Alkermes plc.
Form 10-K
May 18, 2012

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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Form 10-K

(Mark One)

ý **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the fiscal year ended March 31, 2012

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 PUBLIC LIMITED COMPANY

(Exact name of registrant as specified in its charter)

Ireland	**98-1007018**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
Connaught House **1 Burlington Road** **Dublin 4, Ireland**	
(Address of principal executive offices)	(Zip code)

+353-1-772-8000
(Registrant's telephone number, including area code)

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

Ordinary shares, $0.01 par value	NASDAQ Global Select Stock Market
Title of each class	**Name of each exchange on which registered**

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

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

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 ý

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 ý No o

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files): Yes ý No o

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

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

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

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

The aggregate market value of the registrant's ordinary shares held by non-affiliates of the registrant (without admitting that any person whose shares are not included in such calculation is an affiliate) computed by reference to the price at which the ordinary shares was last sold as of the last business day of the registrant's most recently completed second fiscal quarter was $1,947,523,774.

As of May 11, 2012, 130,241,192 shares of ordinary shares were issued and outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the definitive proxy statement for our Annual General Meeting of Shareholders' for the fiscal year ended March 31, 2012 are incorporated by reference into Part III of this report.

ALKERMES PLC AND SUBSIDIARIES

ANNUAL REPORT ON FORM 10-K
FOR THE FISCAL YEAR ENDED MARCH 31, 2012

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FORWARD-LOOKING STATEMENTS

This document contains and incorporates by reference "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. In some cases, these statements can be identified by the use of forward-looking terminology such as "may," "will," "could," "should," "would," "expect," "anticipate," "continue" or other similar words. These statements discuss future expectations, and contain projections of results of operations or of financial condition, or state trends and known uncertainties or other forward looking information. Forward-looking statements in this Annual Report on Form 10-K include, without limitation, statements regarding:

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

our expectations regarding the commercialization of our products, including the sales and marketing efforts of our partners and, for VIVITROL® (naltrexone for extended-release injectable suspension), our ability to establish and maintain successful sales and marketing, reimbursement and distribution arrangements;

our efforts and ability to evaluate and license products and build our pipeline;

our expectations regarding our products, including the development, regulatory review (including expectations about regulatory approval and regulatory timelines) and therapeutic and commercial potential of such products and the costs and expenses related thereto;

our expectations regarding the initiation, timing and results of clinical trials of our products;

our expectations regarding the successful manufacture of our products, by us or our partners, for commercial sale;

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

our expectations regarding the financial impact of healthcare reform legislation and currency exchange rate fluctuations and valuations;

the impact of new accounting pronouncements;

our ability to protect our intellectual property rights, not infringe third-party intellectual property rights and the impact of recent patent legislation;

our expectations regarding near-term changes in the nature of our market risk exposures or in management's objectives and strategies with respect to managing such exposures;

our ability to comply with restrictive covenants of our indebtedness and our ability to fund our debt service obligations;

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

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

other risk factors described in "*Item 1A Risk Factors*" in this prospectus.

Actual results might differ materially from those expressed or implied by these forward-looking statements because these forward-looking statements are subject to risks, assumptions and uncertainties. You are cautioned not to place undue reliance on forward-looking statements, which speak only as of the date of this Annual Report. All subsequent written and oral forward-looking statements concerning

the matters addressed in this Annual Report and attributable to us or any person acting on our behalf are expressly qualified in their entirety by the cautionary statements contained or referred to in this section. Except as required by applicable law or regulation, we do not undertake any obligation to update publicly or revise any forward-looking statements, whether as a result of new information, future events or otherwise. In light of these risks, uncertainties and assumptions, the forward-looking events discussed in this Annual Report might not occur. For more information regarding the risks and uncertainties of our business, see "Item 1A Risk Factors."

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

PART I

Item 1. ***Business***

The following discussion contains forward-looking statements. Actual results may differ significantly from those projected in the forward-looking statements. See "Forward-Looking Statements." Factors that might cause future results to differ materially from those projected in the forward-looking statements also include, but are not limited to, those discussed in "Item 1A Risk Factors" and elsewhere in this Annual Report.

On September 16, 2011, the business of Alkermes, Inc. ("Old Alkermes") and the drug technologies business ("EDT") of Elan Corporation, plc ("Elan") were combined (this combination is referred to as the "Business Combination," the "acquisition of EDT," or the "EDT acquisition") under Alkermes plc. As part of the Business Combination, Antler Acquisition Corp., a wholly owned subsidiary of Alkermes plc, merged with and into Old Alkermes (the "Merger"), with Old Alkermes surviving as an indirect, wholly-owned subsidiary of the Company. Prior to the Merger, EDT was carved-out of Elan and reorganized under the Company.

Use of the terms such as "us," "we," "our" or the "Company" in this prospectus is meant to refer to Alkermes plc ("Alkermes") and its consolidated subsidiaries, except when the context makes clear that the time period being referenced is prior to September 16, 2011, in which case such terms shall refer to Old Alkermes. Prior to September 16, 2011, Old Alkermes was an independent biotechnology company incorporated in the Commonwealth of Pennsylvania and traded on the NASDAQ Global Select Stock Market (the "NASDAQ") under the symbol "ALKS."

Overview

Alkermes develops medicines that address the unmet needs and challenges of people living with serious chronic disease. A fully integrated global biopharmaceutical company, Alkermes applies proven scientific expertise, proprietary technologies and global development capabilities to create innovative treatments for major clinical conditions with a focus on central nervous system ("CNS") disorders, such as schizophrenia, addiction and depression.

We create new, proprietary pharmaceutical products for our own account, and we collaborate with other pharmaceutical and biotechnology companies. We are increasingly focused on maintaining rights to commercialize our leading product candidates in certain markets.

We are an Irish public limited company incorporated in Dublin, Ireland, with a research and development ("R&D") center in Waltham, Massachusetts and manufacturing facilities in Athlone, Ireland; Gainesville, Georgia; and Wilmington, Ohio. Our corporate headquarters are located at Connaught House, 1 Burlington Road, Dublin 4, Ireland.

For a more detailed discussion of the Business Combination, please refer to the notes to our consolidated financial statements, including Note 1, *The Company*, and Note 3, *Acquisitions*, in the accompanying consolidated financial statements.

Our Strengths and Strategy

The products that we develop leverage multiple proprietary technologies to create new medicines that are designed to address therapeutic areas of significant unmet medical need and improve patient outcomes. As of March 31, 2012, we and our pharmaceutical and biotechnology partners had more than 20 commercialized products sold worldwide, including the United States ("U.S."). We earn manufacturing and/or royalty revenues on net sales of products commercialized by our partners and earn revenue on net sales of VIVITROL, which is a proprietary product that we manufacture, market and sell in the U.S. Our five key products are expected to generate significant revenues for us in the

near- and medium-term, as they possess long patent lives, are singular or competitively advantaged products in their class and are generally in the launch phases of their commercial lives. These five key products are: RISPERDAL® CONSTA® and INVEGA® SUSTENNA®/XEPLION®, both antipsychotics marketed by Ortho-McNeil-Janssen Pharmaceuticals, Inc. and Janssen Pharmaceutica International, a division of Cilag International AG ("Janssen"); AMPYRA®/FAMPYRA® for the improvement of walking in patients with multiple sclerosis and marketed by Acorda Therapeutics, Inc. ("Acorda") in the U.S. and by Biogen Idec, Inc. ("Biogen Idec") outside the U.S.; BYDUREON™, the only once-weekly treatment for type 2 diabetes, which in the U.S. is, and outside the U.S. will soon be, marketed by Amylin Pharmaceuticals, Inc. ("Amylin"); and VIVITROL, the only once-monthly, injectable, non-addictive treatment available for the prevention of relapse to opioid dependence and for alcohol dependence, which is marketed by us.

We have a portfolio of product candidates across all stages of development. Backed by decades of experience, we are able to streamline the traditional drug development process with a goal of increasing the probability of late-stage product success. Our R&D approach involves little basic discovery and allows us to assess the viability of new pipeline candidates early and devote our resources to advancing the most promising candidates quickly to registration-stage trials. Our R&D efforts have been highly productive and have yielded a pipeline that we expect will generate meaningful new drugs that will become sources of significant revenue for our company into the next decade and beyond. We are increasingly focused on maintaining rights to commercialize our leading product candidates in certain markets.

Our Competitive Strengths

We believe our principal competitive strengths include:

- our broad and diverse product portfolio and pipeline, which, as of March 31, 2012, included more than 20 marketed products as well as six proprietary pipeline candidates and partnered pipeline programs;
- our five key commercial products that are expected to generate significant revenues for the company in the near- and medium-term;
- our focused R&D approach that leverages proprietary technologies and our extensive experience in developing CNS treatments, with the proven ability to advance candidates from well-informed preclinical testing to cost-effective proof-of-concept studies;
- our extensive and long-lived intellectual property covering composition of matter, process, formulation and/or methods-of-use for our currently marketed products and for our product candidates in development;
- our three established manufacturing facilities that are compliant with current Good Manufacturing Practices ("cGMP"), can produce multiple dosage forms and are fully scaled to meet the manufacturing needs of ourselves and our collaborative partners; and
- our experienced management team and personnel who have grown our business to be an established biopharmaceutical company with a track record of more than 40 years of development, regulatory, manufacturing and partnering expertise.

Our Strategy

Capitalize on growth from our five key commercial products. Our key commercialized products are generally in their launch stages for large and growing disease areas, with significant opportunity for growth. We expect that the revenues that we earn from the portfolio RISPERDAL CONSTA and INVEGA SUSTENNA/XEPLION, AMPYRA/FAMPYRA, BYDUREON and VIVITROL will

continue to increase in the near- and medium-term, as they address large and growing markets and are competitively advantaged. We expect that revenues generated from these products will enable us to meet our near- and medium-term financial goals and position the company for sustainable profitability.

Continue to advance our pipeline. Our R&D approach is based on return on investment and, between us and our partners, we have a broad and diverse pipeline of new drug candidates. We currently have clinical studies underway for a product candidate in phase 3, three candidates that are in phase 2 and one candidate that is in phase 1. We also have one partnered product candidate for which a New Drug Application ("NDA") has been submitted to the U.S. Food and Drug Administration ("FDA") and other proprietary candidates in preclinical testing. Our proprietary product candidates have undergone extensive preclinical testing prior to reaching the clinical development stage, which we believe improves these candidates' probability of success in later-stage drug development.

Grow revenues and manage our expenses to expand our margins. We intend to manage our business with the goal of achieving continued margin expansion. Our five key products are expected to grow our revenues in the near- and medium-term, and we will seek to manage our expenses to grow at a slower pace than revenues.

Products and Development Programs

Commercial Products

Our commercial products are described in the table below, including, among other things, the territory where currently sold and the source of revenues for us.

Product	Indication	Technology	Territory	Revenue Source	Marketer
RISPERDAL CONSTA	Schizophrenia Bipolar I Disorder	Extended-release microsphere	Worldwide	Manufacturing and Royalty	Janssen
INVEGA SUSTENNA *XEPLION*	Schizophrenia	NanoCrystal®	Worldwide	Royalty	Janssen
AMPRYA *FAMPYRA*	Treatment for multiple sclerosis ("MS")	OCR (MXDAS®)	U.S. United Kingdom, Australia, Germany, Norway, Denmark Iceland, Canada	Manufacturing and Royalty	Acorda Therapeutics, Inc. in U.S. Biogen Idec (ex-U.S. under sublicense from Acorda)
BYDUREON	Type 2 diabetes	Extended-release microsphere	U.S. European Union U.A.E.	Royalty	Amylin
VIVITROL	Alcohol dependence Opioid dependence	Extended-release microsphere	U.S. Russia and Commonwealth of Independent States ("CIS")	Product sales Manufacturing and Royalty	Alkermes plc Janssen
TRICOR® *LIPANTHYL®* *LIPIDIL®* *SUPRALIP®*	Cholesterol lowering	NanoCrystal	Worldwide	Royalty	Abbott
ZANAFLEX® CAPSULES® *ZANAFLEX® TABLETS*	Muscle spasticity	OCR (SODAS®)	U.S.	Manufacturing and Royalty	Acorda
AVINZA®	Chronic moderate to severe pain	OCR (SODAS)	U.S.	Manufacturing and Royalty	Pfizer
EMEND®	Nausea associated with chemotherapy and surgery	NanoCrystal	Worldwide	Royalty	Merck
FOCALIN® XR *RITALIN LA®*	Attention Deficit Hyperactivity Disorder	OCR (SODAS)	Worldwide	Manufacturing and Royalty	Novartis
MEGACE® ES	Cachexia associated with AIDS	NanoCrystal	U.S.	Royalty	Strativa Pharmaceuticals (a business division of Par Pharmaceutical Companies, Inc.)

LUVOX CR®	Obsessive-compulsive disorder	OCR (SODAS)	U.S.	Manufacturing and Royalty	Jazz Pharmaceuticals plc
RAPAMUNE®	Prevention of renal transplant rejection	NanoCrystal	Worldwide	Manufacturing	Pfizer
NAPRELAN®	Various mild to moderate pain indications	OCR (IPDAS®)	U.S. Canada	Manufacturing	Shionogi Sunovion Pharmaceuticals Canada, Inc.
VERAPAMIL SR VERELAN® VERELAN® PM VERAPAMIL PM VERECAPS® UNIVER®	Hypertension	OCR (SODAS)	Licensed on country/region basis throughout the world	Manufacturing	UCB Kremers-Urban Watson; Cephalon; Aspen; Orient Europharma
DILZEM SR DILZEM XL DILTELAN ACALIX CD DINISOR TILAZEM CR CARDIZEM CD	Hypertension and/or Angina	OCR (SODAS)	Licensed on country/region basis throughout the world	Manufacturing and Royalty (for CARDIZEM CD only)	Cephalon; Pfizer; Roemmers; Kun Wha; Orient Europharma; Sanofi-Aventis
AFE Ditab® CR (AB Rated to Adalat CC®) (Nifedipine) (A)	Hypertension	OCR (MXDAS®)	U.S.	Manufacturing	Watson Pharmaceutical

We have five principal commercial products which either currently, or in the future, are expected to contribute meaningfully to our revenues.

RISPERDAL CONSTA* and *INVEGA SUSTENNA/XEPLION

RISPERDAL CONSTA and INVEGA SUSTENNA/XEPLION, which are two long-acting atypical antipsychotics, incorporate our extended-release injectable technology. They are products of Janssen.

RISPERDAL CONSTA is the first and only long-acting, atypical antipsychotic approved by the U.S. Food and Drug Administration ("FDA") for the treatment of schizophrenia and for the treatment of bipolar I disorder. INVEGA SUSTENNA/XEPLION is a once-monthly, long-acting injectable atypical antipsychotic approved by the FDA for the acute and maintenance treatment of schizophrenia in adults.

Revenues from Janssen accounted for approximately 48%, 83% and 83% of our consolidated revenues for the fiscal years ended March 31, 2012, 2011 and 2010, respectively. See "*Collaborative Arrangements*" below for information about our relationship with Janssen.

For the treatment of schizophrenia

RISPERDAL CONSTA (risperidone long-acting injection) uses our polymer-based microsphere injectable extended-release technology to deliver and maintain therapeutic medication levels in the body through just one injection every two weeks. RISPERDAL CONSTA is exclusively manufactured by us and is marketed and sold by Janssen in more than 90 countries, including the U.S., United Kingdom ("UK"), Japan, Italy, Spain and Germany. It was first approved for the treatment of schizophrenia in the U.S. in 2003 and in countries in Europe in 2002.

