTA were slightly lower in the year ended March 31, 2008, as compared to the year ended March 31, 2007, as Janssen managed its levels of product inventory, due in part to increased efficiencies and reliability in our RISPERDAL CONSTA manufacturing processes.

Cost of goods manufactured and sold for VIVITROL in the year ended March 31, 2009 consisted of $8.4 million of cost of goods manufactured for Cephalon incurred prior to the Termination Date, less $0.7 million of product previously sold to Cephalon that was reversed in connection with the termination of the VIVITROL collaboration. In addition, we had cost of goods sold of $3.6 million relating to product sold by us in the U.S. after the Termination Date and $0.5 million of cost of goods manufactured for Cilag for resale in Russia. VIVITROL cost of goods manufactured for the year ended March 31, 2008 consisted of $3.2 million of product shipments to Cephalon and $2.7 million of idle capacity costs, which consisted of current year manufacturing costs allocated to cost of goods manufactured which were related to underutilized VIVITROL manufacturing capacity. VIVITROL cost of goods manufactured for the year ended March 31, 2007 consisted of $11.6 million of product shipments to Cephalon and $3.7 million of idle capacity costs. We began shipping VIVITROL to Cephalon for the first time during the quarter ended June 30, 2006, and during the remainder of the fiscal year ended March 31, 2007 we shipped quantities sufficient to build inventory to support the commercial launch of the product.

Research and Development Expense

	Years Ended March 31,			Change Favorable/(Unfavorable)	
	2009	2008	2007	2009-2008	2008-2007
	(In millions)				
Research and development	$ 89.5	$ 125.3	$ 117.3	$ 35.8	$ (8.0)

The decrease in research and development expenses for the year ended March 31, 2009, as compared to the year ended March 31, 2008, was primarily due to the termination of the AIR Insulin development program in March 2008, the termination of the AIR PTH development program in August 2007 and reductions in costs incurred on the exenatide once weekly development program as the program neared the submission of the NDA to the FDA, which occurred in May 2009. In connection with the termination of the AIR Insulin development program, we closed our AIR commercial manufacturing facility located in Chelsea, Massachusetts and reduced our workforce by approximately 150 employees (the 2008 Restructuring). In addition to the labor, non-cash compensation, occupancy and depreciation expense savings realized from the 2008 Restructuring, there were reductions in laboratory expenses including clinical raw materials, professional service and third-party packaging fees related to the AIR Insulin and AIR PTH programs. These expense

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reductions were partially offset by increased clinical study costs related to the ALKS 33 and four-week RISPERDAL CONSTA development programs, which began phase 1 clinical trials in December 2008 and January 2009, respectively, and the ALKS 36 program, which we expect to initiate a phase 1 clinical trial in the second half of calendar 2009 and the VIVITROL opioid dependence development program, in which a multi-center registration study was initiated in June 2008.

The increase in research and development expenses for the year ended March 31, 2008, as compared to the year ended March 31, 2007, was primarily due to increased costs on the exenatide once weekly and AIR Insulin development programs, partially offset by decreased external costs related to the completion of legacy clinical trials for VIVITROL and decreased share-based compensation expense.

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

Selling, General and Administrative Expense

	Years Ended March 31,			Change Favorable/(Unfavorable)	
	2009	2008	2007	2009-2008	2008-2007
	(In millions)				
Selling, general and administrative	$ 59.0	$ 59.5	$ 66.4	$ 0.5	$ 6.9

The decrease in selling, general and administrative costs for the year ended March 31, 2009, as compared to the year ended March 31, 2008, was primarily due to a decrease in share-based compensation expense, professional fees, taxes and depreciation, partially offset by the increased sales and marketing costs related to VIVITROL as we became responsible for the marketing and sale of VIVITROL on December 1, 2008. On the Termination Date, we became responsible for the commercialization of VIVITROL in the U.S. and hired approximately 50 individuals that comprise the VIVITROL sales force. The decrease in selling, general and administrative expenses for the year ended March 31, 2008, as compared to the year ended March 31, 2007, was primarily due to decreased share-based compensation expense.

