ALKERMES INC
Form 10-K
June 14, 2006

Table of Contents

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

Form 10-K

þ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the fiscal year ended March 31, 2006

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(b) of the Act:
None

Securities registered pursuant to Section 12(g) of the Act:
Common Stock, par value $0.01 per share
Series A Junior Participating Preferred Stock Purchase Rights
(Title of Class)

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 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, or a non-accelerated filer. See definition of accelerated filer and large accelerated filer in Rule 12b-2 of the Exchange Act.

Large accelerated filer þ Accelerated filer o Non-accelerated filer 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, 2005 (the last business day of the second fiscal quarter) the aggregate market value of the 88,390,866 outstanding shares of voting and non-voting common equity held by non-affiliates of the registrant was $1,484,966,549. Such aggregate value was computed by reference to the closing price of the common stock reported on the NASDAQ National Market on September 30, 2005.

As of May 31, 2006, 91,894,457 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, 2006 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, 2006

INDEX

Table of Contents

PART I

Item 1. *Business*

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

General

Alkermes, Inc. (together with its subsidiaries, referred to as we , us , our or the Registrant), a Pennsylvania corporati organized in 1987, is a biotechnology company that develops products based on sophisticated drug delivery technologies to enhance therapeutic outcomes in major diseases. We have two commercial products. RISPERDAL® CONSTA® [(risperidone) long-acting injection] is the first and only long-acting atypical antipsychotic medication approved for use in schizophrenia and is marketed worldwide by Janssen-Cilag (Janssen), a subsidiary of Johnson & Johnson. VIVITROL™ (naltrexone for extended-release injectable suspension) is the first and only once-monthly injection approved for the treatment of alcohol dependence and is marketed in the United States (U.S.) primarily by Cephalon, Inc. (Cephalon). We have a pipeline of extended-release injectable products and pulmonary products based on our proprietary technologies and expertise. Our product development strategy is twofold: we partner our proprietary technology systems and drug delivery expertise with several of the world s finest pharmaceutical and biotechnology companies; and we also develop novel, proprietary drug candidates for our own account. Our headquarters are located in Cambridge, Massachusetts, and we operate research and manufacturing facilities in Massachusetts and Ohio.

Our Strategy

We are leveraging our unique drug delivery capabilities and technologies to become a profitable growth company by developing, both with partners and on our own, novel and important drug products that enhance patient outcomes in major therapeutic areas.

We have entered into select collaborations with pharmaceutical and biotechnology companies to develop significant new product candidates, based on existing drugs and incorporating our technologies. Our partner, Janssen, currently markets RISPERDAL CONSTA, a formulation developed and manufactured by us that utilizes our proprietary Medisorb® drug delivery technology and Janssen s atypical antipsychotic drug RISPERDAL® (risperidone). RISPERDAL CONSTA is the only long-acting atypical antipsychotic drug on the market today. We also have two important initiatives in diabetes with corporate partners. The first is an inhaled formulation of insulin (AIR® insulin), based on our AIR pulmonary drug delivery technology, which is being developed with Eli Lilly and Company (Lilly). The second is exenatide LAR, a long-acting formulation of the diabetes drug BYETTA® (exenatide), which is being developed with our partners Amylin Pharmaceuticals, Inc. (Amylin) and Lilly, using our Medisorb drug delivery technology.

In addition, we develop our own proprietary therapeutics by applying our innovative drug delivery technologies to certain pharmaceuticals. Our drug VIVITROL, which was approved by the U.S. Food and Drug Administration (FDA) in April 2006, is the first and only once-monthly injectable medication for the treatment of alcohol dependence. It is an extended-release formulation of the oral medication, naltrexone, based on our proprietary Medisorb drug delivery technology.

We are also working to create value by establishing our own specialized sales and marketing capabilities. Under our VIVITROL collaboration with Cephalon we support the product commercialization effort with a team of managers of market development. They work with the Cephalon field sales team to facilitate local and health care system level approaches to marketplace education and awareness and program support. Under our agreement, we have the option to develop our own field sales force, in addition to the managers of market development, at the time of the first sales force expansion, which has not yet occurred. If we elect to develop

Table of Contents

our own sales force, we may seek to expand our commercial presence by developing or acquiring additional products to market.

Products and Development Programs

The following discusses the primary indications, development stage and collaborative partner, if any, for our products and certain of our product candidates. We are developing other product candidates that are in preclinical development for various other indications that are not discussed below. The results from preclinical testing and early clinical trials may not be predictive of results obtained in subsequent clinical trials and there can be no assurance that our, or our collaborators , clinical trials will demonstrate the safety and efficacy of any product candidates necessary to obtain regulatory approval.

RISPERDAL CONSTA. We have developed a long-acting formulation of Janssen s antipsychotic drug RISPERDAL, called RISPERDAL CONSTA, using our Medisorb drug delivery technology for the treatment of schizophrenia, a brain disorder, characterized by disorganized thinking, delusions and hallucinations. RISPERDAL CONSTA is administered via intramuscular injection every two weeks, as opposed to RISPERDAL tablets, which must be taken daily. RISPERDAL CONSTA is marketed in more than 55 countries around the world including the U.S., United Kingdom, Spain, France and Germany. The product has been approved in more than 75 countries, and Janssen continues to launch the product around the world. RISPERDAL is the most commonly prescribed drug for the treatment of schizophrenia and, along with RISPERDAL CONSTA, had sales of over $3.6 billion worldwide in calendar year 2005. In December 2005, Janssen presented data at the American Psychiatric Association meeting which demonstrated that stable patients treated with RISPERDAL CONSTA showed low rates of relapse and rehospitalization.

In January 2005, Johnson & Johnson initiated a Phase III clinical trial with RISPERDAL CONSTA, with the goal of expanding the label to include an indication for maintenance therapy for bipolar disorder. In May 2006, Janssen presented additional data supporting the use of RISPERDAL CONSTA in schizophrenia and bipolar maintenance.

We are the exclusive manufacturer of RISPERDAL CONSTA for Janssen, and we earn both manufacturing fees and royalties from Janssen. See Collaborative Arrangements Janssen for more information about manufacturing fees and royalties received from Janssen. Our non-recourse RISPERDAL CONSTA secured 7% notes (the 7% Notes) are secured by RISPERDAL CONSTA cash flows. See Note 6 to the consolidated financial statements included in this Form 10-K.

VIVITROL. VIVITROL, our first FDA-approved proprietary product, is an injectable, extended-release Medisorb formulation of naltrexone. Naltrexone, an FDA-approved drug indicated for the treatment of alcohol dependence and for the blockade of effects of exogenously administered opioids, is currently available in daily oral dosage form. VIVITROL, the first and only once-monthly injectable medication for alcohol dependence, is indicated for the treatment of alcohol dependence in patients who are able to abstain from drinking in an outpatient setting and are not actively drinking prior to treatment initiation. Treatment with VIVITROL should be used in combination with psychosocial support, such as counseling or group therapy. VIVITROL was available to physicians and patients in the U.S. beginning on June 13, 2006. VIVITROL is available as a single dose 380mg intramuscular injection.

Alcohol dependence is a serious and chronic disease that affects multiple regions of the brain, providing rationale for the use of medication with psychosocial support as part of an integrated treatment plan. Of the more than approximately 7.8 million Americans who are dependent on alcohol, approximately 2.2 million seek treatment for their alcohol problems. Approximately 75% of these patients relapse within the first year of beginning treatment using currently available treatment options. Vivitrol development has been funded in part with federal funds from the National Institute on Alcohol Abuse and Alcoholism, and the National Institutes of Health.

We and Cephalon are discussing the development and implementation of a clinical program for VIVITROL in opioid dependence.

Table of Contents

In June 2005, we partnered with Cephalon to commercialize VIVITROL in the U.S. We are the exclusive manufacturer of VIVITROL, and we earn manufacturing revenue from Cephalon and share net collaborative profits and losses with Cephalon. See Collaborative Arrangements Cephalon for more information about manufacturing revenues and the profit and loss sharing arrangement with Cephalon.

AIR insulin. We are collaborating with Lilly to develop inhaled formulations of insulin and other potential products for the treatment of diabetes based on our AIR pulmonary drug delivery technology. We believe that our AIR insulin product candidate, currently in Phase III clinical development, may improve the treatment of diabetes by providing a simpler dosing regimen and thereby potentially increasing medication adherence and leading to better health outcomes for patients over time. As part of the comprehensive Phase III pivotal program that began in July 2005, we are currently conducting two long-term safety and efficacy studies: a 24-month study in 400 type-one diabetes patients; and a 12-month study in 600 type-one and type-two diabetes patients with mild to moderate asthma or mild to moderate chronic obstructive lung disease. In addition, in April 2006, we and Lilly announced the initiation of a Phase III clinical trial required for registration for AIR insulin. This study in type-two diabetes patients is designed to compare A1C, an average measure of blood sugar (glucose) over a three-month period, between AIR insulin and injectable pre-meal insulin. Additional studies are planned to commence in calendar year 2006. Lilly is responsible for designing and conducting clinical trials.

In June and September 2005, we and Lilly presented detailed results from a Phase II clinical study of inhaled insulin in people with type-one diabetes, showing that patients using AIR insulin achieved blood sugar levels similar to patients treated with injected insulin. The Phase II trial was a multi-center, cross-over design study with 120 patients with type-one diabetes receiving an inhaled formulation of insulin using AIR technology for a three-month period. Eighty percent (80%) of patients in this study expressed a preference for AIR insulin at mealtime over injected insulin. In addition, results from a Phase I dose response and equivalence study were presented, which showed that AIR insulin and injected insulin lispro were generally well-tolerated and that the overall effect on blood sugar was similar, illustrating that doses could be reliably correlated.

We manufacture AIR insulin for clinical trials. Under our current agreement, we and Lilly will manufacture AIR insulin products for commercial sale, if any.

Exenatide LAR. We are developing a long-acting release (LAR) Medisorb formulation of Amylin s exenatide (exenatide). Exenatide injection (trade name BYETTA) was approved by the FDA in April 2005 as adjunctive therapy to improve blood sugar control in patients with type-two diabetes who have not achieved adequate control on metformin and/or a sulfonylurea, two commonly used oral diabetes medications. BYETTA is a twice-daily injection. Exenatide LAR is being developed as a once-weekly formulation. Amylin entered into a collaboration agreement with Lilly for the development and commercialization of exenatide, including exenatide LAR.

In March 2006, we, Amylin and Lilly announced that, following discussions with the FDA, a long-term comparator clinical study of once-weekly exenatide LAR and twice-daily BYETTA in patients with type-two diabetes had been initiated. This study is designed to generate the type of safety and efficacy data that could form the basis of a new drug application (NDA).

This trial follows the completion of a randomized, placebo-controlled, multi-dose study in patients with type-two diabetes that was designed to assess the safety, tolerability, and pharmacokinetics of exenatide LAR given once a week. In August 2005, we, Amylin and Lilly announced the preliminary results of this study, which found that after 15 weeks, both doses of exenatide LAR were well tolerated and expected therapeutic blood levels of exenatide were achieved. Dose-dependent improvements in hemoglobin A1C and reductions in weight were observed. This multiple-dose study included approximately 45 subjects with type-two diabetes who were failing to achieve adequate glucose control using diet and exercise with or without metformin.

In parallel with clinical activities, manufacturing process development and scale-up activities are underway. The material for this trial is being manufactured at development scale, and the companies are working to determine the overall manufacturing strategy.

Table of Contents

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 LAR and certain technology transfer related thereto. See Collaborative Arrangements Amylin for more information relating to the manufacture of exenatide LAR.

AIR® parathyroid hormone. In January 2006, we and Lilly announced an agreement to develop and commercialize inhaled formulations of parathyroid hormone (PTH) utilizing our AIR pulmonary drug delivery system. The initial development program will utilize our AIR pulmonary drug delivery system in combination with Lilly s recombinant PTH, FORTEO® (teriparatide (rDNA origin) injection). FORTEO was approved in 2002 by the FDA to treat osteoporosis in men and postmenopausal women who are at high risk for bone fracture.

Under the terms of the agreement, we receive funding for product and process development activities and upfront and milestone payments. Lilly will have exclusive worldwide rights to products resulting from the collaboration and will pay us royalties based on product sales, if any.

We are responsible for manufacturing AIR PTH for preclinical studies, and Phase I and Phase II clinical trials, if any.

Collaborative Arrangements

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

Janssen

Pursuant to a 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 more than 75 countries. RISPERDAL CONSTA has been launched in more than 55 countries, including the U.S. and several major international markets. We exclusively manufacture RISPERDAL CONSTA for commercial sale and receive manufacturing revenues when product is shipped to Janssen and royalty revenues upon the final sale of the product.

Under product license agreements, Janssen and an affiliate of Janssen have exclusive worldwide licenses from us to use and sell RISPERDAL CONSTA. Under the license agreements, Janssen is required to pay us certain royalties on all RISPERDAL CONSTA sold to customers. Janssen can terminate the license agreements upon 30 days prior written notice to us.

Pursuant to a manufacturing and supply agreement, Janssen has appointed us as the exclusive supplier of RISPERDAL CONSTA for commercial sales. Under our manufacturing and supply agreement with Janssen, we record manufacturing revenues upon shipment of product by us to Janssen, based on a percentage of Janssen s net selling price. This percentage of net selling price varies based upon the volume of units shipped to Janssen in any given calendar year, with a minimum manufacturing fee of 7.5%. Under our license agreements with Janssen, we also record royalty revenues equal to 2.5% of Janssen s net sales of RISPERDAL CONSTA in the quarter when the product is sold by Janssen.

Under our manufacturing and supply agreement, Janssen is required to pay us certain annual minimum manufacturing revenues relating to our sales of RISPERDAL CONSTA to Janssen. The annual minimum manufacturing revenues from sales of RISPERDAL CONSTA are determined by a formula and, in the aggregate, are currently estimated to be approximately $184.5 million. This amount was automatically increased from $150.0 million as a result of additional

investment by us in the RISPERDAL CONSTA manufacturing infrastructure. As of March 31, 2006, we had recognized approximately $143.4 million of cumulative manufacturing revenues against the estimated $184.5 million minimum.

Table of Contents

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 product license agreements, the royalty rate payable to us on Janssen s net sales of RISPERDAL CONSTA will increase from 2.5% to 5.0%.

Cephalon

In June 2005, we entered into a license and collaboration agreement and supply agreement with Cephalon to jointly develop, manufacture and commercialize extended-release forms of naltrexone, including VIVITROL (the Products), in the U.S. (the Agreements). We have formed a joint development team with Cephalon, and the companies share responsibility for additional development of the Products. We have primary responsibility for conducting such development and 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. We have formed a joint commercialization team with Cephalon, and the companies share responsibility for developing the commercial strategy for the Products. Cephalon has primary responsibility for the commercialization, including distribution and marketing, of the Products in the U.S., and we support this effort with a team of managers of market development. We have the option to staff our own field sales force in addition to our managers of market development at the time of the first sales force expansion, should one occur. We have also formed a joint supply team with Cephalon, and we have primary responsibility for the manufacture of the Products.

In June 2005, Cephalon made a nonrefundable payment of $160.0 million to us upon signing the Agreements. In April 2006, Cephalon made a second nonrefundable payment of $110.0 million to us upon FDA approval of VIVITROL. Cephalon will make additional nonrefundable milestone payments to us of up to $220.0 million if calendar year net sales of the Products exceed certain agreed-upon sales levels. Cephalon will record net sales from the Products in the U.S. Under the terms of the Agreements, we are responsible for the first $120.0 million of net losses incurred on VIVITROL (Product Losses) through December 31, 2007. The Product Losses specifically exclude development costs incurred by us to obtain FDA approval of VIVITROL and costs to complete the first manufacturing line, both of which we are solely responsible for. If Product Losses exceed $120.0 million through December 31, 2007, Cephalon is responsible for paying all Product Losses in excess of $120.0 million during this period. If VIVITROL is profitable through December 31, 2007, net profits will be shared equally between us and Cephalon. After December 31, 2007, all profits and losses earned on VIVITROL will be shared equally between us and Cephalon.

The Agreements are in effect until the later of: (i) the expiration of certain patent rights; or (ii) fifteen (15) years from the date of the first commercial sale of the Products in the U.S.

Cephalon has the right to terminate the Agreements at any time by providing 180 days prior written notice to us, subject to certain continuing rights and obligations between the parties. The supply agreement terminates upon termination or expiration of the license and collaboration agreement or the later expiration of our obligations pursuant to the Agreements to continue to supply Products to Cephalon. In addition, either party may terminate the license and collaboration agreement upon a material breach by the other party which is not cured within 90 days written notice of material breach or, in certain circumstances, a 30 day extension of that period, and either party may terminate the supply agreement upon a material breach by the other party which is not cured within 180 days written notice of material breach or, in certain circumstances, a 30 day extension of that period.

Lilly

AIR insulin

In April 2001, we entered into a development and license agreement with Lilly for the development of inhaled formulations of insulin and other compounds potentially useful for the treatment of diabetes, based on

Table of Contents

our AIR pulmonary drug delivery technology. Pursuant to the agreement, we are responsible for formulation and preclinical testing as well as the development of a device to use in connection with any products developed. Lilly has paid or will pay to us certain initial fees, research funding and milestones payable upon achieving certain development and commercialization goals. Lilly has exclusive worldwide rights to make, use and sell pulmonary formulations of such compounds. Lilly will be responsible for clinical trials, obtaining all regulatory approvals and marketing any AIR insulin products. We will manufacture such product candidates for clinical trials and both we and Lilly will manufacture such products for commercial sales, if any. We will receive certain royalties and commercial manufacturing fees based upon such product sales, if any.

Lilly has the right to terminate the agreement upon 90 days written notice to us at any time prior to the first commercial launch of a product or upon 180 days written notice at any time after such first commercial launch. In addition, either party may terminate the agreement upon a material breach or default by the other party which is not cured within 90 days of written notice of material breach or default.