INVEGA SUSTENNA (paliperidone palmitate) uses our nanoparticle injectable extended-release technology to increase the rate of dissolution and enable the formulation of an aqueous suspension for once-monthly intramuscular administration. INVEGA/SUSTENNA was approved in the U.S. in 2009. Paliperidone palmitate extended-release for injectable suspension is also approved in the European Union ("EU") and other countries worldwide, and is marketed and sold in the EU under the trade name XEPLION. INVEGA SUSTENNA/XEPLION is manufactured and commercialized by Janssen.

What is schizophrenia?

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

For the treatment of bipolar I disorder

The FDA approved RISPERDAL CONSTA as both monotherapy and adjunctive therapy to lithium or valproate in the maintenance treatment of bipolar I disorder in May 2009. RISPERDAL CONSTA is also approved for the maintenance treatment of bipolar I disorder in Canada, Australia and Saudi Arabia.

What is bipolar I disorder?

Bipolar disorder is a brain disorder that causes unusual shifts in a person's mood, energy and ability to function. It is often characterized by debilitating mood swings, from extreme highs (mania) to

extreme lows (depression). Bipolar I disorder is characterized based on the occurrence of at least one manic episode, with or without the occurrence of a major depressive episode. Bipolar disorder is believed to affect approximately 5.7 million American adults, or about 2.6% of the U.S. population aged 18 and older in a given year. The median age of onset for bipolar disorder is 25 years.

AMPYRA/FAMPYRA

Dalfampridine extended-release tablets are marketed and sold in the U.S. under the trade name AMPYRA by Acorda. Prolonged-release fampridine tablets are marketed and sold outside the U.S. under the trade name FAMPYRA by Biogen Idec. AMPYRA was approved by the FDA in January 2010 as a treatment to improve walking in patients with MS as demonstrated by an increase in walking speed. Efficacy was shown in people with all four major types of MS (relapsing remitting, secondary progressive, progressive relapsing and primary progressive). It is the first and, currently, only product to be approved for this indication. A product of Acorda, it incorporates our Oral Controlled Release ("OCR") technology. FAMPYRA received conditional marketing approval in the EU in July 2011 and is currently being sold by Biogen Idec in select European countries, as well as Australia. AMPYRA and FAMPYRA are manufactured by us.

What is multiple sclerosis?

MS is a chronic, usually progressive disease in which the immune system attacks and degrades the function of nerve fibers in the brain and spinal cord. These nerve fibers consist of long, thin fibers, or axons, surrounded by a myelin sheath, which facilitates the transmission of electrical impulses. In MS, the myelin sheath is damaged by the body's own immune system, causing areas of myelin sheath loss, also known as demyelination. This damage, which can occur at multiple sites in the CNS, blocks or diminishes conduction of electrical impulses. People with MS may suffer impairments in any number of neurological functions. These impairments vary from individual to individual and over the course of time, depending on which parts of the brain and spinal cord are affected, and often include difficulty walking. Individuals vary in the severity of the impairments they suffer on a day-to-day basis, with impairments becoming better or worse depending on the activity of the disease on a given day.

BYDUREON

We collaborated with Amylin on the development of a once-weekly formulation of exenatide, BYDUREON, for the treatment of type 2 diabetes. BYDUREON, an injectable formulation of Amylin's BYETTA® (exenatide), uses our polymer-based microsphere injectable extended-release technology. Amylin is responsible for commercializing exenatide products, including BYDUREON, in the U.S. Eli Lilly and Company ("Lilly") has exclusive rights to commercialize exenatide products outside of the U.S. until December 31, 2013 or such earlier date as agreed upon between Lilly and Amylin pursuant to the terms of their transition agreement, following which Amylin will have such exclusive rights.

In June 2011, the European Commission granted marketing authorization for BYDUREON for the treatment of type 2 diabetes in adult patients in combination with metformin, a sulfonylurea, a thiazolidinedione, metformin plus a sulfonylurea or metformin plus a thiazolidinedione. In July 2011, Lilly launched BYDUREON in the UK, and in September 2011, BYDUREON was launched in Germany. We received a $7.0 million milestone payment upon first commercial sale of BYDUREON in the EU, which was recognized during the quarter ended September 30, 2011.

In January 2012, the FDA approved BYDUREON as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes. We received a $7.0 million milestone payment upon first commercial sale of BYDUREON in the U.S., which was recognized as revenue during the quarter ended March 31, 2012. BYDUREON was launched in the U.S. in February 2012.

What is type 2 diabetes?

Diabetes is a disease in which the body does not produce or properly use insulin. Diabetes can result in serious health complications, including cardiovascular, kidney and nerve disease. Diabetes is believed to affect nearly 26 million people in the U.S. and an estimated 347 million adults worldwide. Approximately 90-95% of those affected have type 2 diabetes. According to the U.S. Centers for Disease Control and Prevention's National Health and Nutrition Examination Survey, approximately 60% of people with diabetes do not achieve their target blood sugar levels with their current treatment regimen. In addition, 85% of type 2 diabetes patients are overweight and 55% are considered obese. Data indicate that weight loss (even a modest amount) supports patients in their efforts to achieve and sustain glycemic control.

VIVITROL

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

VIVITROL was approved by the FDA for the treatment of alcohol dependence in April 2006 and was launched in the U.S. for this indication in June 2006. The FDA approved VIVITROL for the prevention of relapse to opioid dependence, following opioid detoxification, in October 2010.

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

What are opioid dependence and alcohol dependence?

Opioid dependence is a serious and chronic brain disease characterized by compulsive, prolonged self-administration of opioid substances that are not used for a medical purpose. According to the 2010 U.S. National Survey on Drug Use and Health, an estimated 1.5 million people aged 18 or older were dependent on pain relievers or heroin.

Alcohol dependence is a serious and chronic brain disease characterized by cravings for alcohol, loss of control over drinking, withdrawal symptoms and an increased tolerance for alcohol. Approximately 18 million people in the U.S. are dependent on or abuse alcohol, half of whom are considered to be alcohol dependent. Adherence to medication is particularly challenging with this patient population.

Other Commercial Products

We expect revenues from our other commercial products will decrease in the future due to existing and expected competition from generic manufacturers. For a more detailed discussion of current and expected future revenue contribution of such products, please see "Management's Discussion and Analysis of Financial Condition and Results of Operations" elsewhere in this Annual Report.

Key Development Programs

ALKS 9070

We are studying ALKS 9070 for the treatment of schizophrenia. ALKS 9070 is an injectable, sustained-release product candidate designed to provide once-monthly dosing of a medication that converts *in vivo* into aripiprazole, a molecule that is commercially available under the name ABILIFY®. ALKS 9070 is our first product candidate to leverage our proprietary LinkeRx™ product platform. In June 2011, we announced positive results from a phase 1b, double-blind, randomized, placebo- controlled, 20-week study that assessed the safety, tolerability and pharmacokinetic profile of a single administration of three ascending doses of ALKS 9070 in 32 patients with chronic, stable schizophrenia. Data from the study showed that ALKS 9070 was generally well tolerated, achieved therapeutically relevant plasma concentrations of aripiprazole with a pharmacokinetic profile that supports once-monthly dosing. In December 2011, based on these results, we advanced ALKS 9070 into a multicenter, double-blind, placebo-controlled phase 3 study designed to assess the efficacy, safety and tolerability of ALKS 9070 in approximately 690 patients experiencing acute exacerbation of schizophrenia; these patients will be randomized to receive one of two doses of ALKS 9070 or placebo. The clinical data from this study, which are expected mid-calendar year 2013, may form the basis of an NDA to the FDA for ALKS 9070 for the treatment of schizophrenia.

During the three months ended March 31, 2012, we transferred ALKS 9070, including all ALKS 9070 intellectual property, from the U.S. to Ireland.

ALKS 37

We are developing ALKS 37, an orally active, peripherally restricted opioid antagonist for the treatment of opioid-induced constipation ("OIC"). According to IMS Health information, an estimated 280 million prescriptions were written for opioids in the U.S. during 2010. Many studies indicate that a high percentage of patients receiving opioids are likely to experience side effects affecting gastrointestinal motility. OIC can be severe and adversely impact quality of life, compromising patient compliance with opioid therapy in order to achieve pain management.

In May 2011, we presented positive results from a phase 2 double-blind, randomized, placebo-controlled, multidose clinical study of ALKS 37 for the treatment of OIC. Data from the study showed that ALKS 37 significantly improved gastrointestinal motility, demonstrated by increased frequency of bowel movements in patients with OIC, while simultaneously preserving the analgesic effects of opioid treatment. The study also demonstrated that ALKS 37 was generally well tolerated. In July 2011, we announced the initiation of a multicenter, randomized, double-blind, placebo-controlled, repeat-dose phase 2b study of ALKS 37 to assess the safety, tolerability, efficacy and pharmacokinetic profile of ALKS 37 in approximately 150 patients. In October 2011, we announced the initiation of a second phase 2b study of ALKS 37. This multicenter, randomized, double-blind, placebo-controlled, fixed-dose study is designed to assess the safety and efficacy of daily administration of a 100 mg dose of ALKS 37 versus placebo for 12 weeks in approximately 80 patients with OIC. The results of this phase 2b study, along with those from the repeat-dose, four-week phase 2b study initiated earlier in 2011, are expected in mid-calendar year 2012.

ALKS 33

ALKS 33 is an oral opioid modulator characterized by limited hepatic metabolism and durable pharmacologic activity in modulating brain opioid receptors.

We conducted two phase 1 studies and one phase 2 study of ALKS 33. The first phase 1 study was a randomized, double-blind, placebo-controlled, multidose study designed to assess the steady-state pharmacokinetics, safety and tolerability of ALKS 33. In the study, ALKS 33 demonstrated rapid oral

absorption and sustained pharmacologically active plasma levels supporting once-daily dosing. The second phase 1 study was a randomized, single-blind, placebo-controlled, single-dose study designed to test the ability of ALKS 33 to block the subjective and objective effects of a potent opioid agonist, remifentanil, a commercially available analgesic. Data showed that the onset of action of ALKS 33 was rapid and observed as early as 15 minutes following oral administration. A full blockade of the opioid agonist was observed and sustained for more than 24 hours following a single administration of ALKS 33. ALKS 33 was generally well tolerated in both studies.

The phase 2 study of ALKS 33 was designed to assess the safety, tolerability, pharmacokinetics and efficacy of daily oral administration of three different dose levels of ALKS 33 compared to placebo in 400 alcohol dependent patients. The phase 2 study showed that ALKS 33 was generally well tolerated and characterized by its potential for daily dosing, non-hepatic metabolism, extended pharmacologic benefit in the event of missed doses and pharmacologic activity in reducing heavy drinking behavior. ALKS 33 is currently being evaluated as a potential treatment for alcohol dependence. There are currently no ongoing clinical trials of ALKS 33 for the treatment of alcohol dependence.

ALKS 5461

ALKS 5461 is a combination of ALKS 33 and buprenorphine that we are developing to be a non-addictive therapy for the treatment of major depressive disorder ("MDD"), in patients who have an inadequate response to standard antidepressant therapies, and for the treatment of cocaine dependence.

Major Depressive Disorder

In January 2012, we announced positive results from a phase $^{1}/_{2}$ study of ALKS 5461 compared to placebo in 32 patients with MDD who did not adequately respond to standard antidepressant therapies. In the study, ALKS 5461 was shown to significantly reduce depressive symptoms, as measured by the Hamilton Depression Rating Scale (HAM-D17; a standard, clinician-assessed measure of depression severity), in patients who received ALKS 5461 for the seven-day treatment period. In addition, data from the study showed that ALKS 5461 was generally well tolerated. Based on these results, we initiated a randomized, double-blind, multicenter, placebo-controlled phase 2 study to evaluate the efficacy and safety of ALKS 5461 when administered once daily for four weeks in approximately 130 patients with MDD who have inadequate response to antidepressant therapy. Data from the study are expected in the first half of calendar year 2013.

Cocaine Dependence

Our randomized, double-blind, multidose, placebo-controlled phase 1 clinical study assessed the safety, tolerability and pharmacodynamic effects of the combination of ALKS 33 and buprenorphine when administered alone, and in combination as ALKS 5461, to 12 opioid-experienced users. Data from the study showed that ALKS 5461 was generally well-tolerated and sublingual administration of ALKS 33 effectively blocked the agonist effects of buprenorphine.

Based on these positive results, we filed an Investigational New Drug application ("IND") for ALKS 5461 for the treatment of cocaine dependence in June 2011. In the second half of 2011, we initiated a phase 1b study of ALKS 5461 for cocaine dependence, which is being funded through a grant from the National Institute on Drug Abuse ("NIDA"). NIDA has granted us up to $2.4 million to accelerate the clinical development of ALKS 5461 for the treatment of cocaine dependence. Currently, there are no medications approved for the treatment of cocaine dependence. The results of this phase 1b study are expected in mid-calendar year 2012.

ZOHYDRO™

ZOHYDRO (hydrocodone bitartrate) extended-release capsules is a novel, oral, single-entity (without acetaminophen), controlled-release formulation of hydrocodone in development by Zogenix, Inc. ("Zogenix") for the U.S. market. ZOHYDRO utilizes our oral controlled-release technology, which potentially enables longer-lasting and more consistent pain relief with fewer daily doses than the commercially available formulations of hydrocodone. In August 2011, Zogenix announced positive top-line results from its pivotal phase 3 efficacy study of ZOHYDRO for the treatment of moderate to severe chronic pain in patients requiring around-the-clock opioid therapy. On May 2, 2012, Zogenix announced that it submitted a NDA to the FDA for ZOHYDRO. We will earn manufacturing revenues in the U.S. for ZOHYDRO and are entitled to receive a royalty on U.S. sales of ZOHYDRO, if approved. We have maintained all rights to the product in territories outside the U.S. and will seek to develop and license the product through commercial partnerships in those territories.

Our Research and Development Expenditures

We devote significant resources to R&D programs. We focus our R&D efforts on identifying novel therapeutics in areas of high unmet medical need. Please see "Item 6. Selected Financial Data" for our R&D expenditures for our previous five fiscal years.

Collaborative Arrangements

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

Janssen

RISPERDAL CONSTA

Under a product development agreement, we collaborated with Janssen on the development of RISPERDAL CONSTA. Under the development agreement, Janssen provided funding to us for the development of RISPERDAL CONSTA, and Janssen is responsible for securing all necessary regulatory approvals for the product.

Under license agreements, we granted Janssen and an affiliate of Janssen exclusive worldwide licenses to use and sell RISPERDAL CONSTA. Under our license agreements with Janssen, we receive royalty payments equal to 2.5% of Janssen's net sales of RISPERDAL CONSTA in each country where the license is in effect based on the quarter when the product is sold by Janssen. This royalty may be reduced in any country based on lack of patent coverage and significant competition from generic versions of the product. Janssen can terminate the license agreements upon 30 days' prior written notice to us. The licenses granted to Janssen expire on a country-by-country basis upon the later of (i) the expiration of the last patent claiming the product in such country or (ii) fifteen years after the date of the first commercial sale of the product in such country, provided that in no event will the license granted to Janssen expire later than the twentieth anniversary of the first commercial sale of the product in such country, with the exception of certain countries where the fifteen-year limitation shall pertain regardless. After expiration, Janssen retains a non-exclusive, royalty-free license to manufacture, use and sell RISPERDAL CONSTA. We exclusively manufacture RISPERDAL CONSTA for commercial sale. Under our manufacturing and supply agreement with Janssen, we record manufacturing revenues when product is shipped to Janssen, based on 7.5% of Janssen's net unit sales price for RISPERDAL CONSTA for the calendar year.