Impairment and Restructuring Expenses

	Years Ended March 31,			Favorable/(Unfavorable)	
	2009	2008	2007	2009-2008	2008-2007
	(In millions)				

Impairment of long-lived assets	$	$ 11.6	$	$ 11.6	$ (11.6)
Restructuring		6.4		6.4	(6.4)
Total impairment and restructuring expenses	$	$ 18.0	$	$ 18.0	$ (18.0)

In March 2008, our collaborative partner Lilly announced the decision to terminate the AIR Insulin development program. In connection with the program termination, in March 2008 our board of directors approved the 2008 Restructuring and as a result we recorded a restructuring charge of $6.9 million, consisting primarily of lease and severance related costs. As of March 31, 2009, the only costs remaining from the 2008 Restructuring relate to lease costs on the exited facility, which will be paid out through fiscal 2016.

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

Other (Expense) Income

	Years Ended March 31,			Change Favorable/(Unfavorable)	
	2009	2008	2007	2009-2008	2008-2007
	(In millions)				
Gain on sale of investment in Reliant Pharmaceuticals, Inc.	$	$ 174.6	$	$ (174.6)	$ 174.6
Interest income	11.4	17.8	17.7	(6.4)	0.1
Interest expense	(13.7)	(16.4)	(17.7)	2.7	1.3
Other expense, net	(1.6)	(0.4)	(0.5)	(1.2)	0.1
Total other (expense) income	$ (3.9)	$ 175.6	$ (0.5)	$ (179.5)	$ 176.1

We recorded a gain on sale of investment in Reliant Pharmaceuticals, Inc. (Reliant) of $174.6 million in the year ended March 31, 2008. In November 2007, Reliant was acquired by GlaxoSmithKline (GSK) and under the terms of the acquisition we received $166.9 million upon the closing of the transaction in exchange for our investment in Series C convertible, redeemable preferred stock of Reliant. In March 2009, we received an additional $7.7 million of funds, which had been held in escrow subject to the terms of an agreement between GSK and Reliant. We purchased the Series C convertible, redeemable preferred stock of Reliant for $100.0 million in December 2001, and our investment in Reliant had been written down to zero, prior to the time of the sale.

The decrease in interest income for the year ended March 31, 2009, as compared to the year ended March 31, 2008, was due to lower interest rates earned during the year ended March 31, 2009 as compared to March 31, 2008, partially offset by a higher average balance of cash and investments. Interest income for the year ended March 31, 2008 was comparable to the year ended March 31, 2007. We expect our interest earnings to decrease as compared to prior periods due to a general reduction in interest rates on our cash and investments.

The decrease in interest expense for the year ended March 31, 2009, as compared to the year ended March 31, 2008, was the result of our repurchase of an aggregate total of $93.0 million principal amount of the 7% Notes in five separately negotiated transactions during the year ended March 31, 2009. Included in interest expense for the year ended March 31, 2009 is a loss on the extinguishment of the 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 7% Notes. As a result of the purchases, we save approximately $16.5 million in interest expense, which includes $12.9 million in cash payments for interest and $3.6 million of original discount accretion over the remaining life of the 7% Notes. The 7% Notes, which have a remaining principal amount of $77.0 million are scheduled to be paid in full on January 1, 2012. The decrease in interest expense for the year ended March 31, 2008, as compared to the year ended March 31, 2007, was primarily due to the conversion of our 2.5% Subordinated Notes in June 2006. Interest expense for the year ended March 31, 2007 includes a one-time interest charge of $0.6 million for a payment we made in June 2006 in connection

with the conversion of our 2.5% Subordinated Notes to satisfy the Three-Year Interest Make-Whole Provision in the note indenture.

In the years ended March 31, 2009, 2008 and 2007, we recorded other-than-temporary impairments on common stock holdings of our collaborators of $1.2 million, $1.6 million and none, respectively, in other expense, net. In the year ended March 31, 2008, the impairment charge was offset by income earned on the change in the fair value of our investments in warrants of our collaborators.