In February 2002, we entered into an agreement with Lilly that provided for an investment by them in our production facility for inhaled products based on our AIR pulmonary drug delivery technology. This facility, located in Chelsea, Massachusetts, is designed to accommodate the manufacturing of multiple products. Lilly s investment was used to fund a portion of AIR insulin production and packaging capabilities. This funding is secured by Lilly s ownership of specific equipment located and used in the facility. We have the right to purchase the equipment from Lilly, at any time, at the then-current net book value.

In December 2002, we expanded our collaboration with Lilly following the achievement of development milestones relating to clinical progress and manufacturing activities for our insulin dry powder aerosols and inhalers. In connection with the expansion, Lilly purchased $30.0 million of our newly issued 2002 redeemable convertible preferred stock, $0.01 par value per share (the Preferred Stock) in accordance with the December 2002 preferred stock agreement. Under the expanded collaboration, the royalties payable to us on sales of the AIR insulin product were increased. We agreed to use the proceeds from issuance of the Preferred Stock primarily to fund the AIR insulin development program and to use a portion of the proceeds to fund the AIR hGH development program. We did not record research and development revenue on these programs while the proceeds of the Preferred Stock funded this development. The $30.0 million of research and development expended by us was recognized as research and development expense as incurred. All of the proceeds from the issuance of the Preferred Stock had been spent through fiscal year 2005.

In September 2005, we received a milestone payment of $9.0 million from Lilly upon the initiation of the Phase III clinical program for AIR insulin.

On October 4, 2005, we converted 1,500 shares of the Preferred Stock with a carrying value of $15.0 million into 823,677 shares of our common stock. The conversion secured a proportional increase in the minimum royalty rate payable to us on sales of the AIR insulin product, if approved.

AIR PTH

In December 2005, we entered into an agreement with Lilly to develop and commercialize AIR PTH utilizing our AIR pulmonary drug delivery system. The initial development program will utilize our AIR pulmonary drug delivery system in combination with Lilly s recombinant PTH, FORTEO® (teriparatide (rDNA origin) injection). Forteo was approved by the FDA in 2002 for the treatment of osteoporosis in men and postmenopausal women who are at high risk of bone fracture.

Under the terms of the agreement, we will receive funding for product development activities and upfront and milestone payments. We will have principal responsibility for the formulation and nonclinical development and testing of the compound for use in the product device including device development. Lilly will have principal responsibility for toxicological and clinical development of the product and sole responsibility for the achievement of regulatory approval and commercialization of the product. Lilly will have exclusive worldwide rights to products resulting from the collaboration and will pay us royalties based on product sales, if any, beginning on the date of product launch in the relevant country and ending on the later of either the expiration of AIR patent rights or ten years from product launch in that particular country. We are responsible for the

Table of Contents

manufacture of PTH for preclinical, Phase I and Phase II clinical trials. Not later than the completion of Phase II clinical trials for the product, the parties will negotiate a manufacturing agreement for Phase III clinical trial and commercial supply. Under this manufacturing agreement, Lilly would be obligated to purchase from us an agreed to minimum supply of the product each calendar year.

Lilly may terminate the development and license agreement for any reason at any time, with or without cause, by providing us with 90 days prior written notice prior to product launch or upon 180 days prior written notice after product launch. In addition, either party may terminate the agreement upon a material breach or default by the other party which is not cured within 90 days written notice of material breach or default or, in certain cases, a 90 day extension of this period.

Amylin

In May 2000, we entered into a development and license agreement with Amylin for the development of exenatide LAR, which is under development for the treatment of type-two 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 that Amylin may develop. Amylin has entered into a collaboration agreement with Lilly for the development and commercialization of exenatide, including exenatide LAR. 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. 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. We have the option of becoming the commercial manufacturer of certain additional products developed under 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 or 180 days written notice 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 written notice.

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 LAR and certain technology transfer related thereto. In December 2005, Amylin purchased a facility for the manufacture of exenatide LAR and began construction in early calendar year 2006. Amylin is responsible for all costs and expenses associated with the design and validation of the facility. The parties have agreed that we will transfer our technology for the manufacture of exenatide LAR to Amylin. Following the completion of the technology transfer, Amylin will be responsible for the manufacture of the once-weekly formulation of exenatide LAR 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.

Drug Delivery Technology

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

Injectable Extended-Release Drug Delivery

Our proprietary technology allows us to encapsulate traditional small molecule pharmaceuticals, peptides and proteins, in microspheres made of common medical polymers. The technology is designed to enable novel formulations of pharmaceuticals by providing controlled, extended-release of drugs over time. Drug release from the microsphere is controlled by diffusion of the drug through the microsphere and by biodegradation of

Table of Contents

the polymer. These processes can be modulated through a number of formulation and fabrication variables, including drug substance and microsphere particle sizing and choice of polymers and excipients.

Pulmonary Drug Delivery

The AIR technology is our proprietary pulmonary delivery technology that enables the delivery of both small molecules and macromolecules to the lungs. Our proprietary 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 are developing a family of relatively inexpensive, compact, easy-to-use inhalers. The AIR devices are breath activated and made from injection molded plastic. The powders are designed to quickly discharge from the device over a range of inhalation flow rates, which may lead to low patient-to-patient variability and high lung deposition of the inhaled dose. By varying the ratio and type of excipients used in the formulation, we believe we can deliver a range of drugs from the device that may provide both immediate and extended release.

Manufacturing

We currently maintain manufacturing facilities in Massachusetts and 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 and have limited experience in operating multi-state, multi-line FDA-approved commercial manufacturing sites.

Injectable Extended-Release Drug Delivery

We own and occupy a manufacturing, office and laboratory site in Wilmington, Ohio. We manufacture RISPERDAL CONSTA, VIVITROL and development-scale products at this facility. The facility has been inspected by U.S. and European regulatory authorities, and they have concluded that the facility meets required cGMP standards for continued commercial manufacturing. The facility is undergoing a significant expansion (See Item 2. *Properties* for details of the facility expansion). The expansion of this facility is intended to increase supply of RISPERDAL CONSTA and VIVITROL.

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

Pulmonary Drug Delivery

We lease a 90,000 square foot facility located in Chelsea, Massachusetts that is designed to accommodate manufacturing of multiple products and contains a 40,000 square foot facility used for clinical manufacturing of our AIR products. Our inhalation devices are produced by a contract manufacturer in the U.S under cGMP standards.

Marketing

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

primarily responsible for VIVITROL commercialization, however, we support the product commercialization effort with a team of managers of market development, whose responsibility it is to work in collaboration with the Cephalon field sales team to facilitate local and health care system level approaches to marketplace education and awareness and program support. Together with Cephalon, our goal is to establish a

Table of Contents

steady increase in sales over time and our marketing strategy will initially focus on a core group of receptive, influential and high volume prescribers of medication to treat alcohol dependence, establishing a solid foundation for further expansion. Under the collaboration, we have the option to establish our own field sales force, in addition to the managers of market development, at the time of the first sales force expansion, which has not yet occurred.

Competition

The biotechnology and pharmaceutical industries are subject to rapid and substantial technological change. We face intense competition in the development, manufacturing, marketing and commercialization of our products and product candidates from academic institutions, government agencies, research institutions, biotechnology and pharmaceutical companies, including our collaborators, and other drug delivery companies. Our success in the marketplace depends largely on our ability to identify and successfully commercialize products developed from our research activities and to access financial resources 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, 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 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 drug delivery methods.

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

VIVITROL may compete 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 drug delivery technology, we are aware that there are other companies marketing or developing pulmonary delivery systems for pharmaceutical products. If approved, our AIR insulin product candidate would compete with EXUBERA®, marketed by Pfizer, Inc. in collaboration with Nektar Therapeutics, Inc., which received FDA and EMEA approval for marketing in January 2006. There are a number of large companies currently developing inhaled insulin product candidates that are in late stage clinical trials that would compete with our AIR insulin product, if approved.

Other companies are developing new chemical entities or improved formulations of existing products which, if developed successfully, could compete against our formulations of any products we develop or those of our collaborators. These chemical entities are being designed to have different mechanisms of action or improved safety and efficacy. In addition, our collaborators may develop, either alone or with others, products that compete with the development and marketing of our product candidates.

11

Table of Contents

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, maintaining trade secret protection and operating without infringing upon the proprietary rights of others.

We have a proprietary portfolio of patent rights and exclusive licenses to patents and patent applications. We have filed numerous U.S. and international 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 120 issued U.S. patents. No U.S. patent issued to us that is currently material to our business will expire prior to 2013. In the future, we plan to file further U.S. and foreign patent applications directed to new or improved products and processes. We intend to file additional patent applications when appropriate and defend our patent position aggressively.

We have exclusive rights through licensing agreements with third parties to approximately 35 issued U.S. patents, a number of U.S. patent applications and corresponding foreign patents and patent applications in many countries, subject in certain instances to the rights of the U.S. government to use the technology covered by such patents and patent applications. No issued U.S. patent to which we have licensed rights and which is currently material to our business will expire prior to 2016. Under certain licensing agreements, we currently pay annual license fees and/or minimum annual royalties. During the year ended March 31, 2006, these fees totaled approximately $0.3 million. In addition, under these licensing agreements, we are obligated to pay royalties on future sales of products, if any, covered by the licensed patents.

We know of several U.S. patents issued to other parties that may relate to our products and product candidates. One party has asked us to compare our Medisorb drug delivery technology to that party s patented technology. Another party has asked a collaborative partner to substantiate how our ProLease microspheres are different from that party s patented technology. 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. 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. 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

Table of Contents

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

Government Regulation

Before new pharmaceutical products may be sold in the U.S. and other countries, clinical trials of the products must be conducted and the results submitted to appropriate regulatory agencies for approval. The regulatory approval process requires a demonstration of product safety and efficacy and the ability to effectively manufacture such product. Generally, such demonstration of safety and efficacy includes preclinical testing and clinical trials of such product candidates. The 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 I 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 II 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 III 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 new drug application (NDA) or, for a biological product, a product license application (PLA), for approval to commence commercial sales. Preparing such applications involves considerable data collection, verification, analysis and expense. In responding to an NDA or PLA, 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 may not be approved or will significantly delay approval. 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 effectiveness and are required to gain clearance for the use of a product as a treatment for indications other than those initially approved. 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, financial condition and results of operations.

Table of Contents

Regulatory authorities track information on side effects and adverse events reported during clinical studies and after marketing approval. Non-compliance with FDA safety reporting requirements may result in FDA regulatory action that may include civil action or criminal penalties. Side effects or adverse events that are reported during clinical trials can delay, impede, or prevent marketing approval. Similarly, adverse events that are reported after marketing approval can result in additional limitations being placed on the product s use and, potentially, withdrawal or suspension of the product from the market.

Among the conditions for a NDA or PLA approval is the requirement that the prospective manufacturer s quality control and manufacturing procedures conform with cGMP on an ongoing basis. Before approval of an NDA or PLA, the FDA may perform a pre-approval inspection of a 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. After a facility is licensed, it is subject to periodic inspections by the FDA. Facilities are also subjected to the requirements of other government bodies, such as the U.S. Occupational Safety & Health Administration and the Environmental Protection Agency.

Similarly, NDA or PLA approval may be delayed or denied due to cGMP non-compliance or other issues at contract sites or suppliers included in the NDA or PLA, and the correction of these shortcomings may be beyond our control.

The requirements which we must satisfy to obtain regulatory approval by governmental agencies in other countries prior to commercialization of our product candidates in such countries can be as rigorous and costly as those described above.

We are also subject to various laws and regulations relating to safe working conditions, laboratory and manufacturing practices, experimental use of animals and use and disposal of hazardous or potentially hazardous substances, including radioactive compounds and infectious disease agents, used in connection with our research. 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 31, 2006 we had approximately 760 full-time employees. A significant number of our management and professional employees have prior experience with pharmaceutical, biotechnology or medical product companies. We believe that we have been successful in attracting skilled and experienced scientific and senior management personnel, however, competition for such personnel is intense. None of our employees are covered by a collective bargaining agreement. We consider our relations with employees to be good.

Available Information

Our internet address is www.alkermes.com, at which you can find, free of charge, our annual report on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and all other reports filed with the Securities and Exchange Commission (SEC). All such filings are available on the website as soon as reasonably practicable after filing.

Table of Contents

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. For reasons outside of our control, including those mentioned below, revenues received from the sale of RISPERDAL CONSTA may not meet our partner s expectations. Our revenues also depend heavily on manufacturing fees we receive from our partner for RISPERDAL CONSTA.

VIVITROL

In April 2006, the FDA approved VIVITROL for the treatment of alcohol dependence in patients able to refrain from drinking, and not actively drinking prior to treatment initiation. In June 2006, we entered into an agreement with Cephalon to develop and commercialize VIVITROL for the treatment of alcohol dependence in the U.S. and its territories. Under this agreement, Cephalon is primarily responsible for the marketing and sale of VIVITROL, and we support their efforts with a team of managers of market development. We currently have no sales and marketing experience and a very small team of managers of market development. We expect VIVITROL to become available to physicians and patients in the U.S. by the end of June 2006. If and when VIVITROL is available for 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 specified below.

There can be no assurance that the Phase III 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 other countries, we will have to market VIVITROL ourselves outside of the U.S. or enter into co-promotion or sales and marketing arrangements with other companies for VIVITROL sales and marketing activities outside of the U.S.

In addition, there is no existing data regarding the size of the market for VIVITROL, and it is therefore inherently difficult to assess whether sufficient capacity exists to meet market demand. If demand is higher than our estimates or we are not able to bring online addition capacity, the market for VIVITROL may be materially adversely affected.

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 affect revenues from RISPERDAL CONSTA and VIVITROL (and any of our product candidates that we develop, if and when approved) 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;

Table of Contents

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;

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 material adverse developments with respect to the commercialization of these products may cause our revenue to grow at a slower than expected rate, or even to decrease or end.

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 partner s orders, the timing of shipments, our ability to manufacture successfully, our yield and our production schedule. In order to meet our financial plans, we will need to bring additional manufacturing capacity on line in a timeframe adequate to meet demand and prevent shortfalls in supply. In addition, the costs to manufacture RISPERDAL CONSTA and VIVITROL may be higher than anticipated if certain volume levels are not achieved. In addition, we may not be able to supply the products in a timely manner. If RISPERDAL CONSTA and VIVITROL do not produce significant revenues, if we are unable to supply our partner s requirements, our business, results of operations and financial condition would be materially adversely affected.

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

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

Our manufacturing facilities in Massachusetts and Ohio require specialized personnel and are expensive to operate and maintain. Any delay in the regulatory approval or market launch of product candidates 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.

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

Table of Contents

products, including RISPERDAL CONSTA and VIVITROL. If we are not able to add additional capacity or if anything were to interfere with our continuing manufacturing operations in any of our facilities, it would materially adversely affect our business, results of operations and financial condition.

If we cannot produce sufficient commercial quantities of our products to meet demand, we would need to rely on third-party manufacturers, of which there are currently very few, if any, capable of manufacturing our products as contract suppliers. We cannot be certain that we could reach agreement on reasonable terms, if at all, with those manufacturers. Even if we were to reach agreement, the transition of the manufacturing process to a third party to enable commercial supplies could take a significant amount of time. Our ability to supply products in sufficient capacity to meet demand is also dependent upon third party contractors to provide components and bulk drug, and package, store and distribute such finished products.

If more of our product candidates progress to mid- to late-stage development, we may incur significant expenses in the expansion and/or construction of manufacturing facilities and increases in personnel in order to manufacture product candidates. The development of a commercial-scale manufacturing process is complex and expensive. We cannot assure you that we have the necessary funds or that we will be able to develop this manufacturing infrastructure in a timely or economical manner, or at all.

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

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

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

We are responsible for the entire supply chain for VIVITROL, up to manufacture of final product for sale, including the sourcing of raw materials and active pharmaceutical agents from third parties. We have no previous experience in managing a complex, cGMP supply chain and issues with our supply sources may have a materially adverse effect on our business, results of operations and financial condition. The manufacture of products and product components, 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 systems can be commercialized as stand-alone products but must be combined with a drug. To develop any new proprietary product candidate using one of these drug delivery systems, 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

Table of Contents

not impacted by issues associated with single source providers. Nonetheless, our business could be materially impacted by issues associated with single source providers.

The manufacture of our products is subject to government regulation.

We and our third party providers are generally required to maintain compliance with cGMP, and are subject to inspections by the FDA or comparable agencies in other jurisdictions to confirm such compliance. Any changes of suppliers or modifications of methods of manufacturing require amending our application to the FDA and ultimate amendment acceptance by the FDA prior to release of product to the marketplace. Our inability or the inability of our third party service providers to demonstrate ongoing cGMP compliance could require us to withdraw or recall product and interrupt commercial supply of our products. Any delay, interruption or other issues that arise in the manufacture, formulation, packaging, or storage of our products as a result of a failure of our facilities or the facilities or operations of third parties to pass any regulatory agency inspection could significantly impair our ability to develop and commercialize our products. This could increase our costs, cause us to lose revenue or market share and damage our reputation.

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

Our business involves environmental risks.

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

We rely heavily on collaborative partners.

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

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

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

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

Table of Contents

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 no sales and marketing experience and limited sales capabilities, which may make commercializing our products difficult.

We currently have no marketing or distribution 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 primarily upon Cephalon to market and distribute VIVITROL. In these instances, our future revenues will be materially dependent upon the success of the efforts of these third parties.