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

INVEGA SUSTENNA/XEPLION

Under our license agreement with Janssen Pharmaceutica N.V., we granted Janssen a worldwide exclusive license under our NanoCrystal technology to develop, commercialize and manufacture INVEGA SUSTENNA/XEPLION and related products.

Under our license agreement, we receive certain development milestone payments from Janssen and tiered royalty payments between 5% and 9% of INVEGA SUSTENNA net sales in each country where the license is in effect, with the exact royalty percentage determined based on worldwide net sales. These royalty payments may be reduced in any country based on lack of patent coverage or patent litigation, or where competing products achieve certain minimum sales thresholds. The licenses granted to Janssen expire on a country-by-country basis upon the later of (i) March 31, 2019 or (ii) the expiration of the last of the patents claiming the product in such country. After expiration, Janssen retains a non-exclusive, royalty-free license to develop, manufacture and commercialize the products.

Janssen may terminate the license agreement in whole or in part upon three months' notice to us. We and Janssen have the right to terminate the agreement upon a material breach of the other party, which is not cured within a certain time period or upon the other party's bankruptcy or insolvency.

Acorda

Under an amended and restated license agreement, we granted Acorda an exclusive worldwide license to use and sell and, solely in accordance with our supply agreement, to make or have made, AMPYRA/FAMPYRA. Under our license agreement with Acorda, we receive certain commercial and development milestone payments, license revenues and a royalty of approximately 10% based on sales of AMPYRA/FAMPYRA by Acorda or its sub-licensee, Biogen Idec. This royalty payment may be reduced in any country based on lack of patent coverage, competing products achieving certain minimum sales thresholds, and whether Alkermes manufactures the product.

Acorda has the right to terminate the license agreement upon 90 days' written notice. We have the right to terminate the license agreement for countries in which Acorda fails to launch a product within a specified time after obtaining the necessary regulatory approval or fails to file regulatory approvals within a commercially reasonable time after completion and receipt of positive data from all preclinical and clinical studies required for filing a marketing authorization application. If we terminate Acorda's license in any country, we are entitled to a license from Acorda of its patent rights and know-how relating to the product as well as the related data, information and regulatory files, and to market the product in the applicable country, subject to an initial payment equal to Acorda's cost of developing such data, information and regulatory files and to ongoing royalty payments to Acorda. Subject to the termination of the license agreement, licenses granted under the license agreement terminate on a country-by-country basis on the later of (i) September 2018 or (ii) the expiration of the last to expire of our patents or the existence of a threshold level of competition in the marketplace.

Under our commercial manufacturing supply agreement with Acorda, we manufacture and supply AMPYRA/FAMPYRA for Acorda (and its sub-licensees). Under the terms of the agreement, Acorda may obtain up to 25% of its total annual requirements of product from a second source manufacturer.

We receive royalties equal to 8% of net selling price for all product manufactured by us and a compensating payment for product manufactured and supplied by a third party. We may terminate the supply agreement upon 12 months' prior written notice to Acorda, and either party may terminate the supply agreement following a material and uncured breach of the supply or license agreement or the entry into bankruptcy or dissolution proceedings of the other party. In addition, subject to early termination of the supply agreement noted above, the supply agreement terminates upon the expiry or termination of the license agreement.

In January 2011, we entered into a development and supplemental agreement to our amended and restated license agreement with Acorda. Under the terms of this agreement, we granted Acorda the right, either with us or with a third party, in each case in accordance with certain terms and conditions, to develop new formulations of dalfampridine or other aminopyridines. Under the terms of the agreement, Acorda has the right to select either a formulation developed by us or by a third party for commercialization. If Acorda selects and commercializes a formulation developed by us, we are entitled to development fees, milestone payments (for new indications if not previously paid), license revenues and royalties in accordance with our amended and restated license agreement, and either manufacturing fees as a percentage of net selling price for product manufactured by us or compensating fees for product manufactured by third parties. If Acorda selects a formulation not developed by us, then we will be entitled to various compensation payments and have the first option to manufacture such third-party formulation. The agreement expires upon the expiry or termination of the 2003 license agreement or may be earlier terminated by either party following an uncured breach of the agreement by the other party.

Acorda's financial obligations under this development and supplemental agreement continue for a minimum of ten years from the first commercial sale of such new formulation, and may extend for a longer period of time, depending on the intellectual property rights protecting the formulation, regulatory exclusivity and/or the absence of significant market competition. These financial obligations survive termination.

Amylin

In May 2000, we entered into a development and license agreement with Amylin for the development of exendin products falling within the scope of our patents, which includes the once-weekly formulation of exenatide, BYDUREON. Pursuant to the development and license agreement, Amylin has an exclusive, worldwide license to our polymer-based microsphere technology for the development and commercialization of injectable extended-release formulations of exendins and other related compounds. We receive funding for research and development and milestone payments consisting of cash and warrants for Amylin common stock upon achieving certain development and commercialization goals and will also receive royalty payments based on future product sales, if any. In October 2005 and in July 2006, we amended the development and license agreement. Under the amended agreement, we are responsible for formulation and are principally responsible for non-clinical development of any products that may be developed pursuant to the agreement and for manufacturing these products for use in early-phase clinical trials.

Amylin is responsible for commercializing exenatide products, including BYDUREON, in the U.S. and for U.S. regulatory matters relating to BYDUREON. Lilly, Amylin's former worldwide collaboration partner with respect to exenatide products, continues to have exclusive rights to commercialize exenatide products outside of the U.S. until December 31, 2013 or such earlier date as agreed by the parties pursuant to the terms of their transition agreement, following which Amylin will have such exclusive rights. Subject to these arrangements with Lilly, Amylin is responsible for conducting clinical trials, securing regulatory approvals and marketing any products resulting from the collaboration on a worldwide basis.

In conjunction with the 2005 amendment of the development and license agreement with Amylin, we reached an agreement regarding Amylin's construction of a manufacturing facility for BYDUREON and certain technology transfer related thereto. The facility and technology transfer of our manufacturing processes was completed in 2009. Amylin will be responsible for the manufacture of BYDUREON and will operate the facility.

Until December 31, 2021, we will receive royalties equal to 8% of net sales from the first 40 million units of BYDUREON sold in any particular year and 5.5% of net sales from units sold beyond the first 40 million units for that year. Thereafter, during the term of the development and license agreement, we will receive royalties equal to 5.5% of net sales of products sold. We received a $7.0 million milestone payment in July 2011 upon the first commercial sale of BYDUREON in the EU, and we received a $7.0 million milestone payment upon the first commercial sale of BYDUREON in the U.S. BYDUREON was launched in the U.S. in February 2012.

The development and license agreement terminates on the later of (i) 10 years from the first commercial sale of the last of the products covered by the development and license agreement, or (ii) the expiration or invalidation of all of our patents covering such product. Upon termination, all licenses become non-exclusive and royalty-free. Amylin may terminate the development and license agreement for any reason upon 180 days' written notice to us. In addition, either party may terminate the development and license agreement upon a material default or breach by the other party that is not cured within 60 days after receipt of written notice specifying the default or breach.

Cilag

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

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

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

Rensselaer Polytechnic Institute

In September 2006, we and Rensselaer Polytechnic Institute ("RPI") entered into a license agreement granting us rights to a family of opioid receptor compounds discovered at RPI. These compounds represent an opportunity for us to develop therapeutics for a broad range of diseases and medical conditions, including addiction, pain and other CNS disorders.

Under the terms of the agreement, RPI granted us an exclusive worldwide license to certain patents and patent applications relating to its compounds designed to modulate opioid receptors. We will be responsible for the continued research and development of any resulting product candidates. We paid RPI a nonrefundable upfront payment of $0.5 million and are obligated to pay annual fees of up to $0.2 million, and tiered royalty payments of between 1% and 4% of annual net sales in the event any products developed under the agreement are commercialized. In addition, we are obligated to make milestone payments in the aggregate of up to $9.1 million upon certain agreed-upon development events. In July 2008, the parties amended the agreement to expand the license to include certain additional patent applications. We paid RPI an additional nonrefundable payment of $0.1 million and slightly increased the annual fees in consideration of this amendment. In May 2009, the parties further amended the agreement to expand the license to include a patent application covering a joint invention made by the parties.

Other Arrangements

Civitas

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

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

Proprietary Product Platforms

Our proprietary product platforms, which include technologies owned and exclusively licensed to us, address several important development opportunities. We have used these technologies as platforms to establish drug development, clinical development and regulatory expertise.

Injectable Extended-Release Microsphere Technology

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

LinkeRx Technology

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

NanoCrystal Technology

Our NanoCrystal technology is applicable to poorly water-soluble compounds and involves formulating and stabilizing drugs into particles that are nanometers in size. A drug in NanoCrystal form can be incorporated into a range of common dosage forms and administration routes, including tablets, capsules, inhalation devices and sterile forms for injection, with the potential for enhanced oral bioavailability; increased therapeutic effectiveness; reduced/eliminated fed/fasted variability; and sustained duration of intravenous/intramuscular release.

Oral Controlled Release Technology Platform

Our OCR technologies are used to formulate, develop and manufacture oral dosage forms of pharmaceutical products that improve and control the release characteristics and efficacy of standard dosage forms.

Our OCR platform includes technologies for tailored pharmacokinetic profiles including SODAS® technology, IPDAS® technology, CODAS® technology and the MXDAS® drug absorption system, each as described below.

SODAS Technology: SODAS (Spheroidal Oral Drug Absorption System) technology involves producing uniform spherical beads of 1 mm to 2 mm in diameter containing drug plus excipients and coated with product-specific modified-release polymers. Varying the nature and combination of polymers within a selectively permeable membrane enables varying degrees of modified release depending upon the required product profile.

CODAS Technology: CODAS (Chronotherapeutic Oral Drug Absorption System) enables the delayed onset of drug release incorporating the use of specific polymers, resulting in a drug release profile that more accurately complements circadian patterns.

IPDAS Technology: IPDAS (Intestinal Protective Drug Absorption System) technology conveys gastrointestinal protection by a wide dispersion of drug candidates in a controlled and gradual manner, through the use of numerous high-density controlled-release beads compressed into a tablet form. Release characteristics are modified by the application of polymers to the micro matrix and subsequent coatings, which form a rate-limiting semi-permeable membrane.

MXDAS Technology: MXDAS (Matrix Drug Absorption System) formulates the drug candidate in a hydrophilic matrix and incorporates one or more hydrophilic matrix-forming polymers into a solid oral dosage form, which controls the release of drug through a process of diffusion and erosion in the gastrointestinal tract.

Manufacturing and Product Supply

We own and occupy manufacturing, office and laboratory facilities in Wilmington, Ohio; Athlone, Ireland; and Gainesville, Georgia. 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 cGMP and other regulatory agency

regulations. Our manufacturing and development capabilities include formulation through process development, scale-up and full-scale commercial manufacturing and specialized capabilities for the development and manufacturing of controlled substances.

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

Our third-party service providers involved in the manufacture of our products are subject to inspection by the FDA or comparable agencies in other jurisdictions. Any delay, interruption or other issues that arise in the acquisition of active pharmaceutical ingredients ("API"), manufacture, fill-finish, packaging, or storage of our products or product candidates, including as a result of a failure of our facilities or the facilities or operations of third parties to pass any regulatory agency inspection, could significantly impair our ability to sell our products or advance our development efforts, as the case may be. For information about risks relating to the manufacture of our products and product candidates, see "Risk Factors" and specifically those sections entitled " Our revenues largely depend on the actions of our third party collaborators, and if they are not effective, our revenues could be materially adversely affected," " We are subject to risks related to the manufacture of our products," " We rely on third parties to provide services in connection with the manufacture and distribution of our products," " If we or our third party providers fail to meet the stringent requirements of governmental regulation in the manufacture of our products, we could incur substantial remedial costs and a reduction in sales and/or revenues" and " We rely heavily on collaborative partners to develop and commercialize our products."

Commercial Products

We manufacture RISPERDAL CONSTA, VIVITROL and polymer for BYDUREON in our Wilmington, Ohio facility. We are currently operating two RISPERDAL CONSTA lines and one VIVITROL line at commercial scale. Janssen has granted us an option, exercisable upon 30 days' advance written notice, to purchase the most recently constructed and validated RISPERDAL CONSTA manufacturing line at its then-current net book value. We source our packaging operations for VIVITROL to a third-party contractor. Janssen is responsible for packaging operations for RISPERDAL CONSTA. The facility has been inspected by U.S., European, Japanese, Brazilian and Saudi Arabian regulatory authorities for compliance with required cGMP standards for continued commercial manufacturing.

We manufacture AMPYRA/FAMPYRA, NAPRELAN, LUVOX CR, RAPAMUNE and other products in our Athlone, Ireland facility. The facility has been inspected by U.S., Irish and Mexican regulatory authorities for compliance with required cGMP standards for continued commercial manufacturing.

We manufacture FOCALIN XR, RITALIN LA, AVINZA, VERAPAMIL and other products in our Gainesville, Georgia facility. The facility has been inspected by U.S., Danish and Brazilian regulatory authorities for compliance with required cGMP standards for continued commercial manufacturing. For more information about our manufacturing facilities, see " Properties."

Clinical Products

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

Research & Development

We devote significant resources to research and development programs. We focus our research and development efforts on finding novel therapeutics in areas of high unmet medical need. Our research and development efforts include, but are not limited to, areas such as pharmaceutical formulation, analytical chemistry, process development, engineering, scale-up and drug optimization/delivery. Please see "Management's Discussion and Analysis of Financial Condition and Results of Operations Results of Operations of Alkermes" for our research and development expenditures for our prior three fiscal years.

Permits and Regulatory Approvals

We hold various licenses in respect of our manufacturing activities conducted in Wilmington, Ohio; Athlone, Ireland; and Gainesville, Georgia. The primary licenses held in this regard are FDA Registrations of Drug Establishment and Drug Enforcement Administration ("DEA"), Controlled Substance Registration. We also hold a Manufacturers Authorisation (No. M516), an Investigational Medicinal Products Manufacturers Authorisation (No. IMP008) and Certificates of Good Manufacturing Practice Compliance of a Manufacturer (Ref. 2010-096 and 2010-097) from the Irish Medicines Board ("IMB") in respect of our Athlone facility, and a number of Controlled Substance Licenses granted by the Minister for Health and Children in Ireland. Due to certain U.S. state law requirements, we also hold certain state licenses to cover distribution activities through certain states and not in respect of any manufacturing activities conducted in those states.

We do not generally act as the product authorization holder for products incorporating our drug delivery technologies that have been developed on behalf of a collaborator. In such cases, our collaborator would hold the relevant authorization from the FDA or other national regulator, and we would support this authorization by furnishing a copy of the Drug Master File ("DMF"), or the chemistry, manufacturing and controls data to the relevant regulator to prove adequate manufacturing data in respect of the product. We would generally update this information annually with the relevant regulator. In other cases where we are developing proprietary product candidates, such as VIVITROL, we may hold the appropriate regulatory documentation ourselves.