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Provision for Income Taxes

	Years Ended March 31,			Change Favorable/(Unfavorable)	
	2009	2008	2007	2009-2008	2008-2007
	(In millions)				
Provision for income taxes	$ 0.5	$ 5.9	$ 1.1	$ 5.4	$ (4.8)

The provision for income taxes for the years ended March 31, 2009, 2008 and 2007 related to the U.S. alternative minimum tax (AMT). Utilization of tax loss carryforwards is limited in the calculation of AMT. As a result, a federal tax charge was recorded in the years ended March 31, 2009, 2008 and 2007. The current AMT liability is available as a credit against future tax obligations upon the full utilization or expiration of our net operating loss carryforward. Included in the provision for income taxes for the year ended March 31, 2009 is a $0.3 million estimated benefit as a result of the recently enacted *Housing and Economic Recovery Act of 2008*, which allows for certain taxpayers to forego bonus depreciation in lieu of a refundable cash credit based on certain qualified asset purchases and $0.3 million estimated benefit as a result of the *American Recovery and Reinvestment Act of 2009*. The *American Recovery and Reinvestment Act of 2009* allows certain taxpayers to refund a portion of the Company s historic research or minimum tax credit carryovers in lieu of claiming the bonus depreciation deduction under section 168(k) for eligible qualified property placed in service after March 31, 2008.

At March 31, 2009, we had approximately $222.4 million of federal net operating loss (NOL) carryforwards, $130.6 million of state operating loss carryforwards, and $19.8 million of foreign NOL and foreign capital loss carryforwards, which expire on various dates through the year 2026 or can be carried forward indefinitely. These loss carryforwards are available to reduce future federal and foreign taxable income, if any, and are subject to review and possible adjustment by the applicable taxing authorities. The available loss carryforwards that may be utilized in any future period may be subject to limitation based upon historical changes in the ownership of our stock. We have a full valuation allowance of $111.8 million, which was recorded based upon the uncertainty surrounding future utilization of our deferred tax assets.

Liquidity and Capital Resources

We have funded our operations primarily with funds generated by our business operations and through public offerings and private placements of debt and equity securities, bank loans, term loans, equipment financing arrangements and payments received under research and development agreements and other agreements with collaborators. We expect to incur significant additional research and development and other costs as we expand the development of our proprietary product candidates, including costs related to preclinical studies and clinical trials. Our costs, including research and development 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 interest income and anticipated revenues will generate sufficient cash flows to meet our anticipated liquidity and capital requirements for the foreseeable future.

Our financial condition is summarized as follows:

	March 31,	March 31,

	2009	2008
	(In millions)	
Cash and cash equivalents	$ 86.9	$ 101.2
Investments short-term	236.8	240.1
Investments long-term	80.8	119.1
Total cash, cash equivalents and investments	$ 404.5	$ 460.4
Working capital	$ 307.1	$ 371.1
Outstanding borrowings current and long-term	$ 75.9	$ 160.4

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Cash and Cash Equivalents

Our cash flows for the years ended March 31, 2009, 2008 and 2007 were as follows:

	Years Ended March 31,		
	2009	2008	2007
	(In millions)		
Cash and cash equivalents, beginning of period	$ 101.2	$ 80.5	$ 33.6
Cash provided by operating activities	34.6	42.4	83.5
Cash provided by (used in) investing activities	45.4	61.9	(30.0)
Cash used in financing activities	(94.3)	(83.6)	(6.6)
Cash and cash equivalents, end of period	$ 86.9	$ 101.2	$ 80.5

Operating Activities

Cash provided by operating activities in the year ended March 31, 2009 decreased as compared to the year ended March 31, 2008, primarily due to the purchase of our 7% Notes during the year ended March 31, 2009. During the year ended March 31, 2009, we purchased $93.0 million principal amount of our 7% Notes for $89.4 million. As the 7% Notes were originally issued at a discount, upon purchase of principal we allocated $6.0 million of the payment amount to the original issue discount, which is considered an operating activity. The remaining $83.4 million spent to purchase the 7% Notes was allocated to the original principal and is reflected as a financing activity. Cash provided by operating activities in the year ended March 31, 2009 included $25.5 million we recognized as revenue in the first quarter of fiscal 2009 related to the AIR Insulin Termination Agreement. Cash provided by operating activities in the year ended March 31, 2008 consists primarily of the net income earned during the year, net of adjustments for non-cash charges, which includes share-based compensation, depreciation, impairment charges related to the 2008 Restructuring and the gain on the sale of the investment in Reliant. The decrease in cash provided by operating activities in the year ended March 31, 2008, as compared to the year ended March 31, 2007, was primarily due to a decrease in cash flows from unearned milestone revenue. In the year ended March 31, 2007, we received nonrefundable payment of $110.0 million from Cephalon upon FDA approval of VIVITROL and $4.6 million from Cephalon under our Amendments. In the year ended March 31, 2008, we did not receive any such payments under our Agreements and Amendments with Cephalon.