Under our agreement, Cephalon is primarily responsible for the marketing and sale of VIVITROL. We support Cephalon in its commercialization efforts with a small team of managers of market development. We have limited experience in the commercialization of pharmaceutical products. Therefore, the successful commercial launch of VIVITROL and our future profitability will depend in large part on the success of our collaborative partner in its sales and marketing efforts. We may not be able to attract and retain qualified personnel to serve as managers of market development, or to effectively support those commercialization activities services provided by our collaborative partner. The cost of establishing and maintaining managers of market development may exceed its cost effectiveness. If we fail to develop sales and marketing capabilities, if our collaborative partners sales efforts are not effective or if costs of developing sales and marketing capabilities exceed their cost effectiveness, our business, results of operations and financial condition could 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 We face competition in the biotechnology and pharmaceutical industries, and others. If our delivery technologies or product development efforts fail to generate product candidates that lead to the successful development and commercialization of products, 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

Table of Contents

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 each of our product candidates involve a drug delivery 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. We or our collaborative partners have not submitted INDs or begun clinical trials for these product candidates. Preclinical and clinical development efforts performed by us may not be successfully completed. We may not file further INDs. We or our collaborative partners may not begin clinical trials as planned. Completion of clinical trials may take several years or more. The length of time can vary substantially with the type, complexity, novelty and intended use of the product candidate. The commencement and rate of completion of clinical trials may be delayed by many factors, including:

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

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

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

We depend on independent clinical investigators, contract research organizations and other third party service providers and our collaborators in the conduct of our clinical trials for our product candidates. We rely heavily on these parties for successful execution of our clinical trials but do not control many aspects of their activities. For

example, the investigators are not our employees. However, we are responsible for ensuring that each of our clinical trials is conducted in accordance with the general investigational plan and protocols for the trial. Third parties may not complete activities on schedule or may not conduct our clinical trials in accordance with regulatory requirements or our stated protocols. The failure of these third parties to carry out their obligations could delay or prevent the development, approval and commercialization of our product candidates.

Table of Contents

We may not become profitable on a sustained basis.

With the exception of fiscal year 2006, we have had net operating losses since being founded in 1987. At March 31, 2006, our accumulated deficit was $623.2 million. There can be no assurance we will achieve sustained profitability.

Beginning April 1, 2006, we are required to recognize all share-based payments, including grants of stock options and stock awards, in our financial statements based on the requirements of Statement of Financial Accounting Standard (SFAS) No. 123R, *Share-Based Payment* (SFAS 123R). We estimate that the effect on our results of operations and comprehensive income (loss) will range between $30.0 million and $35.0 million for the year ended March 31, 2007. As a result, we may not be profitable during the fiscal year 2007 or thereafter.

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

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

- obtain and maintain regulatory approval for our products and product candidates in the U.S. and in foreign countries;
- efficiently manufacture our commercial products;
- support the marketing and sale of RISPERDAL CONSTA by our partner Janssen;
- support the commercial launch of, and ongoing sales and marketing efforts related to, VIVITROL by our partner Cephalon;
- enter into agreements to develop and commercialize our products and product candidates;
- develop and expand our capacity to manufacture and market our products and product candidates;
- obtain adequate reimbursement coverage for our products from insurance companies, government programs and other third party payors;
- obtain additional research and development funding from collaborative partners or funding for our proprietary product candidates; 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 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 drug delivery technologies, compounds, product rights or companies; and

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

Table of Contents

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

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

We may require additional funds to complete any of our programs, and may seek funds through various sources, including debt and equity offerings, corporate collaborations, bank borrowings, arrangements relating to assets or other financing methods or structures. The source, timing and availability of any financings will depend on market conditions, interest rates and other factors. If we are unable to raise additional funds on terms that are favorable to us, we may have to cut back significantly on one or more of our programs, give up some of our rights to our technologies, product candidates or licensed products or agree to reduced royalty rates from collaborative partners. If we issue additional equity securities or securities convertible into equity securities to raise funds, our shareholders will suffer dilution of their investment and it may adversely affect the market price of our common stock.

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

Approval from the FDA is required to manufacture and market pharmaceutical products in the U.S. regulatory agencies in foreign countries have similar requirements. The process that pharmaceutical products must undergo to obtain this approval is extensive and includes preclinical testing and clinical trials to demonstrate safety and efficacy and a review of the manufacturing process to ensure compliance with cGMP regulations. The FDA may choose not to communicate with or update us during clinical testing and regulatory review periods. The ultimate decision by the FDA regarding drug approval may not be consistent with prior communications. See 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 manufacturing processes or facilities;
- the FDA or foreign regulatory agencies may change their approval policies or adopt new regulations;
- a product candidate may not be approved for all the indications we or our partners request; or
- the FDA 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, the drug used has not been approved at all or has not been approved for every indication for which it is being tested. Any delay in the approval process for any of our product candidates will result in increased costs that could materially adversely affect our business, results of operations and financial condition.

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

Table of Contents

Legislative or regulatory changes could harm our business.

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.

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

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

Private insurers and government agencies continue to seek price discounts. In addition, certain states have proposed, and certain other states have adopted various programs for their seniors and low income individuals where a condition of coverage is that the manufacturer provides a discounted price, as well as programs involving restrictions on access to certain products, and bulk purchasing of drugs.

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

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

Our activities, including the sale and marketing of our products, are subject to extensive government regulation and oversight, including regulation under the federal Food, Drug and Cosmetic Act and other federal and state statutes. We are also subject to the provisions of a federal law commonly known as the Medicare/Medicaid anti-kickback law, 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

Table of Contents

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, Anti-Kickback Act, 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 appear.

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 and for those of 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. One of those third parties has asked us to compare our Medisorb technology to that third party s patented technology. Another such third party has asked a collaborative partner to substantiate how our ProLease microspheres are different from that third party s patented technology. The manufacture, use, offer for sale, sale or importing of any of these product candidates might be found to infringe the claims of these third party patents. A third 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.

Table of Contents

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 commercial products, we 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 pharmaceutical and biotechnology companies involves complex legal and factual questions, enforceability of patents cannot be predicted with certainty. 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, 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. Furthermore, others may independently develop similar technologies or duplicate any technology that we have developed. 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 collaborative partners, licensors, 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.

We may be exposed to product liability claims and recalls.

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

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

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

In addition to our development work with collaborative partners, we are developing proprietary product candidates for our own account by applying drug delivery technologies to off-patent drugs. 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

Table of Contents

our own account to consume substantial resources. If we are able to develop commercial products on our own, the risks associated with these programs may be greater than those associated with our programs with collaborative partners.

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

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

develop or successfully commercialize new products on a timely basis or at all; or

develop new products in a cost effective manner.

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

develop their products more rapidly than we can;

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

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

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

Foreign currency exchange rates may affect revenue.

We derive more than fifty percent (50%) of our RISPERDAL CONSTA revenues from sales in foreign countries. Such revenues may fluctuate when translated to U.S. dollars as a result of changes in foreign currency exchange rates. We currently do not hedge this exposure. A decrease in the U.S. dollar relative to other currencies in which we have revenues will cause our revenues to be lower than a stable exchange rate. A large decrease in 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 from academic institutions, government agencies, research institutions and biotechnology and pharmaceutical companies, including other drug delivery companies. Some of these competitors are also our collaborative partners. These competitors are working to develop and market other drug delivery systems, products, vaccines and other methods of preventing or reducing disease, and new small-molecule and other classes of drugs that can be used without a drug delivery system.

There are other companies developing extended-release drug delivery systems and pulmonary delivery systems. 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 in the U.S. and Europe, there may be some that we do not now know of that may compete with our drug delivery systems or product

Table of Contents

candidates. Our collaborative partners could choose a competing drug delivery system to use with their drugs instead of one of our drug delivery systems and could develop products that compete with our products.

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

VIVITROL may compete 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 drug delivery technology, we are aware that there are other companies marketing or developing pulmonary delivery systems for pharmaceutical products. If approved, our AIR insulin product candidate would compete with EXUBERA, marketed by Pfizer, Inc. in collaboration with Nektar Therapeutics, Inc., which received FDA and EMEA approval for marketing in January 2006. There are a number of large companies currently developing inhaled insulin product candidates that are in late stage clinical trials that would compete with our AIR insulin product, if approved.

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 drug delivery 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 products do not achieve significant market acceptance, our business, results of operations and financial condition will 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 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, then the note holders may also 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

Table of Contents

technical, scientific or regulatory compliance backgrounds could materially adversely affect our research and development efforts and our business.

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

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

mergers;

acquisitions;

strategic alliances;

licensing agreements; and

co-promotion agreements.

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

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

As discussed above under 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. In addition, we were obligated, at March 31, 2006, to issue 18,824,823 shares of common stock upon the vesting and exercise of stock options and vesting of stock awards, 9,978 shares of common stock issuable upon conversion of the 3.75% convertible subordinated notes, 1,417,367 shares of common stock issuable upon conversion of the redeemable convertible preferred stock and 9,025,271 shares of common stock issuable upon conversion of the 2.5% convertible subordinated notes (2.5% Subordinated Notes). On May 22, 2006, we announced that we had exercised our right to automatically convert all of our outstanding 2.5% Subordinated Notes into approximately 9,025,271 shares of our common stock. 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.

Our common stock price is highly volatile.

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

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

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

announcements of issuances of common stock or acquisitions by us;

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

material public announcements;

Table of Contents

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;

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

changes in government regulations or policies or patent decisions;

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 provides for a dividend of one preferred share purchase right on each outstanding share of our common stock. Each right entitles shareholders to buy 1/1000th of a share of our Series A Junior Participating Preferred Stock at an exercise price of $80.00. Each right will become exercisable following the tenth day after a person or group announces an acquisition of or commences a tender offer to purchase 15% or more of our common stock. We will be entitled to redeem the rights at $0.001 per right at any time on or before the close of business on the tenth day following acquisition by a person or group of 15% or more of our common stock. The shareholder rights plan and Pennsylvania law could make it more difficult for a person or group to, or discourage a person or group from attempting to, acquire control of us, even if the change in control would be beneficial to shareholders. Our articles of incorporation and bylaws also contain certain provisions that could have a similar effect. The articles provide that our board of directors may issue, without shareholder

approval, preferred stock having such voting rights, preferences and special rights as the board of directors may determine. The issuance of such preferred stock could make it more difficult for a third party to acquire us.

We may not recoup any of our $100 million investment in Reliant.

In December 2001, we made a $100.0 million investment in Series C convertible, redeemable preferred units of Reliant Pharmaceuticals, LLC (Reliant) and we own approximately 12% of Reliant. Through March 31, 2004, the investment had been accounted for under the equity method of accounting because

Table of Contents

Reliant was organized as a limited liability company, which is treated in a manner similar to a partnership. Our $100.0 million investment was reduced to $0 in the year ended March 31, 2003 based upon our equity losses in Reliant. Effective April 1, 2004, Reliant converted from a limited liability company to a corporation under Delaware state law. Due to this change, and because Reliant is a privately held company over which Alkermes does not exercise control, our investment in Reliant has been accounted for under the cost method beginning April 1, 2004. Accordingly, we do not record any share of Reliant s net income or losses, but would record dividends, if received. Our investment remains at $0 as of March 31, 2006.

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

Public companies may be the subject of certain claims, including those asserting violations of securities laws and derivative actions.

We cannot predict with certainty the eventual outcome of any future litigation 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, 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 and investigations can be expensive to defend, whether or not the lawsuit 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.

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

On September 22, 2005, in connection with the SEC s periodic review of our reports filed with the SEC, we received a comment letter from the staff (the Staff) with respect to our Annual Report on Form 10-K for the year ended March 31, 2005 and our Quarterly Report on Form 10-Q for the period ended June 30, 2005. We have cooperated fully with the Staff in connection with their review in order to resolve all outstanding comments. As of the date of this Report, we have resolved all comments of the Staff with the exception of one comment related to our accounting for the Preferred Stock we issued and sold to Lilly, and the related amendment to our existing development and license agreement with Lilly for the development of inhaled formulations of insulin and other compounds potentially useful for the treatment of diabetes. The Staff has requested an analysis of various alternatives for the accounting for such security and the provisions of the related agreements. Please see Note 10 to our consolidated financial statements contained in this Form 10-K for an explanation of our accounting relating to our Preferred Stock and the provisions of the related agreements with Lilly. We have provided our analysis to the Staff and have had several conference calls and follow up correspondence with the Staff related to this issue. We have been advised by the Staff that they have not reached a position on the preferred accounting and that they are considering various alternatives, including the accounting which the Company has applied to this security. We believe that our accounting for this transaction was, and remains, in conformity with accounting principles generally accepted in the U.S. (commonly referred to as GAAP).

Item 2. ***Properties***

We lease space in Cambridge, Massachusetts under several leases expiring through the 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 also perform clinical manufacturing at this location.

We lease a building in Chelsea, Massachusetts for clinical and commercial manufacturing. The lease term is for fifteen years, expiring in 2015, with an option to extend the term for up to two five-year periods. The facility is

designed to accommodate the manufacture of multiple products and contains a facility currently used to manufacture clinical supplies of AIR insulin.

We own a 15-acre manufacturing, office and laboratory site in Wilmington, Ohio. The site produces RISPERDAL CONSTA and VIVITROL. The site is undergoing a significant expansion which is expected to

Table of Contents

be substantially completed in calendar year 2008. A significant portion of our capital expenditures will support such expansion. We are currently operating two RISPERDAL CONSTA lines and one VIVITROL line at commercial scale, and three additional lines are under construction for RISPERDAL CONSTA and VIVITROL.

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

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

Item 3. ***Legal Proceedings***

On October 27, 2005, the United States District Court for the District of Massachusetts entered an order dismissing, in its entirety and with prejudice, a purported securities class action lawsuit against us and certain of our current and former officers and directors.

Beginning in October 2003, we and certain of our current and former officers and directors were named as defendants in six purported securities class action lawsuits filed in the United States District Court for the District of Massachusetts. The cases were captioned: Bennett v. Alkermes, Inc., et. al., 1:03-CV-12091 (D. Mass.); Ragosta v. Alkermes, Inc., et. al., 1:03-CV-12184 (D. Mass.); Barry Family LP v. Alkermes, Inc., et. al., 1:03-CV-12243 (D. Mass.); Waltzer v. Alkermes, Inc., et. al., 1:03-CV-12277 (D. Mass.); Folkerts v. Alkermes, Inc., et. al., 1:03-CV-12386 (D. Mass.); and Slavas v. Alkermes, Inc., et. al., 1:03-CV-12471 (D. Mass.). On May 14, 2004, the six actions were consolidated into a single action captioned: In re Alkermes Securities Litigation, Civil Action No. 03-CV-12091-RCL (D. Mass.). On July 12, 2004, a single consolidated amended complaint was filed on behalf of purchasers of our common stock during the period April 22, 1999 to July 1, 2002. The consolidated amended complaint generally alleged, among other things, that, during such period, the defendants made misstatements to the investing public relating to the manufacture and FDA approval of our RISPERDAL CONSTA product. The consolidated amended complaint sought unspecified damages. On September 10, 2004, we and the individual defendants filed a motion seeking dismissal of the litigation on numerous legal grounds, and the Court referred that motion to a federal magistrate judge of the United States District Court for the District of Massachusetts for issuance of a report and recommendation as to disposition of the motion to dismiss. The Court heard oral argument on the motion on January 12, 2005. On October 6, 2005, the federal magistrate judge issued a report and recommendation for dismissal, in its entirety, of the above-captioned purported securities class action litigation. After issuance of this ruling, on October 21, 2005, we, the individual defendants and the lead plaintiff filed a stipulation with the United States District Court for the District of Massachusetts providing for dismissal of this action, in its entirety and with prejudice.

From time to time, we may be subject to other legal proceedings and claims in the ordinary course of business. We are not currently 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 or 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 year ended March 31, 2006.

Table of Contents

PART II

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

(a) Market Information

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

	Fiscal 2006		Fiscal 2005	
	High	Low	High	Low
1st Quarter	$ 14.09	$ 9.68	$ 16.93	$ 12.06
2nd Quarter	19.87	12.76	13.73	8.48
3rd Quarter	19.87	14.69	15.61	11.16
4th Quarter	$ 26.81	$ 18.96	$ 14.34	$ 10.08

The last reported sale price of our common stock as reported on the NASDAQ National Market on May 31, 2006 was $19.82.

(b) Stockholders

There were 394 shareholders of record for our common stock and one shareholder of record for our non-voting common stock on May 31, 2006.

(c) Dividends

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

(d) Securities authorized for issuance under equity compensation plans

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

(e) Repurchase of equity securities

On September 23, 2005, our Board of Directors authorized a share repurchase program of up to $15.0 million dollars of common stock in the open market or through privately negotiated transactions. We expect to make the repurchases at the discretion of management from time to time depending on market conditions. The repurchase program has no set expiration date and may be suspended or discontinued at any time. During the period covered by this report, we

have not made any repurchases. As of the close of trading on the NASDAQ National Market on June 12, 2006, we had repurchased 134,630 shares of common stock at a weighted average price of $19.52.