Marketing, Sales and Distribution

We focus our sales and marketing efforts on specialist physicians in private practice and in public treatment systems. We use customary pharmaceutical company practices to market our product and to educate physicians, such as sales representatives calling on individual physicians, advertisements, professional symposia, selling initiatives, public relations and other methods. We provide customer service and other related programs for our product, such as product-specific websites, insurance research services and order, delivery and fulfillment services. Our sales force for VIVITROL in the U.S. consists of approximately 70 individuals. VIVITROL is sold directly to pharmaceutical wholesalers, specialty pharmacies and a specialty distributor. Product sales of VIVITROL during the fiscal year ended March 31, 2012, to McKesson Corporation, AmerisourceBergen Drug Corporation, CVS Caremark Corporation and Cardinal Health ("Cardinal"), represented approximately 19%, 16%, 14% and 13%, respectively, of total VIVITROL sales.

Effective April 1, 2009, we entered into an agreement with Cardinal Health Specialty Pharmaceutical Services ("Cardinal SPS"), a division of Cardinal, to provide warehouse, shipping and administrative services for VIVITROL. Our expectation for fiscal year 2013 is to continue to distribute VIVITROL through Cardinal SPS.

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

Competition

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

The biotechnology and pharmaceutical industries are characterized by intensive research, development and commercialization efforts and rapid and significant technological change. Many of our competitors are larger and have significantly greater financial and other resources than we do. We expect our competitors to develop new technologies, products and processes that may be more effective than those we develop. The development of technologically improved or different products or technologies may make our product candidates or product platforms obsolete or noncompetitive before we recover expenses incurred in connection with their development or realize any revenues from any commercialized product.

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

With respect to our proprietary injectable product platform, we are aware that there are other companies developing extended-release delivery systems for pharmaceutical products. RISPERDAL CONSTA and INVEGA SUSTENNA may compete with a number of other injectable products including ZYPREXA® RELPREVV® ((olanzapine) For Extended Release Injectable Suspension), which is marketed and sold by Lilly in the U.S., the EU and Australia/New Zealand, and other products currently in development, including a once-monthly injectable formulation of ABILIFY® (aripiprazole) developed by Otsuka Pharmaceutical Co., Ltd. ("Otsuka") which is currently under FDA review. RISPERDAL CONSTA and INVEGA SUSTENNA may also compete with new oral compounds currently on the market or being developed for the treatment of schizophrenia.

In the treatment of alcohol dependence, VIVITROL competes with CAMPRAL® (acamprosate calcium) sold by Forest Laboratories and ANTABUSE® sold by Odyssey as well as currently marketed drugs also formulated from naltrexone. Other pharmaceutical companies are developing product candidates that have shown some promise in treating alcohol dependence and that, if approved by the FDA, would compete with VIVITROL.

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

BYDUREON competes with established therapies for market share. Such competitive products include sulfonylureas, metformin, insulins, thiazolidinediones, glinides, dipeptidyl peptidase type IV inhibitors, insulin sensitizers, alpha-glucosidase inhibitors and sodium-glucose transporter-2 inhibitors. BYDUREON also competes with other glucagon-like peptide-1 ("GLP-1") agonists, including VICTOZA® (liraglutide (rDNA origin) injection), which is marketed and sold by Novo Nordisk A/S. Other pharmaceutical companies are developing product candidates for the treatment of type 2 diabetes that, if approved by the FDA, could compete with BYDUREON.

AMPYRA/FAMPYRA is, to our knowledge, the first product that is approved as a treatment to improve walking in patients with MS. However, there are a number of FDA-approved therapies for MS disease management that seek to reduce the frequency and severity of exacerbations or slow the accumulation of physical disability for people with certain types of MS. These products include AVONEX® from Biogen Idec, BETASRON® from Bayer HealthCare Pharmaceuticals, COPAXONE® from Teva Pharmaceutical Industries Ltd., REBIF® from Merck Serono, TYSABRI® from Biogen Idec and Elan, and GILENYA™ and EXTAVIA® from Novartis AG.

With respect to our NanoCrystal technology, we are aware that other technology approaches similarly address poorly water soluble drugs. These approaches include nanoparticles, cyclodextrins, lipid-based self-emulsifying drug delivery systems, dendrimers and micelles, among others, any of which could limit the potential success and growth prospects of products incorporating our NanoCrystal technology. In addition, there are many competing technologies to our OCR technology, some of which are owned by large pharmaceutical companies with drug delivery divisions and other smaller drug delivery specific companies.

Patents and Proprietary Rights

Our success will be dependent, in part, on our ability to obtain and maintain patent protection for our product candidates and those of our collaborators, to maintain trade secret protection and to operate without infringing upon the proprietary rights of others. We have a proprietary portfolio of patent rights and exclusive licenses to patents and patent applications. We have filed numerous patent applications in the U.S. and in other countries 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 more than 200 issued U.S. patents. In the future, we plan to file additional patent applications in the U.S. and in other countries directed to new or improved products and processes. We intend to file additional patent applications when appropriate and defend our patent position aggressively.

Our OCR technology is protected by a patent estate including patents and patent applications filed worldwide. Some of our OCR patent families are product specific whereas others cover generic delivery platforms (e.g. different release profiles, taste masking, etc.). The latest of the patents covering AMPYRA/FAMPYRA, which incorporates our OCR technology, expires in 2027 in the U.S. and 2025 in Europe.

Our NanoCrystal technology patent portfolio contains a number of patents granted throughout the world, including the U.S. and countries outside of the U.S. We also have a significant number of pending patent applications covering our NanoCrystal technology. The latest of the patents covering INVEGA SUSTENNA expires in 2019 in the U.S. and 2018 in the EU. Additional pending applications may provide a longer period of patent coverage, if granted.

We have filed patents worldwide that cover our microsphere technology and have a significant number of patents and pending patent applications covering our microsphere technology. The latest of our patents covering VIVITROL, RISPERDAL CONSTA and BYDUREON expire in 2029, 2023 and 2025 in the U.S., respectively, and 2021, 2021 and 2024 in Europe, respectively.

We have exclusive rights through licensing agreements with third parties to issued U.S. patents, a number of U.S. patent applications and corresponding patents outside the U.S. and patent applications in many countries, subject in certain instances to the rights of the U.S. government to use the technology covered by such patents and patent applications. Under certain licensing agreements, we are responsible for patent expenses, and we pay annual license fees and/or minimum annual royalties. In addition, under these licensing agreements, we are obligated to pay royalties on future sales of products, if any, covered by the licensed patents.

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

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

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

We are involved as a plaintiff in various Paragraph IV litigations in the U.S. and similar suits in Canada and France in respect of five different products: TRICOR 145, FOCALIN XR, AVINZA, LUVOX CR and MEGACE ES.

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

Our trademarks, including VIVITROL, are important to us and are generally covered by trademark applications or registrations in the U.S. Patent and Trademark Office and the patent or trademark offices of other countries. Our partnered products also use trademarks that are owned by our partners, such as the marks RISPERDAL CONSTA and INVEGA SUSTENNA, which are trademarks of Johnson & Johnson Corp., BYDUREON, which is a trademark of Amylin, and AMPYRA and FAMPYRA, which are trademarks of Acorda. Trademark protection varies in accordance with local law, and continues in some countries as long as the mark is used and in other countries as long as the mark is registered. Trademark registrations generally are for fixed but renewable terms.

Revenues and Assets by Region

For fiscal years 2012, 2011 and 2010, our revenue and long-term assets are presented below by geographical area.

	Year Ended March 31,		
(in thousands)	**2012**	**2011**	**2010**
Revenue by region:			
U.S.	$ 212,859	$ 76,701	$ 81,674
Ireland	12,695	805	999
Rest of world	164,423	109,135	95,608
Total long-term assets by region:			
Ireland	$ 171,751	$	$
U.S.	117,894	106,080	108,502
Rest of world			

Regulatory

Regulation of Pharmaceutical Products

Our current and contemplated activities, and the products and processes that result from such activities, are subject to substantial government regulation. Before new pharmaceutical products may be sold in the U.S. and other countries, preclinical studies and clinical trials of the products must be conducted and the results submitted to appropriate regulatory agencies for approval. Clinical trial programs must establish efficacy, determine an appropriate dose and regimen, and define the conditions for safe use. This is a high-risk process that requires stepwise clinical studies in which the candidate product must successfully meet predetermined endpoints. In the U.S., the results of the preclinical and clinical testing of a product are then submitted to the FDA in the form of a Biologics License Application ("BLA"), or an NDA. In response to a BLA or NDA, the FDA may grant marketing approval, request additional information or deny the application if it determines the application does not provide an adequate basis for approval. The FDA may require, as a condition of approval, restricted distribution and use, enhanced labeling, special packaging or labeling, expedited reporting of certain adverse events, pre-approval of promotional materials or restrictions on direct-to-consumer advertising. These criteria are usually referred to as a Risk Evaluation and Mitigation Strategy ("REMS"). Similar submissions are required by authorities in other jurisdictions who independently assess the product and may reach the same or different conclusions. There are currently three potential tracks for marketing approval in EU countries: mutual recognition, decentralized procedures, and centralized procedures. These review mechanisms may ultimately lead to approval in all countries within the EU, but each method grants all participating countries some decision-making authority in product approval.

The receipt of regulatory approval often takes a number of years, involves 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, potential safety signals observed in preclinical or clinical tests, and the risks and benefits demonstrated in clinical trials. On occasion, regulatory authorities may require larger or additional studies, leading to unanticipated delay or expense. Even after initial FDA approval or approvals from other regulatory agencies have been obtained, further clinical trials may be required to provide additional data on safety and effectiveness. Additional trials are required to gain approval for the use of a product as a treatment for indications other than those initially approved. Furthermore, the FDA and other regulatory agencies require companies to register clinical trials and disclose clinical trial results in public databases. Failure to register a trial or disclose study results within the required time periods could result in penalties, including civil monetary penalties.

In the U.S., the FDA may grant "accelerated approval" status to products that treat serious or life-threatening illnesses and that provide meaningful therapeutic benefits to patients over existing treatments. Under this pathway, the FDA may approve a product based on surrogate endpoints, or clinical endpoints other than survival or irreversible morbidity. When approval is based on surrogate endpoints or clinical endpoints other than survival or morbidity, the sponsor will be required to conduct additional post-approval clinical studies to verify and describe clinical benefit. Under the Agency's Accelerated Approval regulations, the FDA may also provide approval with a REMS. In addition, for all products approved under accelerated approval, sponsors must submit all copies of their promotional materials, including advertisements, to the FDA at least 30 days prior to initial dissemination. The FDA may withdraw approval under accelerated approval after a hearing if, for instance, post-marketing studies fail to verify any clinical benefit or it becomes clear that restrictions on the distribution of the product are inadequate to ensure its safe use.

In addition, the FDA may grant "fast track" status to products that treat serious diseases and fill an unmet medical need. Fast track is a process designed to expedite the review of such products by providing, among other things, more frequent meetings with the FDA to discuss the product's development plan, more frequent written correspondence from the FDA about trial design, eligibility for accelerated approval, and rolling review, which allows submission of individually completed sections of an NDA for FDA review before the entire NDA is completed. Fast track status does not ensure that a product will be developed more quickly or receive FDA approval.

If the FDA or other regulatory agency approves a product or new indication, the agency may require us to conduct additional post-marketing studies. If we fail to conduct the required studies, the agency may withdraw its approval. In addition, the FDA and European Medicines Agency ("EMA") can impose financial penalties for failing to comply with certain post-marketing commitments, including REMS.

Regulatory authorities track information on side effects and adverse events reported during clinical studies and after marketing approval. Non-compliance with regulatory authorities' safety reporting requirements may result in civil or criminal penalties. Side effects or adverse events that are reported during clinical trials can delay, impede or prevent marketing approval. Regulatory authorities may conduct post-marketing safety surveillance and may require additional post-approval studies or clinical trials. These requirements may affect our ability to maintain marketing approval of our products or require us to make significant expenditures to obtain or maintain such approvals. In addition, adverse events that are reported after marketing approval can result in changes to the product's labeling, additional limitations being placed on the product's use and, potentially, withdrawal or suspension of the product from the market.

If we seek to make certain types of changes to an approved product, such as adding a new indication, making certain manufacturing changes, or changing manufacturers or suppliers of certain

ingredients or components, regulatory authorities, including the FDA and EMA, will need to review and approve such changes in advance. Such regulatory reviews can result in denial or modification of the planned changes, or requirements to conduct additional tests or evaluations that can substantially delay or increase the cost of the planned changes.

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

Good Manufacturing Processes

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

Good Clinical Practices

The FDA, the EMA and other regulatory agencies promulgate regulations and standards, commonly referred to as Good Clinical Practices ("GCP"), for designing, conducting, monitoring, auditing and reporting the results of clinical trials to ensure that the data and results are accurate and that the trial participants are adequately protected. The FDA, the EMA and other regulatory agencies enforce GCP through periodic inspections of trial sponsors, principal investigators, trial sites, contract research organizations ("CROs") and institutional review boards. If our studies fail to comply with applicable GCP, the clinical data generated in our clinical trials may be deemed unreliable, and relevant regulatory agencies may require us to perform additional clinical trials before approving our marketing applications. Noncompliance can also result in civil or criminal sanctions. We rely on third parties, including CROs, to carry out many of our clinical trial-related activities. Failure of such third party to comply with GCP can likewise result in rejection of our clinical trial data or other sanctions.

Hatch-Waxman Act

Under the U.S. Drug Price Competition and Patent Term Restoration Act of 1984 (the "Hatch-Waxman Act"), Congress created an abbreviated FDA review process for generic versions of pioneer, or brand-name, drug products. The law also provides incentives by awarding, in certain circumstances, non-patent-related marketing exclusivities to pioneer drug manufacturers. Newly approved drug products and changes to the conditions of use of approved products may benefit from periods of non-patent-related marketing exclusivity in addition to any patent protection the drug product may have. The Hatch-Waxman Act provides five years of new chemical entity ("NCE") marketing exclusivity

to the first applicant to gain approval of a NDA for a product that contains an active ingredient not found in any other approved product. The FDA is prohibited from accepting any abbreviated NDA ("ANDA") for a generic drug or 505(b)(2) application for five years from the date of approval of the NCE, or four years in the case of an ANDA or 505(b)(2) application containing a patent challenge. A 505(b)(2) application is an NDA wherein the applicant relies in part on data from clinical studies not conducted by or for it and for which the applicant has not obtained a right of reference; this type of application allows the sponsor to rely, at least in part, on the FDA's findings of safety and/or effectiveness for a previously approved drug. This exclusivity will not prevent the submission or approval of a full NDA, as opposed to an ANDA or 505(b)(2) application, for any drug, including, for example, a drug with the same active ingredient, dosage form, route of administration, strength and conditions of use.

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

The Hatch-Waxman Act requires NDA applicants and NDA holders to provide certain information about patents related to the drug for listing in the Orange Book. ANDA and 505(b)(2) applicants must then certify regarding each of the patents listed with the FDA for the reference product. A certification that a listed patent is invalid or will not be infringed by the marketing of the applicant's product is called a "Paragraph IV certification." If the ANDA or 505(b)(2) applicant provides such a notification of patent invalidity or noninfringement, then the FDA may accept the ANDA or 505(b)(2) application four years after approval of the NDA. If a Paragraph IV certification is filed and the ANDA or 505(b)(2) application has been accepted as a reviewable filing by the FDA, the ANDA or 505(b)(2) applicant must then, within 30 days, provide notice to the NDA holder and patent owner stating that the application has been submitted and providing the factual and legal basis for the applicant's opinion that the patent is invalid or not infringed. The NDA holder or patent owner may file suit against the ANDA or 505(b)(2) applicant for patent infringement. If this is done within 45 days of receiving notice of the Paragraph IV certification, a one-time 30-month stay of the FDA's ability to approve the ANDA or 505(b)(2) application is triggered. The 30-month stay begins at the end of the NDA holder's data exclusivity period, or, if data exclusivity has expired, on the date that the patent holder is notified. The FDA may approve the proposed product before the expiration of the 30-month stay if a court finds the patent invalid or not infringed, or if the court shortens the period because the parties have failed to cooperate in expediting the litigation.