Investing Activities

The decrease in cash provided by investing activities during the year ended March 31, 2009, as compared to the year ended March 31, 2008, was primarily due to the $166.9 million we received in exchange for our investment in Series C convertible, redeemable preferred stock of Reliant during the year ended March 31, 2008. The Series C convertible, redeemable preferred stock had an original cost of $100.0 million but had been written down to zero prior to the time of the sale. During the year ended March 31, 2009, we collected an additional $7.7 million related to the Reliant transaction, which was released from escrow due to the terms of an agreement between GSK and Reliant. During the year ended March 31, 2009, we had net sales of investments of $35.4 million, received $7.7 million related to the sale of capital equipment to Amylin and spent $5.5 million on capital equipment, whereas during the year ended March 31, 2008, we had net purchases of investments of $83.0 million and spent $21.9 million on capital equipment. The increase in cash provided by investing activities during the year ended March 31, 2008, as compared to the year ended March 31, 2007 was due to the $166.9 million we received from the Reliant transaction during the year ended

March 31, 2008, partially offset by an increase in net investment purchases of $76.8 million and a decrease in capital spend.

Financing Activities

The increase in cash used in financing activities during the year ended March 31, 2009, as compared to the year ended March 31, 2008, was primarily due to the $83.4 million we recorded as a financing activity related to the purchase of our 7% Notes, partially offset by reductions in the purchase of treasury stock.

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During the year ended March 31, 2008, we purchased treasury stock at a cost of $93.4 million, which consisted of $33.4 million of purchases made on the open market and $60.0 million purchased through a structured stock repurchase arrangement with a large financial institution in order to lower the average cost to acquire these shares. The increase in cash used in financing activities in the year ended March 31, 2008, as compared to the year ended March 31, 2007, was primarily due to an increase in the purchase of treasury stock.

Investments

We invest in short-term and long-term investments consisting of U.S. government and agency debt securities, corporate debt securities and other debt securities including student loan backed auction rate securities and asset backed debt securities. We also hold strategic investments which include the common stock of companies we do or did have a collaborative arrangement with. Our investment objectives are, first, to assure liquidity and conservation of capital and, second, to obtain investment income. At March 31, 2009, our short-term investments consist of available-for-sale investments with gross unrealized gains of $2.6 million and gross unrealized losses of less than $0.1 million. At March 31, 2009, our long-term investments consist of $4.7 million of held-to-maturity investments that are restricted and held as collateral under certain letters of credit related to certain of our lease agreements and $76.2 million of available-for-sale investments. The long-term available-for-sale investments have gross unrealized losses of $9.0 million, and we classify these investments as long-term as we believe these losses are temporary but recovery of the losses will extend beyond one year. We have the intent and ability to hold these investments to recovery, which may be at maturity. At March 31, 2009, the fair value of our corporate debt securities, student loan backed auction rate securities and asset backed debt securities are measured using significant unobservable inputs (Level 3 investments) and comprise 18% of our total cash and investment portfolio.

At March 31, 2009, we performed an analysis of our investments with unrealized losses for impairment. We determined that, with the exception of certain of our strategic investments, our investments with unrealized losses are temporarily impaired. During the year ended March 31, 2009, we recorded $1.2 million in other-than-temporary impairments attributed to our strategic investments. Other-than-temporary impairments are realized and recorded in our consolidated statements of income as a component of other income (expense), whereas temporary impairments, or unrealized losses, are recorded in accumulated other comprehensive loss, a component of shareholders equity.