Table of Contents

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

Alkermes, Inc. and Subsidiaries

	Year Ended March 31,				
	2006	**2005**	**2004**	**2003**	**2002**
	(In thousands, except per share data)				
Consolidated Statements of Operations Data:					
REVENUES:					
Manufacturing revenues	$ 64,901	$ 40,488	$ 25,736	$ 14,317	$
Royalty revenues	16,532	9,636	3,790	1,165	
Research and development revenue under collaborative agreements	45,883	26,002	9,528	31,784	54,102
Net collaborative profit	39,285				
Total revenues	166,601	76,126	39,054	47,266	54,102
EXPENSES:					
Cost of goods manufactured	23,489	16,834	19,037	10,910	
Research and development	89,068	91,065	91,097	85,388	92,092
Selling, general and administrative	40,383	28,823	26,029	26,694	24,387
Restructuring(1)		11,527	(208)	6,497	
Total expenses	152,940	148,249	135,955	129,489	116,479
OPERATING INCOME (LOSS)	13,661	(72,123)	(96,901)	(82,223)	(62,377)
OTHER INCOME (EXPENSE):					
Interest income	11,569	3,005	3,409	3,776	15,302
Interest expense	(20,661)	(7,394)	(6,497)	(10,403)	(8,876)
Derivative (loss) income related to convertible subordinated notes(2)	(1,084)	4,385	(4,514)	(4,300)	
Gain on exchange of notes(3)				80,849	
Other income (expense), net(4)(5)	333	(1,789)	2,118		
Total other income (expense)	(9,843)	(1,793)	(5,484)	69,922	6,426
Equity in losses of Reliant Pharmaceuticals, LLC(6)				(94,597)	(5,404)
NET INCOME (LOSS)	$ 3,818	$ (73,916)	$ (102,385)	$ (106,898)	$ (61,355)
EARNINGS (LOSS) PER COMMON SHARE:					

BASIC	$ 0.04	$ (0.82)	$ (1.25)	$ (1.66)	$ (0.96)
DILUTED	$ 0.04	$ (0.82)	$ (1.25)	$ (1.66)	$ (0.96)
WEIGHTED AVERAGE NUMBER OF COMMON SHARES OUTSTANDING:					
BASIC	91,022	90,094	82,083	64,368	63,669
DILUTED	97,377	90,094	82,083	64,368	63,669

Table of Contents

	March 31,				
	2006	2005	2004	2003	2002
Condensed Consolidated Balance Sheets Data:					
Cash, cash equivalents and short-term investments	$ 297,967	$ 202,567	$ 143,936	$ 136,094	$ 152,347
Total assets	477,163	338,874	270,030	255,699	350,350
Long-term debt	279,518	276,485	122,584	166,586	207,800
Unearned milestone revenue current and long-term portions	99,536				
Redeemable convertible preferred stock	15,000	30,000	30,000	30,000	
Shareholders equity (deficit)	33,216	4,112	75,930	(5,046)	99,664

(1) Represents charges (recoveries) in connection with our June 2004 and August 2002 restructurings of operations. The June 2004 and August 2002 restructuring programs were substantially completed during fiscal 2005 and 2003, respectively. However, certain closure costs related to the exited leased facilities will continue to be paid through August 2008.

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

(3) Represents an $80.8 million nonrecurring gain related to the exchange of our 3.75% convertible subordinated notes (3.75% Subordinated Notes) for our 6.52% Senior Notes.

(4) Primarily represents income (expense) recognized on the changes in the fair value of warrants of public companies held by us in connection with collaboration and licensing arrangements, which are recorded as derivatives under the caption Other assets in the consolidated balance sheets. The recorded value of such warrants can fluctuate significantly based on fluctuations in the market value of the underlying securities of the issuer of the warrants.

(5) Includes a charge of approximately $0.3 million for recognizing the cumulative effect of initially applying Financial Accounting Standards Board (FASB) interpretation No. 47, *Accounting for Conditional Asset Retirement Obligations* (FIN 47).

(6) Represents our share of Reliant Pharmaceuticals, LLC s (Reliant) losses recorded under the equity method of accounting. Since we have no further funding commitments to Reliant and the investment is accounted for under the cost method effective April 1, 2004, we will not record any further share of the losses of Reliant in our consolidated statements of operations.

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

Introduction

Alkermes, Inc. (as used in this section, together with our subsidiaries, us , we or our), a Pennsylvania corporation organized in 1987, is a biotechnology company that develops products based on sophisticated drug delivery technologies to enhance therapeutic outcomes in major diseases. We have two commercial products. RISPERDAL® CONSTA® [(risperidone) long-acting injection] is the first and only long-acting atypical antipsychotic medication approved for use in schizophrenia, and is marketed worldwide by Janssen-Cilag, a subsidiary of Johnson & Johnson, together with other affiliates (Janssen). VIVITROL® (naltrexone for extended-release injectable suspension) is the first and only once-monthly injection approved for the treatment of alcohol dependence, and is marketed in the United States (U.S.) primarily by Cephalon, Inc. (Cephalon). We have a pipeline of extended-release injectable products and pulmonary products based on our proprietary technology and expertise. Our product development strategy is twofold: we partner our proprietary technology systems and drug delivery expertise with several of the world s finest pharmaceutical

Table of Contents

and biotechnology companies; and we also develop novel, proprietary drug candidates for our own account. Our headquarters are located in Cambridge, Massachusetts, and we operate research and manufacturing facilities in Massachusetts and Ohio. Since our inception in 1987, we have devoted a significant portion of our resources to research and development programs and the purchase of property, plant and equipment. At March 31, 2006, we had an accumulated deficit of approximately $623.2 million.

We have funded our operations primarily through public offerings and private placements of debt and equity securities, bank loans, term loans, equipment financing arrangements and payments under research and development agreements with collaborators. We have historically developed our product candidates in collaboration with others on whom we rely for funding, development, manufacturing and/or marketing. While we continue to develop product candidates in collaboration with others, we also develop proprietary product candidates for our own account that we fund on our own.

Forward-Looking Statements

Any statements herein or otherwise made in writing or orally by us with regard to our expectations as to financial results and other aspects of our business may constitute forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, including, but not limited to, statements concerning future operating results, the achievement of certain business and operating goals, manufacturing revenues, research and development spending, plans for clinical trials and regulatory approvals, 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, an 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, including but not limited to: statements concerning the achievement of certain business and operating milestones and future operating results and profitability; continued revenue growth from RISPERDAL CONSTA; the successful launch and commercialization of VIVITROL; the launch of VIVITROL by the end of June 2006; recognition of milestone payments from our partner Cephalon related to the future sales of VIVITROL; the successful continuation of development activities for our programs, including exenatide LAR, AIR® insulin and AIR PTH; the successful manufacture of our products and product candidates, including RISPERDAL CONSTA and VIVITROL, and the successful manufacture of exenatide LAR by Amylin Pharmaceuticals, Inc. (Amylin); the building of a selling and marketing infrastructure for VIVITROL by ourselves or our partner Cephalon; whether we can successfully manufacture VIVITROL at a commercial scale; and the successful scale-up, establishment and expansion of manufacturing capacity, 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. Factors which could cause actual results to differ materially from our expectations set forth in our forward-looking statements include, among others: (i) manufacturing and royalty revenues for RISPERDAL CONSTA may not continue to grow, particularly because we rely on our partner, Janssen, to forecast and market this product; (ii) we may be unable to manufacture RISPERDAL CONSTA in sufficient quantities and with sufficient yields to meet Janssen s requirements or to add additional production capacity for RISPERDAL CONSTA, or unexpected events could interrupt manufacturing operations at our RISPERDAL CONSTA facility, which is the sole source of supply for that product; (iii) we may be unable to manufacture VIVITROL economically or in sufficient quantities and with sufficient yields to meet our own or our partner Cephalon s requirements or add additional production capacity for VIVITROL, or unexpected events could interrupt manufacturing operations at our VIVITROL facility, which is the sole source of supply for that product; (iv) we and our partner Cephalon may be unable to develop the selling and marketing capabilities, and/or infrastructure necessary to jointly support the commercialization of VIVITROL; (v) we and our partner Cephalon may be unable to launch VIVITROL successfully and launch VIVITROL on the schedule that we

expect; and if launched, VIVITROL may not produce significant revenues; (vi) because we have limited selling, marketing and distribution experience, we depend significantly on our partner Cephalon to successfully commercialize VIVITROL; (vii) third party payors may not cover or reimburse VIVITROL; (viii) we may be unable to scale-up and manufacture our other

Table of Contents

product candidates, including exenatide LAR and AIR insulin and AIR PTH, commercially or economically; (ix) we may not be able to source raw materials for our production processes from third parties; (x) we may not be able to successfully transfer manufacturing technology for exenatide LAR to Amylin and Amylin may not be able to successfully operate the manufacturing facility for exenatide LAR; (xi) our other 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 and our other partnered, non-proprietary programs; (xiii) we rely on our partner Cephalon to commercialize VIVITROL in the U.S.; (xiv) 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; (xv) our collaborators could elect to terminate or delay programs at any time and disputes with collaborators or failure to negotiate acceptable new collaborative arrangements for our technologies could occur; (xvi) clinical trials may take more time or consume more resources than initially envisioned; (xvii) results of earlier clinical trials are not necessarily predictive of the safety and efficacy results in larger clinical trials; (xviii) our product candidates could be ineffective or unsafe during preclinical studies and clinical trials, and we and our collaborators may not be permitted by regulatory authorities to undertake new or additional clinical trials for product candidates incorporating our technologies, or clinical trials could be delayed; (xix) after the completion of clinical trials for our product candidates and the submission for marketing approval, the FDA or other health authorities could refuse to accept such filings or could request additional preclinical or clinical studies be conducted, each of which could result in significant delays or the failure of such product to receive marketing approval; (xx) even if our product candidates appear promising at an early stage of development, product candidates could fail to receive necessary regulatory approvals, be difficult to manufacture on a large scale, be uneconomical, fail to achieve market acceptance, be precluded from commercialization by proprietary rights of third parties or experience substantial competition in the marketplace; (xxi) technological change in the biotechnology or pharmaceutical industries could render our product candidates obsolete or non-competitive; (xxii) difficulties or set-backs in obtaining and enforcing our patents and difficulties with the patent rights of others could occur; (xxiii) we may not be consistently profitable and could incur losses in the future; (xxiv) the effect of our adoption of SFAS 123R on the results of operations and comprehensive income (loss) depends on a number of factors, including estimates of stock price volatility, option terms, interest rates, the number and type of stock options and stock awards granted during the reporting period, as well as other factors; (xxv) we may not recoup any of our $100.0 million investment in Reliant Pharmaceuticals, LLC (Reliant); and (xxvi) we may need to raise substantial additional funding to continue research and development programs and clinical trials and could incur difficulties or setbacks in raising such funds.

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

Critical Accounting Policies

While our significant accounting policies are more fully described in Note 2 to our consolidated financial statements included in this Form 10-K for the year ended March 31, 2006, we believe the following accounting policies are important to the portrayal of our financial condition and results of operations and can require estimates from time to time.

Revenue Recognition

Multiple Element Arrangements

When a collaborative arrangement contains more than one revenue generating element, we allocate revenue between the elements based on each element s relative fair value, provided that each element meets the criteria for treatment as a separate unit of accounting. An item is considered a separate unit of accounting if it has value on a stand-alone basis and there is objective and reliable evidence of the fair value of the

Table of Contents

undelivered items. Fair value is determined based upon objective and reliable evidence, which includes terms negotiated between us and our collaborative partners.

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

Our revenue recognition policy related to the Agreements complies with the SEC s Staff Accounting Bulletin No. 101, *Revenue Recognition in Financial Statements,* and Emerging Issues Task Force Issue 00-21, *Revenue Arrangements with Multiple Deliverables* (EITF 00-21) for multiple element revenue arrangements entered into or materially amended after June 30, 2003. For purposes of revenue recognition, the deliverables under these Agreements are generally separated into three units of accounting: (i) shared profits and losses on the sustained-release forms of naltrexone, including VIVITROL (the Products); (ii) manufacturing of the Products; and (iii) development and licenses for the Products.

Under the terms of the Agreements, we are responsible for the first $120.0 million of net losses incurred on VIVITROL (Product Losses) through December 31, 2007. If cumulative Product Losses exceed $120.0 million through December 31, 2007, Cephalon will be responsible for paying all Product Losses in excess of $120.0 million during this period. If VIVITROL is profitable through December 31, 2007, net profits will be shared equally between us and Cephalon. After December 31, 2007, net profits and losses earned on VIVITROL will be shared equally between us and Cephalon.

We and Cephalon reconcile the costs incurred by each party to develop, commercialize and manufacture the Products, excluding certain development and registration costs for VIVITROL for the initial indication of alcohol dependence (the Initial Indication) and the completion of the first manufacturing line, to be paid solely by us, against revenues earned on the Products, to determine net profits or losses on VIVITROL. Our share of net profits and losses is recognized in the period earned or incurred by the collaboration and is recorded under the caption Net collaborative profit in the consolidated statements of operations and comprehensive income (loss). Cumulative Product Losses since inception of the Agreements through March 31, 2006 were $41.0 million.

The nonrefundable payment of $160.0 million we received from Cephalon in June 2005, and the nonrefundable milestone payment of $110.0 million we received from Cephalon in April 2006 upon FDA approval of VIVITROL, have been deemed to be arrangement consideration in accordance with EITF 00-21. This arrangement consideration is recognized as milestone revenue across the three accounting units referred to above. The allocation of the arrangement consideration to each of the accounting units was based initially on the fair value of each unit as determined at the date of the Agreements, however, the fair values are reviewed periodically and adjusted, as appropriate. The above nonrefundable payments are, and will be, recorded in the consolidated balance sheets under the captions Unearned milestone revenue current portion and Unearned milestone revenue long-term portion prior to being earned. The classification between the current and long-term portions is based on our best estimate of whether the milestone revenue will be recognized during or after the 12-month period following the reporting period, respectively.

Manufacturing Revenues Related to the Cephalon Agreements

Under the terms of the Agreements, we are responsible for the manufacture of clinical and commercial supplies of sustained-release forms of naltrexone, including VIVITROL, for sale in the U.S. Under the terms of the Agreements, we will bill Cephalon at cost for finished commercial product shipped to them. We will record this manufacturing revenue under the caption Manufacturing revenues in the consolidated statements of operations and comprehensive income (loss). An amount equal to this manufacturing revenue will be recorded as cost of goods manufactured in the consolidated statements of operations and comprehensive income (loss). No manufacturing revenue or cost of goods manufactured related to VIVITROL was recorded in the consolidated statements of operations and comprehensive

income (loss) in the years ended March 31, 2006, 2005 and 2004.

The amount of the arrangement consideration allocated to the accounting unit manufacturing of the Products is based on the estimated fair value of manufacturing profit to be earned over the expected life of

Table of Contents

the Products, not to exceed the total arrangement consideration we receive from Cephalon, less the amount first allocated to the accounting unit shared profits and losses on the Products . Manufacturing profit is initially estimated at 10% of cost of goods manufactured. We will recognize the earned portion of the arrangement consideration allocated to this accounting unit in proportion to the units of finished product shipped during the reporting period, to the total expected units of finished product to be shipped over the expected life of the Products. The estimate of expected units shipped will be adjusted periodically, as necessary, whenever events or changes in circumstances indicate that supply assumptions have changed significantly. Adjustments to the accrual schedule for this milestone revenue that result from changed supply assumptions are recognized prospectively over the remaining expected life of the Products. This milestone revenue will be recorded under the caption Manufacturing revenues in the consolidated statements of operations and comprehensive income (loss). No milestone revenue was recorded for this accounting unit in the consolidated statements of operations and comprehensive income (loss) during the years ended March 31, 2006, 2005 and 2004.

Net Collaborative Profit Related to the Agreements with Cephalon

The amount of the arrangement consideration allocated to the accounting unit shared profits and losses on the Products represents our best estimate of the Product Losses that we are responsible for through December 31, 2007, plus an estimate of those development costs to be incurred by us in the period preceding FDA approval of VIVITROL and to complete the first manufacturing line, for which we are solely responsible. We estimate this loss to be approximately $137.0 million. We recognize the earned portion of the arrangement consideration allocated to this accounting unit through the period that we are responsible for Product Losses, being the period ending December 31, 2007. This milestone revenue directly offsets our expenses incurred on VIVITROL and Cephalon s net losses on VIVITROL. This milestone revenue is recorded under the caption Net collaborative profit in the consolidated statements of operations and comprehensive income (loss). During the years ended March 31, 2006, 2005 and 2004, we recorded $60.5 million, $0 and $0, respectively, for this accounting unit in the consolidated statements of operations and comprehensive income (loss).

Under the terms of the Agreements, we granted Cephalon a co-exclusive license to our patents and know-how necessary to use, sell, offer for sale and import the Products for all current and future indications in the U.S. On a combined basis, the development and license deliverables under the Agreements have value to us on a stand-alone basis. That is, under the terms of the Agreements, the additional development activities that we perform for the Initial Indication of VIVITROL will result in a marketable product that has value in the market place. Accordingly, the amount of the arrangement consideration allocated to the accounting unit development and licenses for the Products is based on the residual method of allocation as outlined in EITF 00-21, because fair value evidence exists separately for the other two units of accounting under the Agreements but not on a combined basis with this accounting unit. Consequently, arrangement consideration allocated to this accounting unit will equal the total arrangement consideration received from Cephalon less the amounts allocated to the other two accounting units. We recognize the earned portion of this arrangement consideration on a straight-line basis over the expected life of VIVITROL, being ten years. This milestone revenue will be recorded under the caption Net collaborative profit in the consolidated statements of operations and comprehensive income (loss). No milestone revenue was recorded for this accounting unit in the consolidated statements of operations and comprehensive income (loss) during the years ended March 31, 2006, 2005 and 2004.

Under the terms of the Agreements, we reimburse Cephalon for the net losses they incur on VIVITROL, provided these net losses, together with our VIVITROL-related collaboration expenses, do not exceed $120.0 million through December 31, 2007. This reimbursement is recorded under the caption Net collaborative profit in the consolidated statements of operations and comprehensive income (loss). Once VIVITROL becomes profitable, Cephalon will reimburse us for our product-related expenses together with our share of the net profits, and this reimbursement will be recorded under the caption Net collaborative profit in the consolidated statements of operations and comprehensive

income (loss). During the years ended March 31, 2006, 2005 and 2004, we paid Cephalon $21.2 million, $0 and $0, respectively, as reimbursement for the net losses they incurred on VIVITROL.

Table of Contents

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

Under the terms of the Agreements, Cephalon will pay us up to $220 million in nonrefundable milestone payments if calendar year net sales of the Products exceed certain agreed-upon sales levels. Under current accounting guidance, we expect to recognize these milestone payments in the period earned, under the caption Net collaborative profit in the consolidated statement of operations and comprehensive income (loss).

Other Manufacturing Revenues Other manufacturing revenues consist of revenues earned under certain manufacturing and supply agreements with Janssen for RISPERDAL CONSTA. Manufacturing revenues are earned when product is shipped to our collaborative partner. Manufacturing revenues recognized by us for RISPERDAL CONSTA are based on information supplied to us by Janssen and require estimates to be made. In June 2004, we announced a decision to discontinue commercialization of NUTROPIN DEPOT® with Genentech, Inc. (Genentech). Manufacturing revenues for NUTROPIN DEPOT ceased in the year ended March 31, 2004.