In addition, the recently enacted health reform legislation in the U.S. included an abbreviated approval pathway for biosimilars. Similar pathways already exist in the EU.

Sales and Marketing

Pharmaceutical manufacturers are subject to various U.S. federal and state laws pertaining to healthcare fraud and abuse, including anti-kickback laws and false claims laws. Anti-kickback laws make it illegal for a prescription drug manufacturer to solicit, offer, receive, or pay any remuneration in exchange for, or to induce, the referral of business, including the purchase or prescription of a particular drug. Due to the breadth of the U.S. statutory provisions and the absence of guidance in the form of regulations and very few court decisions addressing industry practices, it is possible that our practices might be challenged under anti-kickback or similar laws. False claims laws prohibit anyone from knowingly and willingly presenting, or causing to be presented, for payment to third-party payors (including Medicare and Medicaid) claims for reimbursed drugs or services that are false or fraudulent, claims for items or services not provided as claimed, or claims for medically unnecessary items or

services. In addition, several U.S. states require that companies implement compliance programs or comply with industry ethics codes, adopt spending limits and report to state governments any gifts, compensation and other remuneration provided to physicians. The recently enacted U.S. healthcare reform legislation will require disclosure to the federal government of payments to physicians commencing in 2012. Activities relating to the sale and marketing of our products may be subject to scrutiny under these laws. Violations of fraud and abuse laws may be punishable by criminal and/or civil sanctions, including fines and civil monetary penalties, as well as the possibility of exclusion from federal healthcare programs (including Medicare and Medicaid). In addition, under certain federal laws and many state laws, there is the ability for private individuals to bring similar actions. See "Risk Factors" and specifically those sections entitled " If we fail to comply with the extensive legal and regulatory requirements affecting the healthcare industry, we could face increased costs, penalties and a loss of business," " Revenues generated by sales of our products depend on the availability of reimbursement from third-party payors, and a reduction in payment rate or reimbursement or an increase in our financial obligation to governmental payors could result in decreased sales of our products and revenue" and " We may be exposed to product liability claims and recalls."

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

Pricing and Reimbursement

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

The U.S. government and governments outside the U.S. regularly consider reforming healthcare coverage and costs. Such reform may include changes to the coverage and reimbursement of our products, which may have a significant impact on our business. In 2010, significant healthcare reform legislation was enacted in the U.S., which has had and will continue to have an impact our business by increasing the Medicaid rebate; expanding our obligation to pay such rebate to Medicaid managed care; expanding eligibility under the 340B/PHS drug pricing program; establishing a fee to be paid by manufacturers of branded prescription drugs; requiring manufacturers to offer product discounts to Medicare beneficiaries in the Medicare Part D coverage gap; and changing the calculation of average manufacturer price ("AMP").

Medicare is a federal program that is administered by the federal government that covers individuals age 65 and over as well as those with certain disabilities. Medicare Part B pays physicians who administer our products under a payment methodology using average sales price ("ASP") information. Manufacturers, including us, are required to provide ASP information to the Centers for Medicare and Medicaid Services ("CMS") on a quarterly basis. This information is used to compute

Medicare payment rates, which are generally set at ASP plus 6% and are updated quarterly. Effective January 1, 2006, Medicare began to use the same ASP plus 6% payment methodology to determine Medicare rates paid for products furnished by hospital outpatient departments. As of January 1, 2009, the reimbursement rate in the hospital outpatient setting was ASP plus 4%. The reimbursement rate in the hospital outpatient setting was increased to ASP plus 5% effective January 1, 2011. If a manufacturer is found to have made a misrepresentation in the reporting of ASP, the statute provides for civil monetary penalties for each misrepresentation for each day in which the misrepresentation was applied.

The U.S. Medicare Prescription Drug Improvement and Modernization Act of 2003 established the Medicare Part D program to provide voluntary prescription drug benefit to enrolled Medicare patients. This is a voluntary benefit that is being implemented through private plans under contractual arrangements with the federal government. Similar to pharmaceutical coverage through private health insurance, Part D plans are expected to negotiate discounts from drug manufacturers and pass on some of those savings to Medicare beneficiaries.

Medicaid is a joint federal and state program that is administered by the states for low-income and disabled beneficiaries. Under the Medicaid rebate program, we are required to pay a rebate for each unit of product reimbursed by the state Medicaid programs. The amount of the rebate for each product is set by law as the greater of 23.1% of AMP or the difference between AMP and the best price available from us to any commercial or non-federal governmental customer. The rebate amount must be adjusted upward where the AMP for a product's first full quarter of sales, when adjusted for increases in the Consumer Price Index Urban, is less than the AMP for the current quarter with the upward adjustment equal to the excess amount. The rebate amount is required to be recomputed each quarter based on our report of current AMP and best price for each of our products to CMS. The terms of our participation in the rebate program imposes a requirement for us to report revisions to AMP or best price within a period not to exceed 12 quarters from the quarter in which the data was originally due. Any such revisions could have the impact of increasing or decreasing our rebate liability for prior quarters, depending on the direction of the revision. In addition, if we were found to have knowingly submitted false information to the government, the statute provides for civil monetary penalties per item of false information in addition to other penalties available to the government.

The availability of federal funds to pay for our products under the Medicaid and Medicare Part B programs requires that we extend discounts under the 340B/PHS drug pricing program. The 340B/PHS drug pricing program extends discounts to a variety of community health clinics and other entities that receive health services grants from Public Health Services ("PHS") as well as hospitals that serve a disproportionate share of poor Medicare beneficiaries.

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

Under the 2008 U.S. National Defense Authorization Act, we are required to treat the TRICARE retail pharmacy program, which reimburses military personnel for drug purchases from retail

pharmacies, as an element of the Department of Defense to ensure the application of the VHC Act's pricing standards.

Other Regulations

Foreign Corrupt Practices Act: We are subject to the U.S. Foreign Corrupt Practices Act ("FCPA"), which prohibits U.S. corporations and their representatives from paying, offering to pay, promising, authorizing, or making payments of anything of value to any foreign government official, government staff member, political party, or political candidate in an attempt to obtain or retain business or to otherwise influence a person working in an official capacity. In many countries, the health-care professionals we regularly interact with may meet the FCPA's definition of a foreign government official. The FCPA also requires public companies to make and keep books and records that accurately and fairly reflect their transactions and to devise and maintain an adequate system of internal accounting controls.

In 2010, the Bribery Act was passed in the UK, which proscribes giving and receiving bribes in the public and private sectors, bribing a foreign public official, and failing to have adequate procedures to prevent employees and other agents from giving bribes. Foreign corporations that conduct business in the UK generally will be subject to the Bribery Act. Penalties under the Bribery Act include potentially unlimited fines for corporations and criminal sanctions for corporate officers under certain circumstances.

Environmental, Health and Safety Laws: Our operations are subject to complex and increasingly stringent environmental, health and safety laws and regulations in the countries where we operate and in particular where we have manufacturing facilities, namely the U.S. and Ireland. Environmental and health and safety authorities in the relevant jurisdictions, including the Environmental Protection Agency and the Occupational Safety and Health Administration in the U.S. and the Environmental Protection Agency and the Health and Safety Authority in Ireland, administer laws which regulate, among other matters, the emission of pollutants into the air (including the workplace), the discharge of pollutants into bodies of water, the storage, use, handling and disposal of hazardous substances, the exposure of persons to hazardous substances, and the general health, safety and welfare of employees and members of the public. In certain cases, such laws and regulations may impose strict liability for pollution of the environment and contamination resulting from spills, disposals or other releases of hazardous substances or waste and/or any migration of such hazardous substances or waste. Costs, damages and/or fines may result from the presence, investigation and remediation of such contamination at properties currently or formerly owned, leased or operated by us and/or off-site locations, including where we have arranged for the disposal of hazardous substances or waste. In addition, we may be subject to third-party claims, including for natural resource damages, personal injury and property damage, in connection with such contamination.

Other Laws: We are subject to a variety of financial disclosure and securities trading regulations as a public company in the U.S., including laws relating to the oversight activities of the Securities and Exchange Commission ("SEC") and the regulations of the NASDAQ, on which our shares are traded. We are also subject to various laws, regulations and recommendations relating to safe working conditions, laboratory practices, the experimental use of animals, and the purchase, storage, movement, import and export and use and disposal of hazardous or potentially hazardous substances used in connection with our research work.

Employees

As of May 10, 2012, we had approximately 1,200 full-time employees. A significant number of our management and professional employees have prior experience with pharmaceutical, biotechnology or medical product companies. We believe that we have been successful in attracting skilled and experienced scientific and senior management personnel; however, competition for such personnel is intense. None of our employees is covered by a collective bargaining agreement. We consider our relations with our employees to be good.

Available Information

We were incorporated in Ireland on May 4, 2011 as a private limited company, under the name Antler Science Two Limited (registration number 498284). On July 25, 2011, Antler Science Two Limited was re-registered as a public limited company under the name Antler Science Two plc. On September 14, 2011, we were re-named Alkermes plc.

Our principal executive offices are located at Connaught House, 1 Burlington Road, Dublin 4, Ireland. Our telephone number is +353-1-772-8000 and our website address is www.alkermes.com. Information that is contained in, and can be accessed through, our website is not incorporated into, and does not form a part of, this prospectus. We make available free of charge through the Investors section of our website our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and all amendments to those reports as soon as reasonably practicable after such material is electronically filed with, or furnished to, the SEC. We also make available on our website (i) the charters for the committees of our Board of Directors, including the Audit and Risk Committee, Compensation Committee, and Nominating and Corporate Governance Committee, and (ii) our Code of Business Conduct and Ethics governing our directors, officers and employees. We intend to disclose on our website any amendments to, or waivers from, our Code of Business Conduct and Ethics that are required to be disclosed pursuant to the rules of the SEC. You may read and copy materials we file with the SEC at the SEC's Public Reference Room at 100 F Street, N.E., Washington, D.C. 20549. You may obtain information on the operation of the Public Reference Room by calling the SEC at 1-800-SEC-0330. The SEC maintains an internet site that contains reports, proxy and information statements and other information regarding issuers that file electronically with the SEC at www.sec.gov.

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

Investing in our company involves a high degree of risk. In deciding whether to invest in our ordinary shares, you should consider carefully the risks described below in addition to the financial and other information contained in this prospectus, including the matters addressed under the caption "Forward-Looking Statements." If any events described by the following risks actually occur, they could materially adversely affect our business, financial condition or operating results. This could cause the market price of our ordinary shares to decline, and could cause you to lose all or a part of your investment.

Our revenues largely depend on the actions of our third-party collaborators, and if they are not effective, our revenues could be materially adversely affected.

The revenues from the sale of our products may fall below our expectations, the expectations of our partners or those of investors, which could have a material adverse effect on our results of operations and the price of our ordinary shares, and will depend on numerous factors, many of which are outside our control.

RISPERDAL CONSTA, AMPYRA/FAMPYRA, BYDUREON AND INVEGA SUSTENNA/XEPLION

While we manufacture RISPERDAL CONSTA and AMPYRA/FAMPYRA, we are not involved in the commercialization efforts for those products. RISPERDAL CONSTA is commercialized by Janssen.

AMPYRA/FAMPYRA is commercialized by Acorda in the U.S. and by Biogen Idec outside the U.S. Our revenues depend on manufacturing fees and royalties we receive from Janssen, Acorda and Biogen Idec, each of which relates to sales of such products by or on behalf of our partners. Accordingly, our revenues will depend in large part on the efforts of our partners, and we will not be able to control this.

Pursuant to our arrangements with Amylin and Janssen, we are not responsible for the clinical development, manufacture or commercialization efforts for BYDUREON or INVEGA SUSTENNA/XEPLION, respectively. In addition, in November 2011, Lilly terminated their collaboration agreement pursuant to which they collaborated in the global development and commercialization of exenatide, including BYDUREON. Historically, Lilly and Amylin jointly commercialized exenatide products in the U.S., and Lilly solely commercialized such products outside of the U.S. Commencing on November 30, 2011, however, Amylin assumed the exclusive right to commercialize exenatide products in the U.S.. While Lilly continues to have exclusive rights to commercialize exenatide products outside of the U.S. until December 31, 2013 (or such earlier date as may be agreed by Amylin and Lilly), after that time Amylin will assume the exclusive right to commercialize exenatide products outside of the U.S. as well. This transition represents the first time that Amylin will assume sole responsibility for the commercialization of exenatide products on a global basis, and we cannot assure you that Amylin will be successful in that role.

For these and other reasons outside of our control, our revenues from the sale of RISPERDAL CONSTA, AMPYRA/FAMPYRA, BYDUREON and INVEGA SUSTENNA/XEPLION may not meet our or our partners' expectations or those of investors.

VIVITROL

In December 2007, we exclusively licensed the right to commercialize VIVITROL for the treatment of alcohol dependence and opioid dependence in Russia and other countries in the CIS to Cilag. Cilag has primary responsibility for securing all necessary regulatory approvals for VIVITROL and Janssen-Cilag, an affiliate of Cilag, has full responsibility for the commercialization of the product in these countries. We receive manufacturing revenues and royalty revenues based upon product sales. Our revenues from the sale of VIVITROL in Russia and countries of the CIS may not be significant and will depend on numerous factors, many of which are outside of our control.

REMAINING COMMERCIAL PORTFOLIO

In addition, we are not responsible for, or involved with, the sales and marketing efforts for many of our other products and, in some instances, we are also not involved in their manufacture.

We are substantially dependent on revenues from our principal product.

While our dependence on revenues from RISPERDAL CONSTA has decreased following the Business Combination, we still depend substantially upon continued sales of RISPERDAL CONSTA by our partner, Janssen. Any significant negative developments relating to this product, such as safety or efficacy issues, the introduction or greater acceptance of competing products, or adverse regulatory or legislative developments, would have a material adverse effect on our business, results of operations, cash flows and financial condition. Although we have developed and continue to develop additional products for commercial introduction, a decline in sales from this product would adversely affect our business.

We rely heavily on collaborative partners to develop and commercialize our products.

Our arrangements with collaborative partners are critical to bringing our products to the market and successfully commercializing them. We rely on these parties in various respects, including providing

funding for product candidate development programs; to conduct preclinical testing and clinical trials; to participate actively in, or manage, the regulatory approval process; and to commercialize our products.

The process of establishing collaborative arrangements with third parties to develop particular products or to accelerate the development of early-stage product candidates is difficult, time-consuming and involves significant uncertainty. We face, and will continue to face, significant competition in seeking appropriate collaborative partners. If we are unable to establish and maintain collaborative arrangements on acceptable terms, we may have to delay or discontinue further development of one or more of our product candidates or manufacture, seek regulatory approval and/or undertake commercialization activities for the product at our own expense.