During the three months ended March 31, 2009, certain of our investments in corporate debt securities with an original cost of $66.0 million had little or no trades. These securities consist primarily of investment grade subordinated, medium term, callable step-up floating rate notes (FRN) issued by several large European and U.S. banks. At March 31, 2009, the FRN s had composite ratings by Moody s, Standard & Poor s (S&P) and Fitch of between AA and A-. These FRN s did not trade either because they were nearing their scheduled call dates or due to increasing credit spreads on the debt of the issuers. We estimate the fair value of the FRN s to be $59.7 million at March 31, 2009. Similar securities we have held have been called at par by issuers prior to maturity.

Since the FRN s were not actively trading in the credit markets and fair value could not be derived from quoted prices, we used a discounted cash flow model to determine the estimated fair value of the securities at March 31, 2009. The assumptions used in the discounted cash flow model included estimates for interest rates, expected holding periods and risk adjusted discount rates, which we believe to be the most critical assumptions utilized within the analysis. Our valuation analysis considered, among other items, assumptions that market participants would use in their estimates of fair value, such as the creditworthiness and credit spreads of the issuer and when callability features may be exercised by the issuer. These securities were also compared, where possible, to other observable market data with similar characteristics to the securities held by us.

In making the determination that the decline in fair value of the FRN s was temporary, we considered various factors, including but not limited to: the length of time each security was in an unrealized loss position, the extent to which

fair value was less than cost, financial condition and near term prospects of the issuers and our intent and ability to hold each security for a period of time sufficient to allow for any

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

Our two investments in auction rate securities each had an original cost of $5.0 million and invest in taxable student loan revenue bonds issued by the Colorado Student Obligation Bond Authority (Colorado) and Brazos Higher Education Service Corporation (Brazos) which service student loans under the Federal Family Education Loan Program. The bonds are collateralized by student loans purchased by the authorities which are guaranteed by state sponsored agencies and reinsured by the U.S. Department of Education. Liquidity for these securities is typically provided by an auction process that resets the applicable interest rate at pre-determined intervals. The Colorado securities are Aaa rated by Moody s and the Brazos securities were downgraded during the three months ended March 31, 2009 to Baa3 by Moody s due to the increase in funding costs due to the continuing and prolonged dislocation of the auction rate securities market. Due to repeated failed auctions since January 2008, we no longer consider these securities to be liquid and classified them as long-term investments in our consolidated balance sheets. The securities continue to pay interest at predetermined interest rates during the periods in which the auctions have failed.

We estimate the fair value of the auction rate securities to be $8.1 million. Since the security auctions have failed and fair value cannot be derived from quoted prices, we used a discounted cash flow model to determine the estimated fair value of the securities at March 31, 2009. The assumptions used in the discounted cash flow model includes estimates for interest rates, timing of cash flows, expected holding periods and risk adjusted discount rates, which include a provision for default risk, which we believe to be the most critical assumptions utilized within the analysis. Our valuation analysis considers, among other items, assumptions that market participants would use in their estimates of fair value, such as the collateral underlying the security, the creditworthiness of the issuer and any associated guarantees, the timing of expected future cash flows, and the expectation of the next time the security will have a successful auction or when callability features may be exercised by the issuer. These securities were also compared, where possible, to other observable market data with similar characteristics to the securities held by us.

In making the determination that the decline in fair value of the auction rate securities was temporary, we considered various factors, including but not limited to: the length of time each security was in an unrealized loss position, the extent to which fair value was less than cost, financial condition and near term prospects of the issuers and our intent and ability to hold each security for a period of time sufficient to allow for any anticipated recovery in fair value. The estimated fair value of the auction rate securities could change significantly based on future financial market conditions. We will continue to monitor the securities and the financial markets and if there is continued deterioration, the fair value of these securities could decline further resulting in an other-than-temporary impairment charge.