Royalty Revenues Royalty revenues consist of revenues earned under certain license agreements for RISPERDAL CONSTA. Royalty revenues are earned on sales of RISPERDAL CONSTA made by our collaborative partner and are recorded in the period the product is sold by our collaborative partner. Royalty revenues recognized by us for RISPERDAL CONSTA are based on information supplied to us by our collaborative partner. Royalty revenues for NUTROPIN DEPOT ceased in the year ended March 31, 2005.

Research and Development Revenue Under Collaborative Arrangements Research and development revenue consists of nonrefundable research and development funding under collaborative arrangements with various collaborative partners. Research and development funding generally compensates us for formulation, preclinical and clinical testing related to the collaborative research programs, and is recognized as revenue at the time the research and development activities are performed under the terms of the related agreements, when the collaborative partner is obligated to pay and when no future performance obligations exist.

Fees for the licensing of technology or intellectual property rights on initiation of collaborative arrangements are recorded as deferred revenue upon receipt and recognized as income on a systematic basis, based upon the timing and level of work performed, or on a straight-line basis if not otherwise determinable, over the period that the related products or services are delivered or obligations, as defined in the relevant agreement, are performed. Revenue from milestone or other upfront payments is recognized as earned in accordance with the terms of the related agreements. Accounting guidance may require deferral of such revenue to future periods.

Derivatives Embedded in Certain Debt Securities In June 2005, the Financial Accounting Standards Board (FASB) released DIG Issue B39 *Embedded Derivatives: Application of Paragraph 13(b) to Call Options That Exercisable Only by the Debtor* (DIG Issue B39) which modified accounting guidance for determining whether an embedded call option held by the issuer of a debt contract would require separate accounting recognition. We adopted the provisions of DIG Issue B39 in the reporting period beginning January 1, 2006, at which time the carrying value of the embedded derivative contained in our 2.5% Subordinated Notes was combined with the carrying value of the host contract. Beginning January 1, 2006, we no longer record changes in the estimated fair value of the embedded derivative in the consolidated results of operations and comprehensive income (loss).

Certain of our debt securities have contained features providing for cash payments to be made in the event of our stock price exceeding certain levels and triggering conversions of the debt to common stock. In general, these features call for make-whole payments equal to two or three years of interest on the debt less any amounts paid or accrued

prior to the date conversion is triggered. These features expire once the holder has received a defined number of interest payments. These features represent embedded derivatives which are required to be accounted for separately from the related debt securities through the reporting period ended December 31, 2005. The estimated fair value of these features had been valued using a simulation model that

Table of Contents

incorporates factors such as the current price of our common stock, its volatility, and time to expiration. Changes in the estimated fair value of the liability represented by these factors had been charged to the consolidated statements of operations and comprehensive income (loss) under the caption Derivative (loss) income related to convertible subordinated notes through the reporting period ended December 31, 2005. These adjustments were required until the features were either triggered or expired as of the reporting period ended December 31, 2005.

Warrant Valuation We hold warrants to purchase securities of certain publicly held companies, received in connection with our collaboration and licensing activities. The warrants are valued using a Black-Scholes pricing model and changes in value are recorded in the consolidated statement of operations and comprehensive income (loss) under the caption Other income (expense), net. The recorded value of the warrants can fluctuate significantly based on changes in the value of the underlying securities of the issuer of the warrants.

Cost of Goods Manufactured Our cost of goods manufactured includes estimates made in allocating employee compensation and related benefits, occupancy costs, depreciation expense and other allocable costs directly related to our manufacturing activities. Cost of goods manufactured is incurred related to the manufacture of RISPERDAL CONSTA and NUTROPIN DEPOT, until the termination of the NUTROPIN DEPOT manufacturing and supply and license agreements with Genentech in June 2004.

Research and Development Expenses Our research and development expenses include employee compensation and related benefits, laboratory supplies, temporary help costs, external research costs, consulting costs, occupancy costs, depreciation expense and other allocable costs directly related to our research and development activities. Research and development expenses are incurred in conjunction with the development of our technologies, proprietary product candidates, collaborators product candidates and in-licensing arrangements. External research costs relate to toxicology studies, pharmacokinetic studies and clinical trials that are performed for us under contract by external companies, hospitals or medical centers. All such costs are expensed as incurred.

Restructuring Charges We have, at times, announced restructuring programs and, accordingly, recorded certain charges in connection with implementing such programs. These charges generally include employee separation costs, including severance and related benefits, as well as facility consolidation and closure costs, the timing of facility subleases and sublease rates we may negotiate with third parties. Actual costs may differ from those estimates, and in the event that we under- or over-estimate the restructuring charges and related accruals, our reported expenses for a reporting period may be overstated or understated and may require adjustment in the future.

Accrued Expenses As part of the process of preparing our financial statements, we are required to estimate certain accrued expenses. This process involves identifying services that third parties have performed on our behalf and estimating the level of service performed and the associated cost incurred for these services as of the balance sheet date in our financial statements. Examples of estimated accrued expenses are contract service fees, such as amounts due to clinical research organizations, professional service fees, such as attorneys and accountants, and investigators in conjunction with clinical trials. Accruals are based on significant estimates. In connection with these service fees, our estimates are most affected by our understanding of the status and timing of services provided relative to the actual level of services incurred by the service providers. In the event that we do not identify certain costs that have been incurred or we under- or over-estimate the level of services or the costs of such services, our reported expenses for a reporting period could be overstated or understated. The date on which certain services commence, the level of services performed on or before a given date, and the cost of services is sometimes subject to our judgment.

Income Taxes Deferred income taxes are provided for temporary differences between the financial reporting and tax bases of assets and liabilities and for net operating loss and credit carryforwards. Deferred income taxes are recognized at enacted rates expected to be in effect when temporary differences reverse. Valuation allowances are provided to the extent that it is more likely than not that the deferred tax assets will not be recoverable.

Table of Contents

Stock Options and Awards We use the intrinsic value method to measure compensation expense associated with the grants of stock options and awards to employees. We account for stock options and awards to non-employees using the fair-value method. Under the intrinsic value method, compensation associated with stock options and awards to employees is determined as the difference, if any, between the current fair value of the underlying common stock on the measurement date and the price an employee must pay to exercise the award. Under the fair-value method, compensation associated with stock awards is determined based on the estimated fair value of the award itself, measured using either current market data or an established option-pricing model. The measurement date for employee awards is generally the grant date, and the measurement date for non-employee awards is generally the date performance of certain services is complete.

In December 2004, the FASB issued SFAS 123R, which is a revision of SFAS 123, *Accounting for Stock-Based Compensation* , and supersedes Accounting Principles Board Opinion No. 25, *Accounting for Stock Issued to Employees* . SFAS 123R requires all share-based payments, including grants of stock options and stock awards, to be recognized in the financial statements based generally on their grant date fair values. SFAS 123R is effective for us in the reporting period beginning April 1, 2006. We estimate that the effect on the results of operations and comprehensive income (loss) will range between $30.0 million and $35.0 million for the year ended March 31, 2007.

Results of Operations

Net income in accordance with GAAP for the year ended March 31, 2006 was $3.8 million or $0.04 per basic and diluted share, as compared to a net loss of $73.9 million or a net loss of $0.82 per basic and diluted share for the year ended March 31, 2005 and a net loss of $102.4 million or a net loss of $1.25 per basic and diluted share for the year ended March 31, 2004.

Total revenues were $166.6 million for the year ended March 31, 2006 compared to $76.1 million and $39.1 million for the years ended March 31, 2005 and 2004, respectively.

Total manufacturing and royalty revenues were $81.4 million for the year ended March 31, 2006 compared to $50.1 million and $29.5 million for the years ended March 31, 2005 and 2004, respectively.

Total manufacturing revenues were $64.9 million and $40.5 million for the years ended March 31, 2006 and 2005, respectively. The increase in manufacturing revenues for the year ended March 31, 2006 as compared to the year ended March 31, 2005 was due to increased shipments of RISPERDAL CONSTA to Janssen. In the year ended March 31, 2006, our manufacturing revenues were based on an average of 7.5% of Janssen s net sales price for RISPERDAL CONSTA compared to 8.1% in the year ended March 31, 2005. For the year ended March 31, 2004, total manufacturing revenues were $25.7 million. The increase in manufacturing revenues for the year ended March 31, 2005 as compared to the year ended March 31, 2004 was due to increased shipments of RISPERDAL CONSTA to Janssen. In the year ended March 31, 2004, our manufacturing revenues were based on an average of 9.8% of Janssen s net sales price for RISPERDAL CONSTA. Under our manufacturing and supply agreement with Janssen, we record manufacturing revenues upon shipment of product by us to Janssen based on a percentage of Janssen s net selling price. These percentages are based on the volume of units shipped to Janssen in any given calendar year, with a minimum manufacturing fee of 7.5%.

Total royalty revenues were $16.5 million and $9.6 million for the years ended March 31, 2006 and 2005, respectively, including $16.5 million and $9.5 million, respectively, of royalty revenues from sales of RISPERDAL CONSTA. The increase in royalty revenues for the year ended March 31, 2006 as compared to the year ended March 31, 2005 was due to an increase in global sales of RISPERDAL CONSTA by Janssen. For the year ended March 31, 2004, total royalty revenues were $3.8 million, including $3.1 million of royalty revenues from sales of RISPERDAL CONSTA. The increase in royalty revenues for the year ended March 31, 2005 as compared to the year

ended March 31, 2004 was due to an increase in global sales of RISPERDAL CONSTA by Janssen. Under our license agreements with Janssen, we record royalty revenues equal to 2.5% of Janssen s net sales of RISPERDAL CONSTA in the quarter when the product is sold by Janssen.

Research and development revenue under collaborative arrangements was $45.9 million, $26.0 million and $9.5 million for the years ended March 31, 2006, 2005 and 2004, respectively. The increase in this

Table of Contents

revenue for the year ended March 31, 2006 as compared to the year ended March 31, 2005 was primarily the result of a $17.3 million increase in revenues related to our AIR insulin program with Lilly, which includes a $9.0 million milestone payment we received from Lilly in September 2005 upon the initiation of the Phase III clinical program, as well as an increase in revenues related to the exenatide LAR program. For the year ended March 31, 2004, research and development revenue under collaborative arrangements was $9.5 million. The increase in this revenue for the year ended March 31, 2005 as compared to the year ended March 31, 2004 was primarily the result of an increase in revenues related to our AIR insulin and AIR hGH programs with Lilly, as well as changes in the stage of development of several other collaborative programs.

Net collaborative profit was $39.3 million for the year ended March 31, 2006. This represents a new source of revenue for us in fiscal 2006. The three components to net collaborative profit are: the recognition of milestone revenue to offset net losses incurred by both us and Cephalon on VIVITROL; the recognition of milestone revenue related to the license for VIVITROL; and the flow of funds between the two companies with respect to our share of VIVITROL net profits or losses. During the year ended March 31, 2006, we recognized $60.5 of milestone revenue to offset losses incurred on VIVITROL by both us and Cephalon. This consists of $19.8 million that we incurred on behalf of the collaboration, $19.5 million that we incurred with respect to our ongoing efforts to obtain approval of VIVITROL and to complete validation of the manufacturing line, for which we are solely responsible, and $21.2 million of expenses incurred by Cephalon on behalf of the collaboration. We did not recognize any milestone revenue related to the license during the year ended March 31, 2006 because VIVITROL had not yet been approved by the FDA. During the year ended March 31, 2006, we made payments of $21.2 million to Cephalon as reimbursement for losses they incurred on VIVITROL. In the aggregate, net collaborative profit of $39.3 million for the year ended March 31, 2006 consists of $60.5 million of milestone revenue recognized to offset losses incurred by us and Cephalon on VIVITROL, partially offset by the $21.2 million of payments we made to Cephalon as reimbursement for losses they incurred on VIVITROL.

We are responsible for the first $120.0 million of net losses incurred on VIVITROL (Product Losses) through the period ending December 31, 2007. If the Product Losses exceed $120.0 million during this period, Cephalon is responsible for all Product Losses in excess of $120.0 million and would reimburse us for all our VIVITROL-related expenses. Through March 31, 2006, the cumulative losses incurred by us and Cephalon on VIVITROL, against this $120.0 million, were $41.0 million, of which $19.8 million was incurred by us on behalf of the collaboration and $21.2 million was incurred by Cephalon on behalf of the collaboration.

Net collaborative profit for the year ended March 31, 2006 was as follows:

Net Collaborative Profit Summary	**(In thousands)**
Milestone revenue cost recovery:	
Alkermes expenses incurred on behalf of the collaboration	$ 19,791
Cephalon net losses incurred on behalf of the collaboration	21,179
Alkermes expenses related to VIVITROL for which Alkermes was solely responsible	19,495
Total milestone revenue cost recovery	60,465
Milestone revenue license	
Payments made to Cephalon to reimburse their net losses	(21,179)
Net collaborative profit	$ 39,286

Cost of goods manufactured was $23.5 million in the year ended March 31, 2006, related entirely to RISPERDAL CONSTA. Cost of goods manufactured was $16.8 million in the year ended March 31, 2005, consisting of $14.5 million related to RISPERDAL CONSTA and $2.3 million related to NUTROPIN DEPOT. The increase in cost of goods manufactured in the year ended March 31, 2006 as compared to the year ended March 31, 2005 was due to increased shipments of RISPERDAL CONSTA to meet increased demand for the product, offset by the impact of discontinuing the manufacture of NUTROPIN DEPOT under the termination of a license agreement and manufacturing and supply agreement with Genentech in June 2004. Cost of goods

Table of Contents

manufactured in the year ended March 31, 2005 included a one-time write-off of NUTROPIN DEPOT inventory of $1.3 million following the decision to discontinue manufacture of the product. For the year ended March 31, 2004, cost of goods manufactured was $19.0 million, consisting of approximately $13.0 million related to RISPERDAL CONSTA and $6.0 million related to NUTROPIN DEPOT. The decrease in cost of goods manufactured in the year ended March 31, 2005 as compared to the year ended March 31, 2004 was primarily due to the impact of discontinuing the manufacture of NUTROPIN DEPOT under the termination of a license agreement and manufacturing and supply agreement with Genentech in June 2004.

Research and development expenses were $89.1 million for the year ended March 31, 2006 compared to $91.1 million and $91.1 million for the years ended March 31, 2005 and 2004, respectively. Research and development expenses for the year ended March 31, 2006 were lower than the year ended March 31, 2005 primarily due to reductions in external research expenses related to the completion of certain clinical trial programs for VIVITROL, partially offset by an increase in personnel-related costs, an increase in utility costs and a one-time lease charge in the amount of approximately $1.5 million, of which $1.2 million was recorded as research and development expense. In November 2005, we entered into a sublease agreement in which the total sublease income over the sublease period was less than our lease expense, resulting in a loss on the sublease. In addition, during the year ended March 31, 2006, we capitalized into inventory certain raw materials costs to be used in the manufacture of VIVITROL, which in previous years had been recorded in research and development expenses. In total, research and development expenses in the year ended March 31, 2005 were consistent with the year ended March 31, 2004. This reflects a decrease in external research expenses due to the completion of certain clinical trials related to VIVITROL, in addition to the termination of a development agreement with Serono in October 2004, offset by an increase in personnel costs, an increase in occupancy costs related to the expansion of our facilities in both Massachusetts and Ohio, and costs incurred in the completion and filing of the VIVITROL NDA. In addition, in the year ended March, 31 2005, we conformed our accounting for lease expenses to the views of the SEC whereby lease expenses must be recognized on a straight-line basis, rather than as incurred. This resulted in a cumulative one-time, non-cash charge of $2.5 million, related to the previous five years since lease inception. Of this amount, $2.3 million was reported within research and development expenses. The amount was not material to our reported results in any one quarter or any one year. The remaining $0.2 million of this amount was reported in selling, general and administrative expenses.

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

Selling, general and administrative expenses were $40.4 million, $28.8 million and $26.0 million for the years ended March 31, 2006, 2005 and 2004, respectively. The increase in selling, general and administrative expenses for the year ended March 31, 2006 as compared to the year ended March 31, 2005 was primarily due to an increase in personnel-related costs within the commercial organization as we continued to prepare for the commercialization of VIVITROL, an increase in utility costs and a one-time lease charge in the amount of approximately $1.5 million, of which $0.3 million was recorded as selling, general and administrative expenses. In November 2005, we entered into a sublease agreement in which the total sublease income over the sublease period was less than our lease expense, resulting in a loss on the sublease. The increase in selling, general and administrative expenses for the year ended

March 31, 2005 as compared to the year ended March 31, 2004 was primarily due to increases in sales and marketing costs as we prepared for the potential

Table of Contents

future commercialization of VIVITROL, higher personnel costs and an increase in legal fees related to the securities litigation, and accountant fees related to Sarbanes-Oxley compliance.

In June 2004, Alkermes and Genentech announced the decision to discontinue commercialization of NUTROPIN DEPOT (the 2004 Restructuring). The decision was based on the significant resources required by both companies to continue manufacturing and commercializing the product. In connection with this decision, we ceased commercial manufacturing of NUTROPIN DEPOT and recorded restructuring charges of approximately $11.9 million in the quarter ended June 30, 2004. The restructuring charges consisted of a write-off of equipment and leasehold improvements related to the manufacture of NUTROPIN DEPOT, as well as employee separation costs, including severance and related benefits. The restructuring charges also included lease costs and significant estimates related to the costs to maintain the facility in which NUTROPIN DEPOT was produced through the end of its lease term, August 2008. In addition to the restructuring charges, we recorded a one-time write-off of NUTROPIN DEPOT inventory of approximately $1.3 million which was recorded under the caption Cost of goods manufactured in the consolidated statement of operations and comprehensive loss. In the quarter ended March 31, 2005, we reversed a reserve, through restructuring, that we had been carrying related to a yield loss penalty originally due under the manufacturing and supply agreement for NUTROPIN DEPOT. This penalty was forgiven and the reserve was reversed. The final net restructuring charge for the year ended March 31, 2005 was approximately $11.5 million. As of March 31, 2006, we had paid in cash or written off an aggregate of approximately $9.0 million in facility closure costs and $0.1 million in employee separation costs in connection with the 2004 Restructuring. The amounts remaining in the 2004 Restructuring accrual at March 31, 2006 relate primarily to estimates of lease costs associated with the exited facility and are expected to be paid through the fiscal year ended March 31, 2009.