Our collaborative partners may also choose to use their own or other technology to develop an alternative product and withdraw their support of our product candidate, or to compete with our jointly developed product. Alternatively, proprietary products we may develop in the future could compete directly with products we developed with our collaborative partners. Disputes may also arise between us and a collaborative partner, and may involve the ownership of technology developed during a collaboration or other issues arising out of collaborative agreements. Such a dispute could delay the related program or result in expensive arbitration or litigation, which may not be resolved in our favor.

Most of our collaborative partners can terminate their agreements with us without cause, and 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 a partner's sales, may materially adversely affect our business, financial condition, cash flows and results of operations.

Our revenues may be lower than expected as a result of failure by the marketplace to accept our products or for other factors.

We cannot be assured that our products will be, or will continue to be, accepted in the U.S. or in any markets outside the U.S. or that sales of our products will not decline or cease in the future. A number of factors may cause revenues from sales of our products to grow at a slower than expected rate, or even to decrease or cease, including:

- perception of physicians and other members of the healthcare community as to our products' safety and efficacy relative to that of competing products;
- the cost-effectiveness of our products;
- patient and physician satisfaction with our products;
- the successful manufacture of our commercial products on a timely basis;
- the cost and availability of raw materials necessary for the manufacture of our products;
- the size of the markets for our products;
- reimbursement policies of government and third-party payors;
- unfavorable publicity concerning our products, similar classes of drugs or the industry generally;
- the introduction, availability and acceptance of competing treatments, including treatments marketed and sold by our collaborators;
- the reaction of companies that market competitive products;

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

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

our continued ability to access third parties to vial, label and distribute our products on acceptable terms;

the unfavorable outcome of patent litigation, including so-called "Paragraph IV" litigation, related to any of our products;

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

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

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

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

exchange rate valuations and fluctuations; and

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

Our revenues will also fluctuate from quarter to quarter based on a number of other factors, including the acceptance of our products in the marketplace, our partners' orders, the timing of shipments, our ability to manufacture successfully, our yield and our production schedule. The unit costs to manufacture our products may be higher than anticipated if certain volume levels are not achieved. In addition, we may not be able to supply the products in a timely manner or at all.

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

The manufacture of pharmaceutical products is a highly complex process in which a variety of difficulties may arise from time to time including, but not limited to, product loss due to material failure, equipment failure, vendor error, operator error, labor shortages, inability to obtain material, equipment or transportation, physical or electronic security breaches, natural disasters and many other factors. Problems with manufacturing processes could result in product defects or manufacturing failures, which could require us to delay shipment of products or recall products previously shipped, or could impair our ability to expand into new markets or supply products in existing markets. We may not be able to resolve any such problems in a timely fashion, if at all.

We rely solely on our manufacturing facility in Wilmington, Ohio for the manufacture of RISPERDAL CONSTA, VIVITROL, polymer for BYDUREON and some of our product candidates. We rely on our manufacturing facility in Athlone, Ireland for the manufacture of AMPYRA/FAMPYRA and some of our other products using our NanoCrystal and OCR technologies. We rely on our manufacturing facility in Gainesville, Georgia for the manufacture of RITALIN LA/FOCALIN XR and some of our other products using our OCR technologies.

Due to regulatory and technical requirements, we have limited ability to shift production among our facilities or to outsource any part of our manufacturing to third parties. If we cannot produce sufficient commercial quantities of our products to meet demand, there are currently very few, if any, third-party manufacturers capable of manufacturing our products as contract suppliers. We cannot be certain that we could reach agreement on reasonable terms, if at all, with those manufacturers. Even if we were to reach agreement, the transition of the manufacturing process to a third party to enable commercial supplies could take a significant amount of time and money, and may not be successful.

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

of the sale of our products, to be manufactured in our facilities may cause operating losses as we continue to operate these facilities and retain specialized personnel. In addition, any interruption in manufacturing could result in delays in meeting contractual obligations and could damage our relationships with our collaborative partners, including the loss of manufacturing and supply rights.

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

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

The manufacture of products and product components, including the procurement of bulk drug product, packaging, storage and distribution of our products, require successful coordination among us and multiple third-party providers. For example, we are responsible for the entire supply chain for VIVITROL, up to the sale of final product and including the sourcing of key raw materials and active pharmaceutical agents from third parties. We have limited experience in managing a complex cGMP supply chain and product distribution network. Issues with our-third party providers, including our inability to coordinate these efforts, lack of capacity available at such third-party providers 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 and have a material adverse effect on our business, financial condition, cash flows and results of operations.

Due to the unique nature of the production of our products, there are several single-source providers of our key raw materials. For example, certain solvents and kit components used in the manufacture of RISPERDAL CONSTA are single-sourced. We endeavor to qualify new vendors and to develop contingency plans so that production is not impacted by issues associated with single-source providers. Nonetheless, our business could be materially and adversely affected by issues associated with single-source providers.

We are also dependent in certain cases on third parties to manufacture products. Where the manufacturing rights to the products in which our technologies are applied are granted to or retained by our third-party licensee or approved sub-licensee, we have no control over the manufacturing, supply or distribution of the product.

If we or our third-party providers fail to meet the stringent requirements of governmental regulation in the manufacture of our products, we could incur substantial remedial costs and a reduction in sales and/or revenues.

We and our third-party providers are generally required to comply 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 products 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 various regulatory agencies outside the U.S. have inspected and approved our commercial manufacturing facilities. We cannot guarantee that the FDA or any other regulatory agencies will approve any other facility we or our suppliers may operate or, once approved, that any of these facilities will remain in compliance with cGMP regulations. Any third party we use to manufacture bulk drug product, or package, store or distribute our products to be sold in the U.S., must be licensed by the FDA. Failure to gain or maintain regulatory compliance with the FDA or regulatory agencies outside the U.S. could materially adversely affect our business, financial condition, cash flows and results of operations.

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

In both U.S. and non-U.S. markets, sales of our products depend, in part, on the availability of reimbursement from third-party payors such as state and federal governments, including Medicare and Medicaid in the U.S. and similar programs in other countries, managed care providers and private insurance plans. Deterioration in the timeliness, certainty and amount of reimbursement for our products, including the existence of barriers to coverage of our products (such as prior authorization, criteria for use or other requirements), limitations by healthcare providers on how much, or under what circumstances, they will prescribe or administer our products or unwillingness by patients to pay any required co-payments could reduce the use of, and revenues generated from, our products and could have a material adverse effect on our business, financial condition, cash flows and results of operations.

The government-sponsored healthcare systems in Europe and many other countries are the primary payors for healthcare expenditures, including payment for drugs and biologics. While mandatory price reductions have been a recurring aspect of business for the pharmaceutical and biotechnology industries in Europe, given the current worldwide economic conditions, certain European national governments have increased the frequency and size of such mandatory price reductions to extract further cost savings. We expect that countries may take actions to reduce expenditure on drugs and biologics, including mandatory price reductions, preference for generic or biosimilar products or reduction in the amount of reimbursement. While we cannot fully predict the extent of price reductions by countries in Europe or the impact such price reductions will have on our business, such reductions in price and/or the coverage and reimbursement for our products in European countries could have a material adverse effect on our product sales and/or revenues and results of operations.

In addition, public and private insurers have pursued, and continue to pursue, aggressive cost containment initiatives, including increased focus on comparing the effectiveness, benefits and costs of similar treatments, which may result in lower reimbursement rates for our products.

The Patient Protection and Affordable Care Act and the Health Care and Education Reconciliation Act of 2010 were signed into law in the U.S. on March 23, 2010 and March 30, 2010, respectively. A number of the provisions of those laws require further rulemaking action by governmental agencies to implement. Among other things, this legislation imposes cost containment measures that have adversely affected the amount of reimbursement for our products. These measures include increasing the minimum rebates we pay to U.S. state Medicaid programs in the U.S. for our drugs covered by Medicaid; extending such rebates to drugs dispensed to Medicaid beneficiaries enrolled in Medicaid managed care organizations; and expanding the 340B/PHS drug discount program under which we must provide certain discounts on our drugs to eligible purchasers. Additional provisions of the healthcare reform legislation may negatively affect our revenues and prospects for profitability in the future. Beginning in 2011, a new fee also became payable by all branded prescription

drug manufacturers and importers. This fee is calculated based upon each organization's percentage share of total branded prescription drugs sales to qualifying U.S. government programs, including Medicare and Medicaid. In addition, as part of the healthcare reform legislation's provisions closing a coverage gap that currently exists in the Medicare Part D prescription drug program (the "Donut Hole"), we are also required to provide a 50% discount on brand-name prescription drugs sold to beneficiaries who fall within the Donut Hole. Future rulemaking could increase rebates, reduce prices or the rate of price increases for healthcare products and services, or require additional reporting and disclosure. We cannot predict the timing or impact of any future rulemaking.

Patent protection for our products is important and uncertain.

The following factors are important to our success:

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

Patent protection only provides rights of exclusivity for the term of the patent. We are 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. In this regard, we try to protect our proprietary position by filing patent applications in the U.S. and elsewhere related to our proprietary product inventions and improvements that are important to the development of our business. Our pending patent applications, together with those we may file in the future, or those we may license from third parties, may not result in patents being issued. Even if issued, such patents may not provide us with sufficient proprietary protection or competitive advantages against competitors with similar technology. The development of new technologies or pharmaceutical products may take a number of years, and there can be no assurance that any patents which may be granted in respect of such technologies or products will not have expired or be due to expire by the time such products are commercialized.

Although we believe that we make reasonable efforts to protect our intellectual property rights and to ensure that our proprietary technology does not infringe the rights of other parties, we cannot ascertain the existence of all potentially conflicting claims. Therefore, there is a risk that third parties may make claims of infringement against our products or technologies. We know of several U.S. patents issued in the U.S. to third parties that may relate to our product candidates. We also know of patent applications filed by other parties in the U.S. and various countries outside the U.S. that may relate to some of our product candidates if such patents are issued in their present form. If patents are issued that cover our product candidates, we may not be able to manufacture, use, offer for sale, import or sell such 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. A patent holder might also file an infringement action against us claiming that the manufacture, use, offer for sale, import or sale of our product candidates infringed one or more of its patents. Even if we believe that such claims are without merit, our cost of defending such an action is likely to be high and we might not receive a favorable ruling, and the action could be time-consuming and distract management's attention and resources. Claims of intellectual property infringement also might require us to redesign affected products, enter into costly settlement or license agreements or pay costly damage awards, or face a temporary or permanent injunction prohibiting us

from marketing or selling certain of our products. Even if we have an agreement to indemnify us against such costs, the indemnifying party may be unable to uphold its contractual obligations. If we cannot or do not license the infringed technology at all, license the technology on reasonable terms or substitute similar technology from another source, our revenue and earnings could be adversely impacted.

Because the patent positions of pharmaceutical and biotechnology companies involve complex legal and factual questions, enforceability of patents cannot be predicted with certainty. The ultimate degree of patent protection that will be afforded to biotechnology products and processes, including ours, in the U.S. and in other important markets, remains uncertain and is dependent upon the scope of protection decided upon by the patent offices, courts and lawmakers in these countries. The recently enacted America Invents Act, which reformed certain patent laws in the U.S., may create additional uncertainty. Patents, if issued, may be challenged, invalidated or circumvented. As more products are commercialized using our proprietary product platforms, or as any product achieves greater commercial success, our patents become more likely to be subject to challenge by potential competitors. The laws of certain countries may not protect our intellectual property rights to the same extent as do the laws of the U.S. Thus, any patents that we own or license from others may not provide any protection against competitors. Furthermore, others may independently develop similar technologies outside the scope of our patent coverage.

We also rely on trade secrets, know-how and technology, which are not protected by patents, to maintain our competitive position. We try to protect this information by entering into confidentiality agreements with parties that have access to it, such as our collaborative partners, licensees, employees and consultants. Any of these parties may breach the agreements and disclose our confidential information, or our competitors might learn of the information in some other way. To the extent that our employees, consultants or contractors use intellectual property owned by others in their work for us, disputes may arise as to the rights in related or resulting know-how and inventions. 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, such event could materially adversely affect our business, results of operations, cash flows and financial condition.

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

There is considerable uncertainty within the biotechnology industry about the validity, scope and enforceability of many issued patents in the U.S. and elsewhere in the world and, to date, there is not consistency regarding the breadth of claims allowed in biotechnology patents. We cannot currently determine the ultimate scope and validity of patents which may be granted to third parties in the future or which patents might be asserted to be infringed by the manufacture, use and sale of our products.

In part as a result of this uncertainty, there has been, and we expect that there may continue to be, significant litigation in the biotechnology industry regarding patents and other intellectual property rights. We may have to enforce our intellectual property rights against third parties who infringe our patents and other intellectual property or challenge our patent or trademark applications. For example, in the U.S., putative generics of innovator drug products (including products in which the innovation comprises a new drug delivery method for an existing product, such as the drug delivery market occupied by us) may file ANDAs and, in doing so, they are not required to include preclinical and clinical data to establish the safety and effectiveness of their drug. Instead, they would rely on such data provided in the innovator drug NDA. However, to benefit from this less costly abbreviated procedure, the ANDA applicant must demonstrate that its drug is "generic" or "bioequivalent" to the innovator drug, and, to the extent that patents protecting the innovator drug are listed in the "Orange Book," the ANDA applicant must write to the innovator NDA holder and the patent holder (to the extent that the Orange Book-listed patents are not owned by the innovator NDA holder) certifying that

its product either does not infringe the innovator's and, if applicable, the patent holder's patents and/or that the relevant patents are invalid. The innovator and the patent holder may sue the ANDA applicant within 45 days of receiving the certification and, if they do so, the FDA may not approve the ANDA for 30 months from the date of certification unless, at some point before the expiry of those 30 months, a court makes a final decision in the ANDA applicant's favor. This type of litigation is commonly known as "Paragraph IV" litigation in the U.S. We and our collaborative partners are involved in a number of Paragraph IV litigations in the U.S. and similar suits in Canada and France in respect of some of our products. These litigations could result in new or additional generic competition to our marketed products and a potential reduction in product revenue.

Litigation and administrative proceedings concerning patents and other intellectual property rights may be expensive, distracting to management and protracted with no certainty of success. Competitors may sue us as a way of delaying the introduction of our products. Any litigation, including any interference or derivation proceedings to determine priority of inventions, oppositions or other post-grant review proceedings to patents in the U.S. or in countries outside the U.S., or litigation against our partners may be costly and time-consuming and could harm our business. We expect that litigation may be necessary in some instances to determine the validity and scope of certain of our proprietary rights. Litigation may be necessary in other instances to determine the validity, scope and/or non-infringement of certain patent rights claimed by third parties to be pertinent to the manufacture, use or sale of our products. Ultimately, the outcome of such litigation could adversely affect the validity and scope of our patent or other proprietary rights or hinder our ability to manufacture and market our products.

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

In September 2011 we entered into a $310 million first lien term loan facility and a $140 million second lien term loan facility, which are guaranteed by certain of our subsidiaries. Our level of indebtedness and the terms of these financing arrangements could adversely affect our business by, among other things:

- requiring us to dedicate a substantial portion of our cash flow from operations to payments on our indebtedness, thereby reducing the availability of our cash flow for other purposes, including business development efforts, research and development and capital expenditures;
- limiting our flexibility in planning for, or reacting to, changes in our business and the industry in which we operate, thereby placing us at a competitive disadvantage compared to competitors with less debt;
- limiting our ability to take advantage of significant business opportunities, such as potential acquisition opportunities; and
- increasing our vulnerability to adverse economic and industry conditions.