Our investments in asset backed debt securities have a cost of $6.9 million and consist of medium term floating rate notes (MTN) of Aleutian Investments, LLC (Aleutian) and Meridian Funding Company, LLC (Meridian), which are qualified special purpose entities (QSPE) of Ambac Financial Group, Inc. (Ambac) and MBIA, Inc. (MBIA), respectively. Ambac and MBIA are guarantors of financial obligations and are referred to as monoline financial guarantee insurance companies. The QSPE s, which purchase pools of assets or securities and fund the purchase through the issuance of MTN s, have been established to provide a vehicle to access the capital markets for asset backed debt securities and corporate borrowers. The MTN s include a sinking fund redemption feature which match-fund the terms of redemptions to the maturity dates of the underlying pools of assets or securities in order to mitigate potential liquidity risk to the QSPE s. At March 31, 2009, $5.5 million of our initial investment in the Meridian MTN s had been redeemed by MBIA through scheduled sinking fund redemptions at par value, and the first sinking fund redemption on the Aleutian MTN is scheduled for June 2009.

The liquidity and fair value of these securities has been negatively impacted by the uncertainty in the credit markets, and the exposure of these securities to the financial condition of monoline financial guarantee insurance companies, including Ambac and MBIA. In April 2009, Moody s downgraded Ambac to Ba3 from

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Baa1, and in November 2008, Standard & Poor s (S&P) downgraded Ambac to A from AA. In February 2009, Moody s downgraded MBIA to B3 from Baa1, and S&P downgraded MBIA to BBB+ from AA. The downgrades were all attributed to Ambac s and MBIA s inability to maintain adequate capital levels. We may not be able to liquidate our investment in these securities before the scheduled redemptions or until trading in the securities resumes in the credit markets, which may not occur.

We estimate the fair value of the asset backed securities to be $6.1 million. Because the MTN s are not actively trading in the credit markets and fair value cannot be derived from quoted prices, we used a discounted cash flow model to determine the estimated fair value of the securities at March 31, 2009. Our valuation analyses consider, among other items, assumptions that market participants would use in their estimates of fair value such as the collateral underlying the security, the creditworthiness of the issuer and the associated guarantees by Ambac and MBIA, the timing of expected future cash flows, including whether the callability features of these investments may be exercised by the issuer. We believe there are several significant assumptions that are utilized in our valuation analysis, the most critical of which is the discount rate, which includes a provision for default and liquidity risk.

At March 31, 2009, we determined that the securities had been temporarily impaired due to the length of time each security was in an unrealized loss position, the extent to which fair value was less than cost, the financial condition and near term prospects of the issuers, current redemptions made by one of the issuers and our intent and ability to hold each security for a period of time sufficient to allow for any anticipated recovery in fair value or until scheduled redemption. We do not expect the estimated fair value of these securities to decrease significantly in the future unless credit market conditions continue to deteriorate significantly or the credit ratings of the issuers are further downgraded.

The other-than-temporary impairment charges taken during the year ended March 31, 2009 on our strategic investments and the illiquid nature of the auction rate and asset backed securities do not have a material impact on our liquidity or our financial flexibility or stability. Based on our ability to access our cash and our expected operating cash flows and other sources of cash, we do not anticipate the lack of liquidity on the auction rate and asset backed securities will affect our ability to execute our current business plan.

Borrowings

At March 31, 2009, our borrowings consisted of $75.9 million of the 7% Notes. We have been making interest payments on the 7% Notes and made our first quarterly principal payment of $6.4 million on April 1, 2009. During the year ended March 31, 2009, we purchased, in five separately negotiated transactions, an aggregate total of $93.0 million principal amount of the 7% Notes for $89.4 million. We recorded a loss on the extinguishment of the 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 7% Notes. As a result of the purchases, we save approximately $16.5 million in interest expense, which includes $12.9 million in cash payments for interest and $3.6 million of original discount accretion over the remaining life of the 7% Notes. The 7% Notes, which have a remaining principal amount of $77.0 million are scheduled to be paid in full on January 1, 2012.