In August 2002, we announced a restructuring program (the 2002 Restructuring) to reduce our cost structure as a result of our expectations regarding the financial impact of a delay in the U.S. launch of RISPERDAL CONSTA by our collaborative partner, Janssen. In connection with the 2002 Restructuring, we recorded charges of approximately $6.5 million in the consolidated statement of operations and comprehensive loss for the year ended March 31, 2003. As of March 31, 2005, we had paid and recovered an aggregate of approximately $1.5 million in employee separation costs and approximately $5.0 million in facility closure costs. There are no remaining liabilities associated with the 2002 restructuring program as of March 31, 2006.

Table of Contents

Pursuant to the restructuring plans, the following charges and payments have been recorded during the year ended March 31, 2006, 2005 and 2004:

	Fiscal 2004				Fiscal 2005			Fiscal 2006		
Type of Liability	Balance March 31, 2003	Recoveries	Payments	Balance March 31, 2004	Charges	Non-Cash Write-Downs and Payments	Balance March 31, 2005	Adjustments	Payments	Balance March 31 2006
2004 Restructuring:										
Employee separation	$	$	$	$	$ 146	$ (137)	$ 9	$	$	$ 9
Facility closure(1)					11,381	(8,416)	2,965		(606)	2,359
					11,527	(8,553)	2,974		(606)	2,368
2002 Restructuring:										
Employee separation	17		(17)							
Facility closure	3,520	(208)	(2,174)	1,138		(749)	389	(34)	(355)	
	3,537	(208)	(2,191)	1,138		(749)	389	(34)	(355)	
Total	$ 3,537	$ (208)	$ (2,191)	$ 1,138	$ 11,527	$ (9,302)	$ 3,363	$ (34)	(961)	$ 2,368

(1) Fiscal 2005 non-cash write-downs and payments consist of $7.7 million of non-cash write-downs and $0.7 million of payments.

We have substantially completed our restructuring programs. However, the remaining restructuring accrual as of March 31, 2006 is an estimate of costs associated with leases or closed facilities and may require adjustment in the future.

Interest income was $11.6 million, $3.0 million and $3.4 million for the years ended March 31, 2006, 2005 and 2004, respectively. The increase for the year ended March 31, 2006 as compared to the year ended March 31, 2005 was primarily due to higher average cash and investment balances held and higher interest rates earned during the respective periods. The decrease for the year ended March 31, 2005 as compared to the year ended March 31, 2004 was primarily due to lower average cash and investment balances held.

Interest expense was $20.6 million for the year ended March 31, 2006 as compared to $7.4 million and $6.5 million for the year ended March 31, 2005 and 2004, respectively. The increase for the year ended March 31, 2006 as compared to the year ended March 31, 2005 was primarily due to a full year of interest on our 7% Notes. The increase for the year ended March 31, 2005 as compared to the year ended March 31, 2004 was primarily due to interest on our 7% Notes incurred since inception of the 7% Notes in February 2005.

Derivative (loss) income related to convertible subordinated notes was a loss of $1.1 million for the year ended March 31, 2006, as compared to an income of $4.4 million and a loss of $4.5 million for the years ended March 31, 2005 and 2004, respectively.

We recorded a derivative liability related to the 6.52% Senior Notes. The Two-Year Interest Make-Whole provision, included in the note indenture and described in Note 9 to our consolidated financial statements included in this annual report on Form 10-K, represented an embedded derivative which was required to be accounted for apart from the underlying 6.52% Senior Notes. At issuance of the 6.52% Senior Notes, the Two-Year Interest Make-Whole feature was estimated to have a fair value of $9.0 million and the initial recorded value of the 6.52% Senior Notes was reduced by this allocation. The estimated value of the Two-Year Interest Make-Whole feature was carried in the consolidated balance sheets under the caption Derivative liability related to convertible subordinated notes and was adjusted quarterly through Derivative (loss) income related to convertible subordinated notes in the consolidated statement of operations and comprehensive income (loss) for changes in the estimated market value of the feature. During the years ended March 31, 2006, 2005 and 2004, we recorded charges of $0, $0 and $3.8 million, respectively, in the consolidated statement of operations and comprehensive income (loss) for changes in the estimated value of the feature after issuance. In June 2003, we announced that we had exercised our automatic conversion right for the 6.52% Senior Notes.

Table of Contents

The embedded derivative was adjusted to the value of the remaining balance of the Two-Year Interest Make-Whole payment, or approximately $17.1 million, at June 30, 2003 and was accounted for as a liability in the consolidated balance sheets. In July 2003, upon conversion of the then outstanding 6.52% Senior Notes and payment of the Two-Year Interest Make-Whole, the embedded derivative was settled in full and the balance was reduced to zero.

We recorded a derivative liability related to the 2.5% Subordinated Notes. The Three-Year Interest Make-Whole represented an embedded derivative which was required to be accounted for apart from the underlying 2.5% Subordinated Notes. At issuance of the 2.5% Subordinated Notes, the Three-Year Interest Make-Whole feature had an estimated initial aggregate fair value of $3.9 million, which reduced the amount of the outstanding debt and was recorded as a derivative liability in the consolidated balance sheets. The $3.9 million initially allocated to the Three-Year Interest Make-Whole feature was treated as a discount on the 2.5% Subordinated Notes and was being accreted to interest expense over five years through September 1, 2008, the first date on which holders of the 2.5% Subordinated Notes have the right to require us to repurchase the 2.5% Subordinated Notes. The estimated value of the Three-Year Interest Make-Whole feature was carried in the consolidated balance sheets under the caption Derivative liability related to convertible notes and was being adjusted to its fair value on a quarterly basis until it expires or is paid. Quarterly adjustments to the fair value of the Three-Year Interest Make-Whole were being charged to Derivative (loss) income related to convertible subordinated notes in the consolidated statement of operations and comprehensive income (loss) until it is paid out or expires. During the years ended March 31, 2006 and 2005, we recorded a loss of $1.1 million and income of $4.4 million, respectively, in the consolidated statement of operations and comprehensive income (loss) for changes in the estimated value of the feature after issuance. The recorded value of the derivative liability related to the 2.5% Subordinated Notes, approximately $0 and $0.3 million at March 31, 2006 and 2005, respectively, fluctuated significantly based on fluctuations in the market value of our common stock. See Note 9 for our modified accounting for embedded derivatives, effective January 1, 2006.

Other income (expense), net was an income of $0.3 million in the year ended March 31, 2006 as compared to an expense of $1.8 million and an income of $2.1 million in the years ended March 31, 2005 and 2004, respectively. Other income (expense), net primarily consists of income or expense recognized on the changes in the fair value of warrants of public companies held by us in connection with collaboration and licensing arrangements, which are recorded under the caption 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. In the year ended March 31, 2006, other income (expense) included, amongst other things: an income of $1.4 million on changes in the fair value of warrants held; an expense of $0.6 million for a loss related to other than temporary impairment on certain equity securities held; and an expense of $0.3 million related to the initial application of FIN 47 *Accounting for Conditional Asset Retirement Obligations.*

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

Reliant

In December 2001, we made a $100.0 million investment in Series C convertible, redeemable preferred units of Reliant Pharmaceuticals, LLC (Reliant) and we currently own approximately 12% of Reliant. Through March 31, 2004, the investment had been accounted for under the equity method of accounting because Reliant was organized as a limited liability company, which is treated in a manner similar to a partnership. Our $100.0 million investment was reduced to $0 in the year ended March 31, 2003 based upon our equity losses in Reliant. Effective April 1, 2004, Reliant converted from a limited liability company to a corporation under Delaware state law. Due to this change, and because Reliant is a privately held company over which Alkermes does not exercise control, our investment in Reliant has been accounted for under the cost method beginning April 1, 2004. Accordingly, we do not record any share of Reliant s net income or losses, but would record dividends, if received. Our investment remains at $0 as of March 31, 2006.

Table of Contents

Financial Condition

Cash and cash equivalents and short-term investments were $298.0 million and $202.6 million as of March 31, 2006 and March 31, 2005, respectively. Short-term investments were $264.4 million and $155.1 million as of March 31, 2006 and March 31, 2005, respectively. During the year ended March 31, 2006, combined cash and cash equivalents and short-term investments increased by $95.4 million, primarily due to a $160.0 million nonrefundable payment we received from Cephalon in June 2005, in connection with the signing of our Agreements, and a $9.0 million nonrefundable milestone payment we received from Lilly in September 2005, partially offset by net cash used to fund our operations, to acquire fixed assets and to service our debt.

We invest in cash equivalents, U.S. government obligations, high-grade corporate notes and commercial paper, with the exception of our $100.0 million investment in Reliant, and warrants we receive in connection with our collaborations and licensing activities. Our investment objectives, other than our investment in Reliant and our warrants, are, first, to assure liquidity and conservation of capital and, second, to obtain investment income. We held approximately $5.1 million and $4.9 million of U.S. government obligations classified as restricted long-term investments as of March 31, 2006, and March 31, 2005, respectively, which are pledged as collateral under certain letters of credit and lease agreements.

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

Receivables were $39.8 million and $18.8 million as of March 31, 2006 and March 31, 2005, respectively. The increase of $21.0 million during the year ended March 31, 2006 was primarily due to increased manufacturing and royalty revenues due from Janssen for both RISPERDAL CONSTA shipments and capital expenditure reimbursements due under our manufacturing and supply agreements, in addition to the timing of payments received from Lilly and Amylin with respect to our collaborative programs. All of our receivables are current.

Inventory, net was $7.3 million and $3.8 million as of March 31, 2006 and March 31, 2005, respectively. The increase of $3.5 million during the year ended March 31, 2006 was due to a $2.5 million increase in VIVITROL raw materials and work in process inventories related to the start of commercial manufacturing. In previous years, we expensed VIVITROL raw materials to research and development expenses because they were used to manufacture clinical supplies. The remaining increase relates to RISPERDAL CONSTA raw materials and finished goods inventory increases due to production volumes and the timing of shipments of the product to Janssen.

Accounts payable and accrued expenses were $36.1 million and $18.8 million as of March 31, 2006 and March 31, 2005, respectively. The increase of $17.3 million during the year ended March 31, 2006 was primarily due to an increase in accounts payable due to the timing of vendor payments, increases in compensation accruals due to the timing of normal payroll and bonus payments, and accruals of $9.0 million for amounts due to Cephalon under our Agreements.

Unearned milestone revenue current portion and long-term portion combined, was $99.5 million and $0 as of March 31, 2006 and 2005, respectively. The increase during the year ended March 31, 2006 was due to the receipt of a $160.0 million nonrefundable payment from Cephalon in June 2005 in connection with the signing of our Agreements, reduced by $60.5 million of milestone revenue we recognized under the caption Net collaborative profit in the consolidated statement of operations and comprehensive income (loss) during the year ended March 31, 2006.

In October 2005, we converted 1,500 shares of our Preferred Stock with a carrying value of $15.0 million into 823,677 shares of common stock. The conversion was made in accordance with the stock purchase agreement with Lilly dated December 13, 2002. The conversion secured a proportional increase in the minimum royalty rate payable

to us on sales of the AIR insulin product by Lilly, if approved. The carrying amount of the Preferred Stock on the consolidated balance sheets as of March 31, 2006 and 2005 was $15.0 million and $30.0 million, respectively.

Table of Contents

As of March 31, 2006, we had approximately $575.0 million of federal net operating loss (NOL) carryforwards, $371.0 million of state operating loss carryforwards, and $25.0 million of foreign net operating loss and foreign capital loss carryforwards, which expire on various dates through 2026 or can be carried forward indefinitely. These loss carryforwards are available to reduce future federal and foreign taxable income, if any. These loss carryforwards are subject to review and possible adjustment by the 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 are presently analyzing historical ownership changes to determine whether the losses are limited under Sec. 382 of the Internal Revenue Code. The valuation allowance of $266.8 million relates to our U.S. net operating losses and deferred tax assets and certain other foreign deferred tax assets and is recorded based upon the uncertainty surrounding future utilization.

Liquidity and Capital Resources

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

We believe that our current cash and cash equivalents and short-term investments, combined with our unused equipment lease line, anticipated interest income, anticipated manufacturing and royalty revenues, and anticipated research and development revenue under collaborative arrangements, and anticipated net collaborative profit from our collaboration with Cephalon, will generate sufficient cash flows to meet our anticipated liquidity and capital requirements through at least March 31, 2008.

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

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

Capital expenditures were approximately $28.7 million for the year ended March 31, 2006, net of $6.0 million in reimbursements from Janssen under our RISPERDAL CONSTA manufacturing and supply agreement for costs

related to the construction of a third bulk manufacturing line for RISPERDAL CONSTA. Our capital expenditures were primarily related to the purchase of equipment to make improvements to and expand our manufacturing facility in Ohio. Our capital expenditures for equipment, facilities and building

Table of Contents

improvements have been financed to-date primarily with proceeds from bank loans and the sales of debt and equity securities. Under the provisions of our existing loans, General Electric Capital Corporation (GE) and Johnson & Johnson Finance Corporation have security interests in certain of our capital assets.

Our manufacturing site in Wilmington, Ohio is undergoing a significant expansion which is expected to be substantially completed in calendar year 2008. Our capital expenditures in FY 2007 are expected to be approximately $40.0 million. The majority of these expenditures are related to our manufacturing site in Wilmington, Ohio. The expansion will add three additional manufacturing lines for RISPERDAL CONSTA AND VIVITROL. In addition to our spending, Janssen is funding the cost related to one of the new lines for RISPERDAL CONSTA in the amount of approximately $11.0 million, of which approximately $5.0 million in funding has been received by us through March 31, 2006.

Off-Balance Sheet Arrangements

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

Contractual Obligations

We have summarized below our material contractual cash obligations as of March 31, 2006:

Contractual Cash Obligations	Total	Less Than One Year (Fiscal 2007)	Two to Three Years (Fiscal 2008-2009)	Four to Five Years (Fiscal 2010-2011)	After Five Years (After Fiscal 2011)
			(In thousands)		
7% Notes principal(1)	$ 170,000	$	$	$ 113,333	$ 56,667
7% Notes interest	55,037	11,900	23,800	16,858	2,479
Convertible subordinated notes principal(2)	125,676	676			125,000
Convertible subordinated notes interest(2)	53,150	3,150	6,250	6,250	37,500
Term loan principal	2,484	1,118	1,366		
Term loan interest	212	153	59		
Capital lease obligations	276	114	162		
Operating lease obligations	184,901	9,976	20,732	20,486	133,707
Purchase obligations	4,898	4,898			
Capital expansion programs	10,837	10,837			
Total contractual cash obligations	$ 607,471	$ 42,822	$ 52,369	$ 156,927	$ 355,353

(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 6 to the consolidated financial statements included in this Form 10-K).

(2) Subsequent to March 31, 2006, we announced that we had exercised our right to automatically convert all of our outstanding 2.5% Subordinated Notes into approximately 9,025,271 shares of common stock, pursuant to the terms of the notes. The conversion date is June 15, 2006.

Table of Contents

Quarterly Financial Data	Three Months Ended June 30, 2005	September 30, 2005	December 31, 2005	March 31, 2006
	(In thousands, except per share data)			
REVENUES:				
Manufacturing revenues	$ 13,983	$ 13,526	$ 14,715	$ 22,677
Royalty revenues	3,604	4,035	4,228	4,665
Research and development revenue under collaborative arrangements	7,251	16,733	9,951	11,948
Net collaborative profit		12,394	12,524	14,367
Total revenues	24,838	46,688	41,418	53,657
EXPENSES:				
Cost of goods manufactured	4,517	4,360	6,077	8,535
Research and development	21,622	19,370	22,501	25,575
Selling, general and administrative	8,952	9,109	9,332	12,990
Total expenses	35,091	32,839	37,910	47,100
OPERATING INCOME (LOSS)	(10,253)	13,849	3,508	6,557
OTHER INCOME (EXPENSE):				
Interest income	1,631	3,019	3,278	3,641
Interest expense	(5,169)	(5,212)	(5,177)	(5,103)
Derivative loss related to convertible subordinated notes	(266)	(503)	(315)	
Other income (expense), net(1)	320	599	113	(699)
Total other income (expense)	(3,484)	(2,097)	(2,101)	(2,161)
NET INCOME (LOSS)	$ (13,737)	$ 11,752	$ 1,407	$ 4,396
EARNINGS (LOSS) PER COMMON SHARE:				
BASIC	$ (0.15)	$ 0.13	$ 0.02	$ 0.05
DILUTED	$ (0.15)	$ 0.12	$ 0.01	$ 0.04
WEIGHTED AVERAGE NUMBER OF COMMON SHARES OUTSTANDING:				
BASIC	90,410	90,558	91,505	91,802
DILUTED	90,410	96,599	96,720	99,754

(1) Includes a charge of approximately $0.3 million in the quarter ended March 31, 2006 for recognizing the cumulative effect of initially applying FIN 47, *Accounting for Conditional Asset Retirement Obligations.*

Table of Contents

Quarterly Financial Data	Three Months Ended June 30, 2004	September 30, 2004	December 31, 2004	March 31, 2005
	(In thousands, except per share data)			
REVENUES:				
Manufacturing revenues	$ 6,155	$ 7,753	$ 13,922	$ 12,656
Royalty revenues	1,810	2,185	2,652	2,991
Research and development revenue under collaborative arrangements	3,509	8,097	7,011	7,385
Total revenues	11,474	18,035	23,585	23,032
EXPENSES(1):				
Cost of goods manufactured	5,241	2,390	4,930	4,273
Research and development	24,132	22,590	20,058	24,285
Selling, general and administrative	7,039	7,379	6,868	7,537
Restructuring	11,896			(369)
Total expenses	48,308	32,359	31,856	35,726
OPERATING LOSS	(36,834)	(14,324)	(8,271)	(12,694)
OTHER INCOME (EXPENSE):				
Interest income	630	660	646	1,069
Interest expense	(1,188)	(1,187)	(1,158)	(3,861)
Derivative income (loss) related to convertible subordinated notes	1,518	1,172	(347)	2,042
Other income (expense), net	(274)	(585)	131	(1,061)
Total other income (expense)	686	60	(728)	(1,811)
NET LOSS	$ (36,148)	$ (14,264)	$ (8,999)	$ (14,505)
LOSS PER COMMON SHARE:				
BASIC	$ (0.40)	$ (0.16)	$ (0.10)	$ (0.16)
DILUTED	$ (0.40)	$ (0.16)	$ (0.10)	$ (0.16)
WEIGHTED AVERAGE NUMBER OF COMMON SHARES OUTSTANDING:				
BASIC	89,409	90,067	90,176	90,345
DILUTED	89,409	90,067	90,176	90,345

(1) Operating expenses in the quarter ended March 31, 2005 include a cumulative charge of approximately $2.5 million to record lease costs on a straight-line basis from their inception through March 31, 2005.