Our term loan facilities impose restrictive covenants on us and require certain payments of principal and interest over time. A failure to comply with these restrictions or to make these payments could lead to an event of default that could result in an acceleration of the indebtedness. Our future operating results may not be sufficient to ensure compliance with these covenants or to remedy any such default. In the event of an acceleration of this indebtedness, we may not have or be able to obtain sufficient funds to make any accelerated payments.

We rely on a limited number of pharmaceutical wholesalers to distribute our product.

As is typical in the pharmaceutical industry, we rely upon pharmaceutical wholesalers in connection with the distribution of our products. A significant amount of our product is sold to end-users through the three largest wholesalers in the U.S. market, Cardinal Health Inc., AmerisourceBergen Corp., and McKesson Corp. If we are unable to maintain our business relationships with these major pharmaceutical wholesalers on commercially acceptable terms, if the buying patterns of these wholesalers fluctuate due to seasonality, wholesaler buying decisions or other factors outside of our control, our financial condition, cash flows and results of operations may be affected.

We have limited experience in the commercialization of products.

We assumed responsibility for the marketing and sale of VIVITROL in the U.S. from Cephalon in December 2008. VIVITROL is the first commercial product for which we have had sole responsibility for commercialization, including but not limited to sales, marketing, distribution and reimbursement-related activities. We are increasingly focused on maintaining rights to commercialize our leading product candidates in certain markets.

We have limited commercialization experience. We may not be able to attract and retain qualified personnel to serve in our sales and marketing organization, to develop an effective distribution network or to otherwise effectively support our commercialization activities. The cost of establishing and maintaining a sales and marketing organization may exceed its cost-effectiveness. If we fail to develop sales and marketing capabilities, if sales efforts are not effective or if the costs of developing sales and marketing capabilities exceed their cost-effectiveness, such events could materially adversely affect our business, results of operations, cash flows and financial condition.

Our product platforms or product development efforts may not produce safe, efficacious or commercially viable products and, if we are unable to develop new products, our business may suffer.

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

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.

Because we fund the development of our proprietary product candidates, there is a risk that we may not be able to continue to fund all such development efforts to completion or to provide the support necessary to perform the clinical trials, obtain regulatory approvals or market any approved products on a worldwide basis. We expect the development of products for our own account to consume substantial resources. If we are able to develop commercial products on our own, the risks associated with these programs may be greater than those associated with our programs with collaborative partners.

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

The FDA or regulatory agencies outside the U.S. may not approve our product candidates or may impose limitations upon any product approval.

We must obtain government approvals before marketing or selling our drug candidates in the U.S. and in jurisdictions outside the U.S. The FDA and comparable regulatory agencies in other countries impose substantial and rigorous requirements for the development, production and commercial introduction of drug products. These include preclinical, laboratory and clinical testing procedures, sampling activities, clinical trials and other costly and time-consuming procedures. In addition, regulation is not static, and regulatory agencies, including the FDA, evolve in their staff, interpretations and practices and may impose more stringent requirements than currently in effect, which may adversely affect our planned drug development and/or our commercialization efforts. Satisfaction of the requirements of the FDA and of other regulatory agencies typically takes a significant number of years and can vary substantially based upon the type, complexity and novelty of the drug candidate. The approval procedure and the time required to obtain approval also varies among countries. Regulatory agencies may have varying interpretations of the same data, and approval by one regulatory agency does not ensure approval by regulatory agencies in other jurisdictions. In addition, the FDA or regulatory agencies outside the U.S. may choose not to communicate with or update us during clinical testing and regulatory review periods. The ultimate decision by the FDA or other regulatory agencies regarding drug approval may not be consistent with prior communications. See " Our revenues may be lower than expected as a result of failure by the marketplace to accept our products or for other factors."

This product development process can last many years, be very costly and still be unsuccessful. Regulatory approval by the FDA or regulatory agencies outside the U.S. can be delayed, limited or not granted at all for many reasons, including:

- a product candidate may not demonstrate safety and efficacy for each target indication in accordance with FDA standards or standards of other regulatory agencies;
- poor rate of patient enrollment, including limited availability of patients who meet the criteria for certain clinical trials;
- data from preclinical testing and clinical trials may be interpreted by the FDA or other regulatory agencies in different ways than we or our partners interpret it;
- the FDA or other regulatory agencies might not approve our or our partners' manufacturing processes or facilities;
- the FDA or other regulatory agencies may not approve accelerated development timelines for our product candidates;
- the failure of third-party clinical research organizations and other third-party service providers and independent clinical investigators to manage and conduct the trials, to perform their oversight of the trials or to meet expected deadlines;
- the failure of our clinical investigational sites and the records kept at such sites, including the clinical trial data, to be in compliance with the FDA's Good Clinical Practices, or EU legislation

governing good clinical practice, including the failure to pass FDA, EMA or EU Member State inspections of clinical trials;

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

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

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

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

Even if regulatory approval to market a drug product is granted, the approval may impose limitations on the indicated use for which the drug product may be marketed and additional post-approval requirements with which we would need to comply in order to maintain the approval of such products. Our business could be seriously harmed if we do not complete these studies and the FDA, as a result, requires us to change related sections of the marketing label for our products. In addition, adverse medical events that occur during clinical trials or during commercial marketing of our products could result in legal claims against us and the temporary or permanent withdrawal of our products from commercial marketing, which could seriously harm our business and cause our stock price to decline.

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

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

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

the potential delay by a collaborative partner in beginning the clinical trial;

the inability to recruit clinical trial participants at the expected rate;

the failure of clinical trials to demonstrate a product candidate's safety or efficacy;

the inability to follow patients adequately after treatment;

unforeseen safety issues;

the inability to manufacture sufficient quantities of materials used for clinical trials; and

unforeseen governmental or regulatory delays.

In addition, we often depend on independent clinical investigators, contract research organizations and other third-party service providers and our collaborators in the conduct of clinical trials for our product candidates. We rely heavily on these parties for successful execution of our clinical trials but do not control many aspects of their activities. For example, while the investigators are not our employees, 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 results from preclinical testing and early clinical trials often have not predicted results of later clinical trials. A number of new drugs have shown promising results in early clinical trials, but subsequently failed to establish sufficient safety and efficacy data to obtain necessary regulatory approvals. Clinical trials conducted by us, by our collaborative partners or by third parties on our behalf may not demonstrate sufficient safety and efficacy to obtain the requisite regulatory approvals for our product candidates.

If a product candidate fails to demonstrate safety and efficacy in clinical trials or if third parties fail to conduct clinical trials in accordance with their obligations, the development, approval and commercialization of our product candidates may be delayed or prevented, which may materially adversely affect our business, financial condition, cash flows and results of operations.

The commercial use of our products may cause unintended side effects or adverse reactions, or incidents of misuse may occur.

We cannot predict whether the commercial use of our products will produce undesirable or unintended side effects that have not been evident in the use of, or in clinical trials conducted for, such products to date. Additionally, incidents of product misuse may occur. These events, among others, could result in product recalls, product liability actions or withdrawals or additional regulatory controls (including additional regulatory scrutiny and requirements for additional labeling), all of which could have a material adverse effect on our business, results of operations, cash flows and financial condition. In addition, the reporting of adverse safety events involving our products and public rumors about such events could cause our stock price to decline or experience periods of volatility.

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

Our activities, and the activities of our collaborators and third-party providers, are subject to comprehensive government regulation. Government regulation by various national, state and local agencies, which includes detailed inspection of, and controls over, research and laboratory procedures, clinical investigations, product approvals and manufacturing, marketing and promotion, adverse event reporting, sampling, distribution, recordkeeping, storage, and disposal practices, and achieving compliance with these regulations, substantially increases the time, difficulty and costs incurred in obtaining and maintaining the approval to market newly developed and existing products. Government regulatory actions can result in delay in the release of products, seizure or recall of products, suspension or revocation of the authority necessary for their production and sale, and other civil or criminal sanctions, including fines and penalties. Pharmaceutical and biotechnology companies have been the target of lawsuits and investigations alleging violations of government regulation, including claims asserting submission of incorrect pricing information, impermissible off-label promotion of pharmaceutical products, payments intended to influence the referral of federal or state healthcare

business, submission of false claims for government reimbursement, antitrust violations or violations related to environmental matters.

Changes in laws affecting the healthcare industry could also adversely affect our revenues and profitability, such as new laws, regulations or judicial decisions, or new interpretations of existing laws, regulations or decisions, related to patent protection and enforcement, healthcare availability, and product pricing and marketing. Changes in FDA regulations and regulations issued by regulatory agencies outside of the U.S., including new or different approval requirements, timelines and processes, may also delay or prevent the approval of new products, require additional safety monitoring, labeling changes, restrictions on product distribution or other measures that could increase our costs of doing business and adversely affect the market for our products. The enactment in the U.S. of healthcare reform, new legislation or implementation of existing statutory provisions on importation of lower-cost competing drugs from other jurisdictions and legislation on comparative effectiveness research are examples of previously enacted and possible future changes in laws that could adversely affect our business.

While we continually strive to comply with these complex requirements, we cannot guarantee that we, our employees, our collaborators, our consultants or our contractors are or will be in compliance with all potentially applicable U.S. federal and state regulations and/or laws or all potentially applicable regulations and/or laws outside the U.S. and interpretations of the applicability of these laws to marketing practices. If we or our agents fail to comply with any of those regulations and/or laws, a range of actions could result, including, but not limited to, the termination of clinical trials, the failure to approve a product candidate, restrictions on our products or manufacturing processes, withdrawal of our products from the market, significant fines, exclusion from government healthcare programs or other sanctions or litigation. Additionally, while we have implemented numerous risk mitigation measures, we cannot guarantee that we will be able to effectively mitigate all operational risks. Failure to effectively mitigate all operational risks may materially adversely affect our product supply, which could have a material adverse effect on our product sales and/or revenues and results of operations.

We face competition in the biotechnology and pharmaceutical industries.

We face intense competition in the development, manufacture, marketing and commercialization of our products and product candidates from many and varied sources, such as academic institutions, government agencies, research institutions and biotechnology and pharmaceutical companies, including other companies with similar technologies, and we can provide no assurance that we will be able to compete successfully. Some of these competitors are also our collaborative partners, who control the commercialization of products for which we receive manufacturing and/or royalty revenues. These competitors are working to develop and market other systems, products, vaccines and other methods of preventing or reducing disease, and new small-molecule and other classes of drugs that can be used with or without a drug delivery system.

The biotechnology and pharmaceutical industries are characterized by intensive research, development and commercialization efforts and rapid and significant technological change. Many of our competitors are larger and have significantly greater financial and other resources than we do. As a result, we expect that our competitors may develop new technologies, products and processes that may be more effective than those we develop. They may also develop their products more rapidly than us, complete any applicable regulatory approval process sooner than we can or offer their newly developed products at prices lower than our prices. The development of technologically improved or different products or technologies may make our product candidates or product platforms obsolete or noncompetitive before we recover expenses incurred in connection with their development or realize any revenues from any commercialized product.

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

With respect to our proprietary injectable product platform, we are aware that there are other companies developing extended-release delivery systems for pharmaceutical products. RISPERDAL CONSTA and INVEGA SUSTENNA may compete with a number of other injectable products including ZYPREXA RELPREVV ((olanzapine) For Extended Release Injectable Suspension), which is marketed and sold by Lilly in the U.S., the EU and Australia/New Zealand, and other products currently in development, including a once-monthly injectable formulation of ABILIFY (aripiprazole) developed by Otsuka Pharmaceutical Co. Ltd. ("Otsuka"), which is currently under FDA review. RISPERDAL CONSTA and INVEGA SUSTENNA may also compete with new oral compounds currently on the market or being developed for the treatment of schizophrenia.

In the treatment of alcohol dependence, VIVITROL competes with CAMPRAL (acamprosate calcium) sold by Forest Laboratories and ANTABUSE sold by Odyssey as well as currently marketed drugs also formulated from naltrexone. Other pharmaceutical companies are developing product candidates that have shown some promise in treating alcohol dependence and that, if approved by the FDA, would compete with VIVITROL.

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

BYDUREON competes with established therapies for market share. Such competitive products include sulfonylureas, metformin, insulins, thiazolidinediones, glinides, dipeptidyl peptidase type IV inhibitors, insulin sensitizers, alpha-glucosidase inhibitors and sodium-glucose transporter-2 inhibitors. BYDUREON also competes with other GLP-1 agonists, including VICTOZA (liraglutide (rDNA origin) injection), which is marketed and sold by Novo Nordisk A/S. Other pharmaceutical companies are developing product candidates for the treatment of type 2 diabetes that, if approved by the FDA, could compete with BYDUREON.

AMPYRA/FAMPYRA is, to our knowledge, the first product that is approved as a treatment to improve walking in patients with MS. However, there are a number of FDA-approved therapies for MS disease management that seek to reduce the frequency and severity of exacerbations or slow the accumulation of physical disability for people with certain types of MS. These products include AVONEX® from Biogen Idec, BETASRON® from Bayer HealthCare Pharmaceuticals, COPAXONE® from Teva Pharmaceutical Industries Ltd., REBIF® from Merck Serono, TYSABRI® from Biogen Idec and Elan, and GILENYA™ and EXTAVIA® from Novartis AG.

With respect to our NanoCrystal technology, we are aware that other technology approaches similarly address poorly water soluble drugs. These approaches include nanoparticles, cyclodextrins, lipid-based self-emulsifying drug delivery systems, dendrimers and micelles, among others, any of which

could limit the potential success and growth prospects of products incorporating our NanoCrystal technology. In addition, there are many competing technologies to our OCR technology, some of which are owned by large pharmaceutical companies with drug delivery divisions and other smaller drug delivery specific companies.

If we are unable to compete successfully in the biotechnology and pharmaceutical industries, it may materially adversely affect our business, financial condition, cash flows and results of operations.

We may not become profitable on a sustained basis.

At March 31, 2012, our accumulated deficit was $524.9 million, which was primarily the result of net losses incurred from 1987, the year we were founded, through March 31, 2012, partially offset by net income over previous fiscal years. There can be no assurance we will achieve sustained profitability.

A major component of our revenue is dependent on our partners' and our ability to commercialize, and our ability to manufacture economically, our marketed products.

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

- obtain and maintain regulatory approval for our products and product candidates, and for our partnered products, both in the U.S. and in other countries;
- efficiently manufacture our products;
- support the commercialization of our products by our collaborative partners;
- successfully market and sell VIVITROL in the U.S.;
- support the commercialization of VIVITROL in Russia and the countries of the CIS by our partner Cilag;
- enter into agreements to develop and commercialize our products and product candidates;
- develop, have manufactured or expand our capacity to manufacture and market our products and product candidates;
- obtain adequate reimbursement coverage for our products from insurance companies, government programs and other third-party payors;
- obtain additional research and development funding from collaborative partners or funding for our proprietary product candidates; and
- achieve certain product development milestones.

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

- the progress of our research and development programs for our product candidates and for our partnered product candidates, including clinical trials;

the time and expense that will be required to pursue FDA and/or non-U.S. regulatory approvals for our products and whether such approvals are obtained;

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

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

the cost of third-party manufacture;

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

how competing technological and market developments affect our product candidates;

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

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

the costs of potential litigation; and

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

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

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

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

Our products or product candidates may cause or contribute to injury or dangerous drug interactions, and we may not learn about or understand those effects until the product or product candidate has been administered to patients for a prolonged period of time.