Capital Requirements

We may continue to pursue opportunities to obtain additional financing in the future. Such financing may be sought through various sources, including debt and equity offerings, corporate collaborations, bank borrowings, arrangements relating to assets or other financing methods or structures. The source, timing and availability of any financings will depend on market conditions, interest rates and other factors. Our future capital requirements will also depend on many factors, including continued scientific progress in our research and development programs (including our proprietary product candidates), the size of these programs, progress with preclinical testing and clinical trials, the

time and costs involved in obtaining regulatory approvals, the costs involved in filing, prosecuting and enforcing patent claims, competing technological and market developments, the establishment of additional collaborative arrangements, the cost of manufacturing facilities and of commercialization activities and arrangements and the cost of product in-licensing and any possible

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acquisitions and, for any future proprietary products, the sales, marketing and promotion expenses associated with marketing such products. We may from time to time seek to retire or purchase our outstanding debt through cash purchases and/or exchanges for equity securities, in open market purchases, privately negotiated transactions or otherwise. Such repurchases or exchanges, if any, will depend on prevailing market conditions, our liquidity requirements, contractual restrictions and other factors. The amounts involved may be material.

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

We expect to spend approximately $13.0 million during the year ended March 31, 2010 for capital expenditures.

Contractual Obligations

The following table summarizes our obligations to make future payments under current contracts at March 31, 2009:

Contractual Cash Obligations	Total	Less Than One Year (Fiscal 2010)	One to Three Years (Fiscal 2011-2012)	Three to Five Years (Fiscal 2013-2014)	More Than Five Years (After Fiscal 2015)
			(In thousands)		
7% Notes principal(1)	$ 77,000	$ 25,667	$ 51,333	$	$
7% Notes interest(1)	8,759	4,716	4,043		
Operating lease obligations	35,918	10,233	20,577	3,844	1,264
Purchase obligations	29,109	29,109			
Capital expansion programs	854	854			
Total contractual cash obligations	$ 151,640	$ 70,579	$ 75,953	$ 3,844	$ 1,264

(1) The 7% Notes were issued by RC Royalty Sub LLC, a wholly-owned subsidiary of Alkermes, Inc. The 7% Notes are non-recourse to Alkermes, Inc. (see Note 9 to the consolidated financial statements included in this Form 10-K).

We enter into license agreements with third parties that may require us to make royalty, milestone or other payments that are contingent upon the occurrence of certain future events linked to the successful development and commercialization of pharmaceutical products. Certain of the payments may be contingent upon the successful achievement of an important event in the development life cycle of these pharmaceutical products, which may or may not occur. If required by the agreements, we may make royalty payments based upon a percentage of the sales of a pharmaceutical product if regulatory approval to market this product is obtained and the product is commercialized.

Because of the contingent nature of these payments, we have not attempted to predict the amount or period in which such payments would possibly be made and thus they are not included in the table of contractual obligations.

This table also excludes any liabilities pertaining to uncertain tax positions as we cannot make a reliable estimate of the period of cash settlement with the respective taxing authorities. In connection with the adoption of FASB Interpretation No. 48, *Accounting for Uncertainty in Income Taxes an Interpretation of FASB Statement No. 109* (FIN No. 48), we have approximately $0.2 million of long term liabilities associated with uncertain tax positions at March 31, 2009.

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

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exclusive worldwide license to certain patents and patent applications relating to its compounds designed to modulate opioid receptors. We will be responsible for the continued research and development of any resulting product candidates. We paid RPI a nonrefundable upfront payment of $0.5 million and are obligated to pay annual fees of up to $0.2 million, and tiered royalty payments of between 1% and 4% of annual net sales in the event any products developed under the agreement are commercialized. In addition, we are obligated to make milestone payments in the aggregate of up to $9.1 million upon certain agreed-upon development events. All amounts paid to RPI under this license agreement have been expensed and are included in research and development expenses.

In April 2009, we entered into a lease agreement in connection with the move of our corporate headquarters from Cambridge, Massachusetts to Waltham, Massachusetts which is scheduled to occur in early calendar 2010. The initial lease term, which begins upon our move into the new facility, is for 10 years with provisions for us to extend the lease term up to an additional 10 years. The Company s rent expense related to this new space will be approximately $2.7 million a year during the initial lease term, and this lease obligation is not included in the contractual obligations table above.

Off-Balance Sheet Arrangements

At March 31, 2009, 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, Product sales and Royalty revenues

For the year ended March 31, 2009, our manufacturing revenues consist of sales from two products, RISPERDAL CONSTA and VIVITROL. 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 revenue and estimated revenues are reconciled and adjusted for in the period in which they become known. Historically, adjustments have not been material based on actual amounts paid by Janssen. W