Recent Accounting Pronouncements

In November 2004, the FASB issued SFAS No. 151, *Inventory Costs*, which amends accounting research bulletin (ARB) No. 43, Chapter 4, *Inventory Pricing,* to clarify the accounting for idle facility expense, freight, handling costs and waste (spoilage). This new standard is effective for inventory costs incurred during fiscal years beginning after June 15, 2005, and, thus, will be effective for us for the reporting period beginning April 1, 2006. We believe our current accounting policies closely align to the new rules. Accordingly, we do not believe this new standard will have a material impact on our consolidated financial statements.

Table of Contents

In December 2004, the FASB issued SFAS 123R, *Share Based Payment,* which is a revision of SFAS 123, *Accounting for Stock-Based Compensation*, and supersedes accounting principles board (APB) Opinion No. 25, *Accounting for Stock Issued to Employees*. SFAS 123R requires all share-based payments, including grants of stock options and stock awards, to be recognized in the financial statements based generally on their grant date fair values. SFAS 123R is effective for us in the reporting period beginning April 1, 2006. We have adopted as of April 1, 2006 the provisions of SFAS 123R using the modified prospective transition method, and will recognize share-based compensation cost on a straight-line basis over the requisite service periods of awards. We will recognize share-based compensation cost for awards that have graded vesting on a straight-line basis over the requisite service period for each separately vesting portion. Under the modified prospective method, share-based compensation expense will be recognized for the portion of outstanding stock options and stock awards granted prior to the adoption of SFAS 123R for which service has not been rendered, and for any future stock options and stock awards. Although the adoption of SFAS 123R is not expected to have a material effect on our cash flows, we expect to record substantial non-cash compensation expense that will have a significant, adverse effect on our results of operations and comprehensive income (loss). The impact of adoption of SFAS 123R depends on estimates of stock price volatility, option terms, interest rates, the number and type of stock options and stock awards granted during the reporting period, as well as other factors. We estimate that the effect on our results of operations and comprehensive income (loss) will range between $30.0 million and $35.0 million for the year ended March 31, 2007.

In March 2005, the FASB issued Interpretation No. 47, *Accounting for Conditional Asset Retirement Obligations* (FIN 47). FIN 47 clarifies that the term conditional asset retirement obligation, as used in SFAS No. 143, *Accounting for Asset Retirement Obligations* (SFAS 143) refers to a legal obligation to perform an asset retirement activity in which the timing or method of settlement are conditional on a future event that may or may not be within the control of the entity. FIN 47 also clarifies that an entity is required to recognize a liability for such an obligation when incurred if the liability s fair value can be reasonably estimated. FIN 47 is required to become effective no later than the end of the first fiscal year ending after December 15, 2005 and, thus, is effective for us for the year ended March 31, 2006. We recorded a charge of $0.3 million in the year ended March 31, 2006 for recognizing the cumulative effect of initially applying FIN 47 under the caption, Other income (expense), net in the consolidated statement of operations and comprehensive income (loss). We believe that this amount was immaterial for separate presentation in the consolidated statement of operations and comprehensive income (loss).

In June 2005, the FASB issued SFAS No. 154, *Accounting Changes and Error Corrections a replacement of APB Opinion No. 20 and FASB Statement No. 3* (SFAS 154). SFAS 154 replaces APB Opinion No. 20, *Accounting Changes* (APB 20), and SFAS No. 3, *Reporting Accounting Changes in Interim Financial Statements*. SFAS 154 requires retrospective application to prior periods financial statements of a voluntary change in accounting principle unless it is impracticable to determine either the period-specific effects or the cumulative effects of the change. APB 20 previously required that most voluntary changes in accounting principle be recognized by including in net income in the period of the change the cumulative effect of changing to the new accounting principle. This standard generally will not apply with respect to the adoption of new accounting standards, as new accounting standards usually include specific transition provisions, and will not override transition provisions contained in new or existing accounting literature. SFAS 154 is effective for fiscal years beginning after December 15, 2005, and, thus, will be effective for us in the reporting period beginning April 1, 2006.

In June 2005, the FASB released Derivatives Implementation Group Issue B39, *Embedded Derivatives: Application of Paragraph 13(b) to Call Options That are Exercisable Only by the Debtor* (DIG Issue B39). DIG Issue B39 modifies current accounting guidance for determining whether an embedded call option in a debt contract that could potentially accelerate the settlement of that instrument would require separate accounting under the provisions of SFAS 133, *Accounting for Derivative Instruments and Hedging Activities*. Essentially, DIG Issue B39 concluded that options exercisable only by the issuer of such a contract will no longer require separate accounting recognition, as long as they satisfy all other criteria in SFAS 133. We adopted the provisions of DIG Issue B39 in the reporting period beginning

January 1, 2006, at which time

Table of Contents

the carrying value of the embedded derivative contained in our convertible subordinated notes (described in more detail in note 9 to the consolidated financial statements) was combined with the carrying value of the host contracts and will no longer require separate recognition or accounting. Implementation of DIG Issue B39 had no impact on our operating cash flows, and we will no longer be required to record changes in the estimated fair value of the embedded derivatives in the results of operations and comprehensive income (loss).

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

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

We also hold certain marketable equity securities, including warrants to purchase the securities of publicly traded companies we collaborate with, that are classified as available-for-sale and recorded at fair value under the caption Other assets in the consolidated balance sheets. These marketable equity securities are sensitive to changes in interest rates. Interest rate changes would result in a change in the fair value of these financial instruments due to the difference between the market interest rate and the rate at the date of purchase of the financial instrument. A 10% increase or decrease in market interest rates would not have a material impact on the consolidated financial statements.

As of March 31, 2006, the fair value of our 7% Notes, our 2.5% Subordinated Notes, and our 3.75% Subordinated Notes approximate the carrying values. The interest rates on these notes, and our capital lease obligations, are fixed and therefore not subject to interest rate risk. A 10% increase or decrease in market interest rates would not have a material impact on the consolidated financial statements.

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

Foreign Currency Exchange Rate Risk

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

The impact on our royalty revenues from foreign currency exchange rate risk is based on a number of factors, including the exchange rate (and the change in the exchange rate from the prior period) between a foreign currency and the U.S. dollar, and the amount of sales by our collaborative partner that are denominated in foreign currencies.

We do not currently hedge our foreign currency exchange rate risk.

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

All financial statements required to be filed hereunder are filed as an exhibit hereto, are listed under Item 15 (a) (1) and (2) and are incorporated herein by reference.

Table of Contents

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

There have been no changes in and no disagreements with our independent registered public accounting firm on accounting and financial disclosure matters.

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

(a) Evaluation of disclosure controls and procedures

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended, or the Exchange Act) as of March 31, 2006. In designing and evaluating our disclosure controls and procedures, our management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives, and our management necessarily applied its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on this evaluation, our Chief Executive Officer and Chief Financial Officer concluded that, as of March 31, 2006, our disclosure controls and procedures were: (1) designed to ensure that material information relating to our company, including our consolidated subsidiaries, is made known to our Chief Executive Officer and Chief Financial Officer by others within those entities, particularly during the period in which this report was being prepared; and (2) effective, in that they provide reasonable assurance that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC s rules and forms.

(b) Evaluation of internal control over financial reporting

Management s Report on Internal Control over Financial Reporting

The management of Alkermes, Inc. (the Company) is responsible for establishing and maintaining adequate internal control over financial reporting, and for performing an assessment of the effectiveness of internal control over financial reporting as of March 31, 2006. Under the supervision and with the participation of management, including the Company s Chief Executive Officer and Chief Financial Officer, management assessed the effectiveness of the Company s internal control over financial reporting based on the criteria in *Internal Control Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on this assessment, management believes that the Company s internal control over financial reporting was effective as of March 31, 2006.

The Company s internal control over financial reporting includes policies and procedures that pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect transactions and dispositions of assets; provide reasonable assurances that transactions are recorded as necessary to permit preparation of financial statements in accordance with accounting principles generally accepted in the United States of America, and that receipts and expenditures are being made only in accordance with authorizations of our management and directors; and provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of our assets that could have a material effect on our financial statements.

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

Management s assessment of the effectiveness of the Company s internal control over financial reporting as of March 31, 2006 has been attested to by Deloitte & Touche LLP, independent registered public accounting firm, as stated in their report which is included herein.

Table of Contents

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

We have audited management s assessment, included in the accompanying Management s Report on Internal Control over Financial Reporting, that Alkermes, Inc. and subsidiaries (the Company) maintained effective internal control over financial reporting as of March 31, 2006, based on criteria established in *Internal Control Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission. The Company s management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting. Our responsibility is to express an opinion on management s assessment and an opinion on the effectiveness of the Company s internal control over financial reporting based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, evaluating management s assessment, testing and evaluating the design and operating effectiveness of internal control, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinions.

A company s internal control over financial reporting is a process designed by, or under the supervision of, the company s principal executive and principal financial officers, or persons performing similar functions, and effected by the company s board of directors, management, and other personnel to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company s internal control over financial reporting includes those policies and procedures that: (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company s assets that could have a material effect on the financial statements.

Because of the inherent limitations of internal control over financial reporting, including the possibility of collusion or improper management override of controls, material misstatements due to error or fraud may not be prevented or detected on a timely basis. Also, projections of any evaluation of the effectiveness of the internal control over financial reporting to future periods are subject to the risk that the controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

In our opinion, management s assessment that the Company maintained effective internal control over financial reporting as of March 31, 2006, is fairly stated, in all material respects, based on the criteria established in *Internal Control Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission. Also in our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of March 31, 2006, based on the criteria established in *Internal Control Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission.

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated financial statements as of and for the year ended March 31, 2006 of the Company and our report dated June 14, 2006 expressed an unqualified opinion on those consolidated financial statements and includes an explanatory paragraph regarding the Company s adoption of DIG Issue B-39.

Boston, Massachusetts
June 14, 2006

Table of Contents

(c) Changes in internal controls

No change in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) occurred during the quarter ended March 31, 2006 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

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

The Company s policy governing transactions in its securities by its directors, officers and employees permits its officers, directors and employees to enter into trading plans in accordance with Rule 10b5-1 under the Exchange Act. During the quarter ended June 30, 2006, subsequent to FDA approval of VIVITROL and the Company s announcement of its financial results for the fiscal year ended March 31, 2006, Mr. Richard F. Pops, Mr. David A. Broecker, Mr. James M. Frates and Mr. Michael J. Landine, executive officers of the Company, entered into trading plans in accordance with Rule 10b5-1 and the Company s policy governing transactions in its securities by its directors, officers and employees. The Company undertakes no obligation to update or revise the information provided herein, including for revision or termination of an established trading plan.

PART III

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

The information required by this item is incorporated herein by reference to our Proxy Statement for our annual shareholders meeting (the 2006 Proxy Statement).

Item 11. ***Executive Compensation***

The information required by this item is incorporated herein by reference to the 2006 Proxy Statement.

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

The information required by this item is incorporated herein by reference to the 2006 Proxy Statement.

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

The information required by this item is incorporated herein by reference to the 2006 Proxy Statement.

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

The information required by this item is incorporated herein by reference to the 2006 Proxy Statement.

PART IV

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

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

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

(3) *Exhibits*

Table of Contents

Exhibit No.	
3.1	Third Amended and Restated Articles of Incorporation as filed with the Pennsylvania Secretary of State on June 7, 2001. (Incorporated by reference to Exhibit 3.1 to the Registrant s Report on Form 10-K for the fiscal year ended March 31, 2001.)
3.1(a)	Amendment to Third Amended and Restated Articles of Incorporation as filed with the Pennsylvania Secretary of State on December 16, 2002 (2002 Preferred Stock Terms). (Incorporated by reference to Exhibit 3.1 to the Registrant s Current Report on Form 8-K filed on December 16, 2002.)
3.1(b)	Amendment to Third Amended and Restated Articles of Incorporation as filed with the Pennsylvania Secretary of State on May 14, 2003 (Incorporated by reference to Exhibit A to Exhibit 4.1 to the Registrant s Report on Form 8-A filed on May 2, 2003.)
3.2	Second Amended and Restated By-Laws of Alkermes, Inc. (Incorporated by reference to Exhibit 3.2 to the Registrant s Current Report on Form 8-K filed on September 28, 2005.)
4.1	Specimen of Common Stock Certificate of Alkermes, Inc. (Incorporated by reference to Exhibit 4 to the Registrant s Registration Statement on Form S-1, as amended (File No. 33-40250).)
4.2	Specimen of Non-Voting Common Stock Certificate of Alkermes, Inc. (Incorporated by reference to Exhibit 4.4 to the Registrant s Report on Form 10-K for the fiscal year ended March 31, 1999 (File No. 001-14131).)
4.3	Specimen of 2002 Preferred Stock Certificate of Alkermes, Inc. (Incorporated by reference to Exhibit 4.1 to the Registrant s Report on Form 8-K filed on December 13, 2002.)
4.4	Indenture, dated as of February 18, 2000, between Alkermes, Inc. and State Street Bank and Trust Company, as Trustee. (3.75% Subordinated Notes) (Incorporated by reference to Exhibit 4.6 to the Registrant s Registration Statement on Form S-3, as amended filed on February 29, 2000 (File No. 333-31354).)
4.5	Form of 3.75% Subordinated Note (Incorporated by reference to Exhibit 4.6 to the Registrant s Registration Statement on Form S-3, as amended filed on February 29, 2000 (File No. 333-31354).)
4.6	Rights Agreement, dated as of February 7, 2003, as amended, between Alkermes, Inc. and EquiServe Trust Co., N.A., as Rights Agent. (Incorporated by reference to Exhibit 4.1 to the Registrant s Report on Form 8-A filed on May 2, 2003.)
4.7	Indenture, dated August 22, 2003, between Alkermes, Inc. and U.S. Bank National Association, as Trustee (2.5% Subordinated Notes.) (Incorporated by reference to Exhibit 4.7 to the Registrant s Registration Statement on Form S-1, as amended filed on September 3, 2003 (File No. 333-108483).)
4.8	Form of 21/2% Subordinated Note (Incorporated by reference to Exhibit 4.7 to the Registrant s Registration Statement on Form S-1, as amended filed on September 3, 2003 (File No. 333-108483).)
4.9	Indenture, dated as of February 1, 2005, between RC Royalty Sub LLC and U.S. Bank National Association, as Trustee. (Incorporated by reference to Exhibit 4.1 to the Registrant s Current Report on Form 8-K filed on February 3, 2005.)
4.10	Form of Risperdal Consta® PhaRMA℠ Secured 7% Notes due 2018. (Incorporated by reference to Exhibit 4.1 to the Registrant s Current Report on Form 8-K filed on February 3, 2005.)
10.1	Amended and Restated 1990 Omnibus Stock Option Plan, as amended. (Incorporated by reference to Exhibit 10.2 to the Registrant s Report on Form 10-K for the fiscal year ended March 31, 1998 (File No. 001-14131).)+
10.2	Stock Option Plan for Non-Employee Directors, as amended. (Incorporated by reference to Exhibit 99.2 to the Registrant s Registration Statement on Form S-8 filed on October, 1, 2003 (File No. 333-109376).)+
10.3	Alkermes, Inc. 1998 Equity Incentive Plan. (Incorporated by reference to Exhibit 10.6 to the Registrant s Report on Form 10-K for the fiscal year ended March 31, 1999 (File No. 001-14131).)+

10.4	1999 Stock Option Plan, as amended. (Incorporated by reference to Exhibit 10.1 to the Registrant s Report on Form 10-Q for the quarter ended September 30, 2004.)+

Table of Contents

Exhibit No.	
10.5	2002 Restricted Stock Award Plan. (Incorporated by reference to Exhibit 10.2 to the Registrant s Report on Form 10-Q for the quarter ended September 30, 2002.)+
10.6	Lease, dated as of October 26, 2000, between FC88 Sidney, Inc. and Alkermes, Inc. (Incorporated by reference to Exhibit 10.3 to the Registrant s Report on Form 10-Q for the quarter ended December 31, 2000.)
10.7	Lease, dated as of October 26, 2000, between Forest City 64 Sidney Street, Inc. and Alkermes, Inc. (Incorporated by reference to Exhibit 10.4 to the Registrant s Report on Form 10-Q for the quarter ended December 31, 2000.)
10.8	Lease, dated July 26, 1993, between the Massachusetts Institute of Technology and Alkermes, Inc. (Incorporated by reference to Exhibit 10.8 to the Registrant s Report on Form 10-K for the fiscal year ended March 31, 1997 (File No. 000-19267).)
10.8(a)	First Amendment of Lease, dated June 9, 1997, between the Massachusetts Institute of Technology and Alkermes, Inc. (Incorporated by reference to Exhibit 10.8(a) to the Registrant s Report on Form 10-K for the fiscal year ended March 31, 1997 (File No. 000-19267).)
10.9	License Agreement, dated as of April 14, 1999, by and between Genentech, Inc. and Alkermes Controlled Therapeutics, Inc. (Incorporated by reference to Exhibit 10.18 to the Registrant s Report on Form 10-K for the fiscal year ended March 31, 1999 (File No. 001-14131).)*
10.10	Manufacture and Supply Agreement, entered into April 5, 2001, by and between Alkermes, Inc. and Genentech, Inc. (Incorporated by reference to Exhibit 10.16 to the Registrant s Report on Form 10-K for the fiscal year ended March 31, 2001.)**
10.11	License Agreement, dated as of February 13, 1996, between Medisorb Technologies International L.P. and Janssen Pharmaceutica International (U.S.) (assigned to Alkermes Controlled Therapeutics Inc. II in March 1996). (Incorporated by reference to Exhibit 10.19 to the Registrant s Report on Form 10-K for the fiscal year ended March 31, 1996 (File No. 000-19267).)***
10.12	License Agreement, dated as of February 21, 1996, between Medisorb Technologies International L.P. and Janssen Pharmaceutica International (worldwide except U.S.) (assigned to Alkermes Controlled Therapeutics Inc. II in March 1996). (Incorporated by reference to Exhibit 10.20 to the Registrant s Report on Form 10-K for the fiscal year ended March 31, 1996 (File No. 000-19267).)***
10.13	Manufacturing and Supply Agreement, dated August 6, 1997, by and among Alkermes Controlled Therapeutics Inc. II, Janssen Pharmaceutica International and Janssen Pharmaceutica, Inc. (Incorporated by reference to Exhibit 10.19 to the Registrant s Report on Form 10-K for the fiscal year ended March 31, 2002.)§
10.13(a)	Letter Agreement and Exhibits to Manufacturing and Supply Agreement, dated February 1, 2002, by and among Alkermes Controlled Therapeutics Inc. II, Janssen Pharmaceutica International and Janssen Pharmaceutica, Inc. (Incorporated by reference to Exhibit 10.19(a) to the Registrant s Report on Form 10-K for the fiscal year ended March 31, 2002.)§
10.13(b)	Addendum to Manufacturing and Supply Agreement, dated August 2001, by and among Alkermes Controlled Therapeutics Inc. II, Janssen Pharmaceutica International and Janssen Pharmaceutica, Inc. (Incorporated by reference to Exhibit 10.19(b) to the Registrant s Report on Form 10-K for the fiscal year ended March 31, 2002.)§
10.14	Fourth Amendment To Development Agreement and First Amendment To Manufacturing and Supply Agreement by and between JPI Pharmaceutica International, Janssen Pharmaceutica Inc. and Alkermes Controlled Therapeutics Inc. II, dated December 20, 2000 (with certain confidential information deleted) (Incorporated by reference to Exhibit 10.4 to the Registrant s Report on Form 10-Q for the quarter ended December 31, 2004.).****

10.15	Third Amendment To Development Agreement, Second Amendment To Manufacturing and Supply Agreement and First Amendment To License Agreements by and between JPI Pharmaceutica International, Janssen Pharmaceutica Inc. and Alkermes Controlled Therapeutics Inc. II, dated April 1, 2000 (with certain confidential information deleted) (Incorporated by reference to Exhibit 10.5 to the Registrant s Report on Form 10-Q for the quarter ended December 31, 2004.)****

Table of Contents

Exhibit No.	
10.16	Agreement by and between JPI Pharmaceutica International, Janssen Pharmaceutica Inc. and Alkermes Controlled Therapeutics Inc. II, dated December 21, 2002 (with certain confidential information deleted) (Incorporated by reference to Exhibit 10.6 to the Registrant s Report on Form 10-Q for the quarter ended December 31, 2004.)****
10.17	Amendment to Agreement by and between JPI Pharmaceutica International, Janssen Pharmaceutica Inc. and Alkermes Controlled Therapeutics Inc. II, dated December 16, 2003 (with certain confidential information deleted) (Incorporated by reference to Exhibit 10.7 to the Registrant s Report on Form 10-Q for the quarter ended December 31, 2004.)****
10.18	Amendment to Manufacturing and Supply Agreement by and between JPI Pharmaceutica International, Janssen Pharmaceutica Inc. and Alkermes Controlled Therapeutics Inc. II, dated December 22, 2003 (with certain confidential information deleted) (Incorporated by reference to Exhibit 10.8 to the Registrant s Report on Form 10-Q for the quarter ended December 31, 2004.)****
10.19	Fourth Amendment To Manufacturing and Supply Agreement by and between JPI Pharmaceutica International, Janssen Pharmaceutica Inc. and Alkermes Controlled Therapeutics Inc. II, dated January 10, 2005 (with certain confidential information deleted) (Incorporated by reference to Exhibit 10.9 to the Registrant s Report on Form 10-Q for the quarter ended December 31, 2004.)****
10.20	Patent License Agreement, dated as of August 11, 1997, between Massachusetts Institute of Technology and Advanced Inhalation Research, Inc., as amended. (Incorporated by reference to Exhibit 10.25 to the Registrant s Report on Form 10-K for the fiscal year ended March 31, 1999 (File No. 001-14131).)*
10.21	Promissory Note by and between Alkermes, Inc. and General Electric Capital Corporation, dated December 22, 2004. (Incorporated by reference to Exhibit 10.1 to the Registrant s Report on Form 10-Q for the quarter ended December 31, 2004.)
10.22	Master Security Agreement by and between Alkermes, Inc. and General Electric Capital Corporation dated December 22, 2004. (Incorporated by reference to Exhibit 10.2 to the Registrant s Report on Form 10-Q for the quarter ended December 31, 2004.)
10.23	Addendum No. 001 To Master Security Agreement by and between Alkermes, Inc. and General Electric Capital Corporation, dated December 22, 2004. (Incorporated by reference to Exhibit 10.3 to the Registrant s Report on Form 10-Q for the quarter ended December 31, 2004.)
10.24	Employment Agreement, entered into as of February 7, 1991, between Richard F. Pops and the Registrant. (Incorporated by reference to Exhibit 10.12 to the Registrant s Registration Statement on Form S-1, as amended (File No. 33-40250).)+
10.25	Change in Control Employment Agreement, dated as of December 19, 2000, between Alkermes, Inc. and Richard F. Pops. (Incorporated by reference to Exhibit 10.1 to the Registrant s Report on Form 10-Q for the quarter ended December 31, 2000.)+
10.26	Change in Control Employment Agreement, of various dates, between Alkermes, Inc. and each of James M. Frates, Michael J. Landine, David A. Broecker and Kathryn Biberstein. (Form of agreement incorporated by reference to Exhibit 10.2 to Registrant s Report on Form 10-Q for the quarter ended December 31, 2000.)+
10.27	Employment Agreement, dated December 22, 2000 by and between David A. Broecker and the Registrant. (Incorporated by reference to Exhibit 10.32 to the Registrant s Report on Form 10-K for the fiscal year ended March 31, 2001.)+
10.28	Employment Agreement, dated January 8, 2003, by and between Kathryn L. Biberstein and the Registrant. (Incorporated by reference to Exhibit 10.31 to the Registrant s Report on Form 10-K for the fiscal year ended March 31, 2003.)+
10.29	

Stock Purchase Agreement, dated December 13, 2002, between Alkermes and Eli Lilly and Company. (Incorporated by reference to Exhibit 4.2 to the Current Report on Form 8-K filed on December 16, 2002.)

Table of Contents

Exhibit No.	
10.30	Registration Rights Agreement, dated August 19, 2003, between Alkermes, Inc. and U.S. Bancorp. Piper Jaffray Inc. (Incorporated by reference to Exhibit 10.33 to the Registrant s Registration Statement on Form S-1, as amended filed on September 3, 2003 (File No. 333-108483).)
10.31	License and Collaboration Agreement between Alkermes, Inc. and Cephalon, Inc. dated as of June 23, 2005. (Incorporated by reference to Exhibit 10.1 to the Registrant s Report on Form 10-Q for the quarter ended June 30, 2005.)*****
10.32	Supply Agreement between Alkermes, Inc. and Cephalon, Inc. dated as of June 23, 2005. (Incorporated by reference to Exhibit 10.2 to the Registrant s Report on Form 10-Q for the quarter ended June 30, 2005.)*****
10.33	Amended and Restated January 1, 2005 to March 31, 2006 Named Executive Bonus Plan. (Incorporated by reference to Exhibit 10.1 to the Registrant s Report on Form 10-Q for the quarter ended September 30, 2005.)+
10.34	Amendment to 1999 Stock Option Plan, as amended. (Incorporated by reference to Exhibit 10.2 to the Registrant s Report on Form 10-Q/A for the quarter ended September 30, 2005.)+
10.35	Form of Incentive Stock Option Certificate pursuant to the 1999 Stock Option Plan, as amended.+#
10.36	Form of Non-Qualified Stock Option Certificate pursuant to the 1999 Stock Option Plan, as amended.+#
10.37	Form of Stock Option Certificate pursuant to Alkermes, Inc. 1998 Equity Incentive Plan.+#
21.1	Subsidiaries of the Registrant#
23.1	Consent of Independent Registered Public Accounting Firm Deloitte & Touche LLP#
24.1	Power of Attorney (included on signature pages)#
31.1	Rule 13a-14(a)/15d-14(a) Certification#
31.2	Rule 13a-14(a)/15d-14(a) Certification#
32.1	Certification pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.#

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

** Confidential status has been granted for certain portions thereof pursuant to a Commission Order granted September 27, 2001. Such provisions have been filed separately with the Commission.

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

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

***** Confidential status has been requested for certain portions of this document. Such provisions have been filed separately with the Commission.

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

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

Filed herewith.

Table of Contents

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

ALKERMES, INC.

By: /s/ Richard F. Pops

Richard F. Pops
Chief Executive Officer

June 14, 2006

POWER OF ATTORNEY

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

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

Signature	Title	Date
/s/ Michael A. Wall Michael A. Wall	Director and Chairman of the Board	June 14, 2006
/s/ Richard F. Pops Richard F. Pops	Director and Chief Executive Officer (Principal Executive Officer)	June 14, 2006
/s/ James M. Frates James M. Frates	Vice President, Chief Financial Officer and Treasurer (Principal Financial and Accounting Officer)	June 14, 2006
/s/ Floyd E. Bloom Floyd E. Bloom	Director	June 14, 2006
/s/ Robert A. Breyer Robert A. Breyer	Director	June 14, 2006

/s/ Gerri Henwood	Director	June 14, 2006
Gerri Henwood		
/s/ Paul J. Mitchell	Director	June 14, 2006
Paul J. Mitchell		

Table of Contents

Signature	Title	Date
/s/ Alexander Rich	Director	June 14, 2006
Alexander Rich		
/s/ Paul Schimmel	Director	June 14, 2006
Paul Schimmel		
/s/ Mark B. Skaletsky	Director	June 14, 2006
Mark B. Skaletsky		

Table of Contents

Report of Independent Registered Public Accounting Firm

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

We have audited the accompanying consolidated balance sheets of Alkermes, Inc. and subsidiaries (the Company) as of March 31, 2006 and 2005, and the related consolidated statements of operations and comprehensive income (loss), shareholders equity, and cash flows for each of the three years in the period ended March 31, 2006. These financial statements are the responsibility of the Company s management. Our responsibility is to express an opinion on these financial statements based on our audits.

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

In our opinion, such consolidated financial statements present fairly, in all material respects, the financial position of Alkermes, Inc. and subsidiaries as of March 31, 2006 and 2005, and the results of its operations and its cash flows for each of the three years in the period ended March 31, 2006, in conformity with accounting principles generally accepted in the United States of America.

As discussed in Note 2 to the consolidated financial statements, in 2006, the Company adopted the provisions of Derivatives Implementation Group Issue B-39, Embedded Derivatives: Application of Paragraph 13(b) to Options that are Exercisable only by the Debtor.

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the effectiveness of the Company s internal control over financial reporting as of March 31, 2006, based on the criteria established in *Internal Control Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated June 14, 2006 expressed an unqualified opinion on management s assessment of the effectiveness of the Company s internal control over financial reporting and an unqualified opinion on the effectiveness of the Company s internal control over financial reporting.

Boston, Massachusetts
June 14, 2006

Table of Contents

ALKERMES, INC. AND SUBSIDIARIES

CONSOLIDATED BALANCE SHEETS
March 31, 2006 and 2005

	2006	2005
	(In thousands, except share and per share amounts)	
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 33,578	$ 47,485
Investments short-term	264,389	155,082
Receivables	39,802	18,815
Inventory, net	7,341	3,766
Prepaid expenses and other current assets	2,782	2,580
Total current assets	347,892	227,728
PROPERTY, PLANT AND EQUIPMENT:		
Land	301	269
Building and improvements	20,966	19,150
Furniture, fixtures and equipment	61,086	66,805
Equipment under capital lease	464	464
Leasehold improvements	45,842	45,991
Construction in progress	23,555	11,307
	152,214	143,986
Less: accumulated depreciation and amortization	(39,297)	(48,798)
Property, plant and equipment net	112,917	95,188
RESTRICTED INVESTMENTS long-term	5,145	4,903
OTHER ASSETS	11,209	11,055
TOTAL ASSETS	$ 477,163	$ 338,874
LIABILITIES, REDEEMABLE CONVERTIBLE PREFERRED STOCK AND SHAREHOLDERS EQUITY		
CURRENT LIABILITIES:		
Accounts payable and accrued expenses	$ 36,141	$ 18,803
Accrued interest	3,239	2,248
Accrued restructuring costs	852	1,228
Unearned milestone revenue current portion	83,338	
Derivative liability related to convertible subordinated notes		265
Deferred revenue current portion	200	
Convertible subordinated notes current portion	676	
Long-term debt current portion	1,214	1,124

Total current liabilities	125,660	23,668
NON-RECOURSE RISPERDAL CONSTA SECURED 7% NOTES	153,653	150,730
CONVERTIBLE SUBORDINATED NOTES LONG-TERM PORTION	124,346	123,022
LONG-TERM DEBT	1,519	2,733
UNEARNED MILESTONE REVENUE LONG-TERM PORTION	16,198	
DEFERRED REVENUE LONG-TERM PORTION	750	
OTHER LONG-TERM LIABILITIES	6,821	4,609
TOTAL LIABILITIES	428,947	304,762
REDEEMABLE CONVERTIBLE PREFERRED STOCK, par value, $0.01 per share; authorized and issued, 1,500 and 3,000 shares at March 31, 2006 and 2005, respectively (at liquidation preference)	15,000	30,000
COMMITMENTS AND CONTINGENCIES (Note 15)		
SHAREHOLDERS EQUITY:		
Capital stock, par value, $0.01 per share; authorized, 4,550,000 shares (includes 2,997,000 shares of preferred stock); issued, none		
Common stock, par value, $0.01 per share; authorized, 160,000,000 shares; issued and outstanding, 91,744,680 and 89,999,526 shares at March 31, 2006 and 2005, respectively	917	900
Nonvoting common stock, par value, $0.01 per share; authorized 450,000 shares; issued and outstanding, 382,632 shares at March 31, 2006 and 2005	4	4
Additional paid-in capital	654,850	630,492
Deferred compensation	(374)	
Accumulated other comprehensive income (loss)	1,064	(221)
Accumulated deficit	(623,245)	(627,063)
Total shareholders equity	33,216	4,112
TOTAL LIABILITIES, REDEEMABLE CONVERTIBLE PREFERRED STOCK AND SHAREHOLDERS EQUITY	$ 477,163	$ 338,874

See notes to consolidated financial statements.

Table of Contents

ALKERMES, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE INCOME (LOSS)
Years Ended March 31, 2006, 2005 and 2004

	2006	2005	2004
	(In thousands, except per share amounts)		
REVENUES:			
Manufacturing revenues	$ 64,901	$ 40,488	$ 25,736
Royalty revenues	16,532	9,636	3,790
Research and development revenue under collaborative arrangements	45,883	26,002	9,528
Net collaborative profit	39,285		
Total revenues	166,601	76,126	39,054
EXPENSES:			
Cost of goods manufactured	23,489	16,834	19,037
Research and development	89,068	91,065	91,097
Selling, general and administrative	40,383	28,823	26,029
Restructuring		11,527	(208)
Total expenses	152,940	148,249	135,955
OPERATING INCOME (LOSS)	13,661	(72,123)	(96,901)
OTHER INCOME (EXPENSE):			
Interest income	11,569	3,005	3,409
Interest expense	(20,661)	(7,394)	(6,497)
Derivative (loss) income related to convertible subordinated notes	(1,084)	4,385	(4,514)
Other income (expense), net	333	(1,789)	2,118
Total other income (expense)	(9,843)	(1,793)	(5,484)
NET INCOME (LOSS)	$ 3,818	$ (73,916)	$ (102,385)
EARNINGS (LOSS) PER COMMON SHARE:			
BASIC	$ 0.04	$ (0.82)	$ (1.25)
DILUTED	$ 0.04	$ (0.82)	$ (1.25)
WEIGHTED AVERAGE NUMBER OF COMMON SHARES OUTSTANDING:			
BASIC	91,022	90,094	82,083
DILUTED	97,377	90,094	82,083

COMPREHENSIVE INCOME (LOSS):			
Net income (loss)	$ 3,818	$ (73,916)	$ (102,385)
Foreign currency translation adjustments			(31)
Unrealized gain (loss) on marketable securities	1,285	(1,231)	1,215
COMPREHENSIVE INCOME (LOSS)	$ 5,103	$ (75,147)	$ (101,201)

See notes to consolidated financial statements.

Table of Contents

ALKERMES, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF SHAREHOLDERS EQUITY
Years Ended March 31, 2006, 2005 and 2004

	Common Stock		Nonvoting Common Stock		Additional		Other Comprehensive Income (Loss)		
	Shares	Amount	Shares	Amount	Paid-In Capital	Deferred Compensation	Foreign Currency Translation	Unrealized Gain (Loss) on Marketable	Accumulated