Claims for or from such injuries or interactions may be brought by consumers, clinical trial participants, our collaborative partners or third parties selling the products. We currently carry product liability insurance coverage in such amounts as we believe are sufficient for our business. However, this coverage may not 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 at all, or our insurer may disclaim coverage as to a future claim. This could prevent or limit our commercialization of our products. We may not be successful in defending ourselves in the litigation and, as a result, our business could be materially harmed. These lawsuits may result in large judgments or settlements against us, any of which could have a negative effect on our financial condition and business if in excess of our insurance coverage. Additionally, lawsuits can be expensive to defend, whether or not they have merit, and the defense of these actions may divert the attention of our management and other resources that would otherwise be engaged in managing our business.

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

Our business involves environmental, health and safety risks.

Our business involves the controlled use of hazardous materials and chemicals and is subject to numerous environmental, health and safety laws and regulations and to periodic inspections for possible violations of these laws and regulations. Under certain of those laws and regulations, we could be liable for any contamination at our current or former properties or third party waste disposal sites. In addition to significant remediation costs, contamination can give rise to third party claims for fines, penalties, natural resource damages, personal injury and damage (including property damage). The costs of compliance with environmental, health and safety laws and regulations are significant. Any violations, even if inadvertent or accidental, of current or future environmental, health or safety laws or regulations, the cost of compliance with any resulting order or fine and any liability imposed in connection with any contamination for which we may be responsible could adversely affect our business, financial condition, cash flows and results of operations.

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

As a result of adverse credit and financial market conditions, organizations that reimburse for use of our products, such as government health administration authorities and private health insurers, may be unable to satisfy such obligations or may delay payment. In addition, federal and state health authorities may reduce reimbursements (including Medicare and Medicaid reimbursements in the U.S.) or payments, and private insurers may increase their scrutiny of claims. We are also dependent on the performance of our collaborative partners, and we sell our products to our collaborative partners through contracts that may not be secured by collateral or other security. Accordingly, we bear the risk if our partners are unable to pay amounts due to us thereunder. Due to the recent tightening of global credit and the volatility in the financial markets, there may be a disruption or delay in the performance of our third-party contractors, suppliers or collaborative partners. If such third parties are unable to pay amounts owed to us or satisfy their commitments to us, or if there are reductions in the availability or extent of reimbursement available to us, our business and results of operations would be adversely affected.

Currency exchange rates may affect revenue.

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

As a result of the Business Combination, we incur substantial operating costs in Ireland. We face exposure to changes in the exchange ratio of the USD and the Euro arising from expenses and payables at our Irish operations that are settled in Euro. The impact of changes in the exchange ratio of the USD and the Euro on our USD denominated manufacturing and royalty revenues earned in countries other than the U.S. is partially offset by the opposite impact of changes in the exchange ratio of the USD and the Euro on operating expenses and payables incurred at our Irish operations that are settled in Euro. For the fiscal year ended March 31, 2012, an average 10% weakening in the USD relative to the Euro would have resulted in an increase to our expenses denominated in Euro of $4.7 million.

We may not be able to retain our key personnel.

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

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

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 ordinary shares. 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 ordinary shares.

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

uncertainties in assessing the value, strengths and potential profitability of, and identifying the extent of all weaknesses, risks, contingent and other liabilities of, the respective parties;

the potential loss of key customers, management and employees of an acquired business;

the consummation of financing transactions, acquisitions or dispositions and the related effects on our business;

the ability to achieve identified operating and financial synergies from an acquisition in the amounts and within the timeframe predicted;

problems that could arise from the integration of the respective businesses, including the application of internal control processes to the acquired business;

difficulties that could be encountered in managing international operations; and

unanticipated changes in business, industry, market or general economic conditions that differ from the assumptions underlying our rationale for pursuing the transaction.

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

Moreover, any acquisition opportunities we pursue could materially affect our liquidity and capital resources and may require us to incur additional indebtedness, seek equity capital or both. Future acquisitions could also result in our assuming more long-term liabilities relative to the value of the acquired assets than we have assumed in our previous acquisitions. Further, acquisition accounting rules

require changes in certain assumptions made subsequent to the measurement period as defined in current accounting standards, to be recorded in current period earnings, which could affect our results of operations.

The recent Business Combination of Old Alkermes and EDT created numerous risks and uncertainties, and we may fail to realize the expected benefits of the Business Combination.

Strategic transactions like the recent Business Combination of Old Alkermes and EDT create numerous risks and uncertainties. This Business Combination entailed many changes, including the integration of EDT and its personnel with those of Old Alkermes, and changes in systems and employee benefit plans. These transition activities are complex, and we may encounter unexpected difficulties or incur unexpected costs, including:

- the diversion of management's attention to integration matters;
- difficulties in achieving anticipated cost savings, synergies, business opportunities and growth prospects from combining the business of EDT with that of Old Alkermes;
- difficulties in the integration of operations and systems;
- difficulties in managing a significantly larger business;
- challenges in controlling additional costs and expenses incurred as a result of the Business Combination;
- difficulties in the assimilation of employees; and
- deterioration of general industry and business conditions.

If any of these factors limits our ability to integrate the operations of EDT with those of Old Alkermes successfully or on a timely basis, the expectations of future results of operations, including certain cost savings and synergies expected to result from the Business Combination, might not be met. As a result, we may not be able to realize the expected benefits that we sought to achieve from the Business Combination. In addition, we may be required to spend additional time or money on integration that otherwise would be spent on the development and expansion of our business.

In addition, the market price of our ordinary shares may decline if the integration of EDT and Old Alkermes is unsuccessful, takes longer than expected or fails to achieve financial benefits to the extent anticipated by financial analysts or investors, or if the effect of the Business Combination on our financial results is otherwise not consistent with the expectations of financial analysts or investors.

Our actual financial position and results of operations may differ materially from the unaudited pro forma financial data included in this Annual Report.

The pro forma financial data contained in this Annual Report are presented for illustrative purposes only and may not be an indication of what our financial condition or results of operations would have been had the Business Combination been completed on the dates indicated. The pro forma financial data have been derived from the audited and unaudited historical financial statements of Old Alkermes and EDT, and certain adjustments and assumptions have been made regarding the combined company after giving effect to the Business Combination. The information upon which these adjustments and assumptions have been made is preliminary, and these kinds of adjustments and assumptions are difficult to make with complete accuracy. For example, the pro forma financial data do not reflect all costs that we expect to incur in connection with the Business Combination. Accordingly, the actual financial condition and results of operations of the combined company following the Business Combination may not be consistent with, or evident from, this pro forma financial data.

In addition, the assumptions used in preparing the pro forma financial information may not prove to be accurate, and other factors may affect our financial condition or results of operations. Any potential decline in our financial condition or results of operations may cause significant variations in our share price.

If goodwill or other intangible assets become impaired, we could have to take significant charges against earnings.

In connection with the accounting for the Business Combination, we recorded a significant amount of goodwill and other intangible assets. Under accounting principles generally accepted in the U.S. ("GAAP"), we must assess, at least annually and potentially more frequently, whether the value of goodwill and other indefinite-lived intangible assets have been impaired. Amortizing intangible assets will be assessed for impairment in the event of an impairment indicator. Any reduction or impairment of the value of goodwill or other intangible assets will result in a charge against earnings, which could materially adversely affect our results of operations and shareholders' equity in future periods.

Our investments are subject to general credit, liquidity, market and interest rate risks, which may be exacerbated by volatility in the U.S. credit markets.

As of March 31, 2012, a significant amount of our investments were invested in U.S. government treasury and agency securities. Our investment objectives are, first, to preserve liquidity and conserve capital and, second, to generate investment income. Should our investments cease paying or reduce the amount of interest paid to us, our interest income would suffer. In addition, general credit, liquidity, market and interest risks associated with our investment portfolio may have an adverse effect on our financial condition.

Our effective tax rate may increase.

As a global biotechnology company, we are subject to taxation in a number of different jurisdictions. As a result, our effective tax rate is derived from a combination of applicable tax rates in the various places that we operate. In preparing our financial statements, we estimate the amount of tax that will become payable in each of these places. Our effective tax rate may fluctuate depending on a number of factors, including the distribution of our profits or losses between the jurisdictions where we operate, differences in interpretation of tax laws, etc. In addition, the tax laws of any jurisdiction in which we operate may change in the future which could impact our effective tax rate. Tax authorities in the jurisdictions in which we operate may audit the Company. If we are unsuccessful in defending any tax positions adopted in our submitted tax returns, we may be required to pay taxes for prior periods, interest, fines or penalties, and may be obligated to pay increased taxes in the future, any of which could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

The Business Combination of Old Alkermes and EDT may limit our ability to use our tax attributes to offset taxable income, if any, generated from such Business Combination.

For U.S. federal income tax purposes, a corporation is generally considered tax resident in the place of its incorporation. Because we are incorporated in Ireland, we should be deemed an Irish corporation under these general rules. However, Section 7874 of the Internal Revenue Code of 1986, as amended ("the Code") generally provides that a corporation organized outside the U.S. that acquires substantially all of the assets of a corporation organized in the U.S. will be treated as a U.S. corporation (and, therefore, a U.S. tax resident) for U.S. federal income tax purposes if shareholders of the acquired U.S. corporation own at least 80% (of either the voting power or the value) of the stock of the acquiring foreign corporation after the acquisition by reason of holding stock in the domestic corporation, and the "expanded affiliated group" (as defined in Section 7874) that includes the

acquiring corporation does not have substantial business activities in the country in which it is organized.

In addition, Section 7874 provides that if a corporation organized outside the U.S. acquires substantially all of the assets of a corporation organized in the U.S., the taxable income of the U.S. corporation during the period beginning on the date the first assets are acquired as part of the acquisition, through the date which is ten years after the last date assets are acquired as part of the acquisition, shall be no less than the income or gain recognized by reason of the transfer during such period or by reason of a license of property by the expatriated entity after such acquisition to a foreign affiliate during such period, which is referred to as the "inversion gain," if shareholders of the acquired U.S. corporation own at least 60% (of either the voting power or the value) of the stock of the acquiring foreign corporation after the acquisition by reason of holding stock in the domestic corporation, and the "expanded affiliated group" of the acquiring corporation does not have substantial business activities in the country in which it is organized. In connection with the Business Combination, Old Alkermes transferred certain intellectual property to one of our Irish subsidiaries, and it is expected that Old Alkermes had sufficient net operating loss carryforwards available to substantially offset any taxable income generated from this transfer. If this rule was to apply to the Business Combination, among other things, Old Alkermes would not have been able to use any of the approximately $274 million of U.S. Federal net operating loss ("NOL") and $38 million of U.S. state NOL carryforwards that it had as of March 31, 2011 to offset any taxable income generated as part of the Business Combination or as a result of the transfer of intellectual property. We do not believe that either of these limitations should apply as a result of the Business Combination. However, the U.S. Internal Revenue Service (the "IRS") could assert a contrary position, in which case we could become involved in tax controversy with the IRS regarding possible additional U.S. tax liability. If we were to be unsuccessful in resolving any such tax controversy in our favor, we could be liable for significantly greater U.S. federal and state income tax than we anticipate being liable for through the Business Combination, including as a result of the transfer of intellectual property, which would place further demands on our cash needs.

Transfers of our ordinary shares may be subject to Irish stamp duty.

In certain circumstances, the transfer of shares in an Irish incorporated company will be subject to Irish stamp duty, which is a legal obligation of the buyer to pay. This duty is currently charged at the rate of 1.0% of the higher of the price paid and the market value of the shares acquired. However, transfers of book-entry interests in the Depository Trust Company ("DTC") representing our ordinary shares should not be subject to Irish stamp duty. Accordingly, transfers by shareholders who hold their ordinary shares beneficially through brokers, which in turn hold those shares through DTC, should not be subject to Irish stamp duty on transfers to holders who also hold through DTC. This treatment is available because our ordinary shares are traded on a recognized stock exchange in the U.S.

In relation to any transfer of our ordinary shares that is subject to Irish stamp duty, our articles of association allow us, in our absolute discretion, to create an instrument of transfer and pay (or procure the payment of) any stamp duty payable by a buyer or otherwise require an instrument of transfer to be executed to effect a transfer. In the event of any such payment, we are (on our behalf or on behalf of our affiliates) entitled to, at our discretion (i) seek reimbursement from the buyer or seller, (ii) set-off the amount of the stamp duty against future dividends payable to the buyer or seller and (iii) claim a first and permanent lien against the ordinary shares on which it has paid stamp duty. Our lien shall extend to all dividends paid on those shares.

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

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

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

Proxy contests have been waged against many companies in the biopharmaceutical industry over the last few years. If faced with a proxy contest, we may not be able to respond successfully to the contest, which would be disruptive to our business. Even if we are successful, our business could be adversely affected by a proxy contest involving us because:

- responding to proxy contests and other actions by activist shareholders can be costly and time-consuming, disrupting operations and diverting the attention of management and employees, and can lead to uncertainty;
- perceived uncertainties as to future direction may result in the loss of potential acquisitions, collaborations or in-licensing opportunities, and may make it more difficult to attract and retain qualified personnel and business partners; and
- if individuals are elected to a board of directors with a specific agenda, it may adversely affect our ability to effectively and timely implement our strategic plan and create additional value for our shareholders.

These actions could cause the market price of our ordinary shares to experience periods of volatility.

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

None.

Item 2. ***Properties***

We lease approximately 8,500 square feet of corporate office space in Dublin, Ireland, which houses our corporate headquarters. This lease expires in 2022 and includes a tenant option to terminate in 2017.

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

We own manufacturing, office and laboratory sites in Wilmington, Ohio (approximately 195,000 square feet); Athlone, Ireland (approximately 460,000 square feet); and Gainesville, Georgia (approximately 90,000 square feet).

We have entered into sublease agreements with various tenants to occupy space that we lease in Cambridge, Massachusetts under two leases, the original terms of which are effective until mid-calendar

year 2012. These leases contain provisions permitting us to extend their terms for up to two ten-year periods. We also have a sublease agreement in place for a commercial manufacturing facility we lease in Chelsea, Massachusetts designed for clinical and commercial manufacturing of inhaled products based on our pulmonary technology that we are not currently utilizing. The lease term is for fifteen years, expiring in 2015, with an option to extend the term for up to two five-year periods. As we are not currently utilizing these facilities, we have no plans to extend the Cambridge or Chelsea leases beyond their expiration dates.

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

Item 3. ***Legal Proceedings***

From time to time, we may be subject to legal proceedings and claims in the ordinary course of business. For example, we are currently involved in various sets of Paragraph IV litigations in the United States and similar suits in Canada and France in respect of certain of our products. We are not aware of any such proceedings or claims that we believe will have, individually or in the aggregate, a material adverse effect on our business, results of operations, cash flows and financial condition.

Item 4. ***Mine Safety Disclosures***

Not Applicable.

PART II

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

Market and Shareholder Information

Our ordinary shares are traded on the NASDAQ Global Select Stock Market under the symbol "ALKS." Set forth below for the indicated periods are the high and low closing sales prices for our ordinary shares. The share price for the period prior to September 16, 2011 is that of Old Alkermes, while the share price for the period after September 16, 2011 is that of Alkermes.

	Fiscal 2012		Fiscal 2011	
	High	Low	High	Low
1st Quarter	$ 18.60	$ 13.06	$ 13.75	$ 10.70
2nd Quarter	19.52	13.91	14.87	12.09
3rd Quarter	18.03	13.88	15.92	10.48
4th Quarter	19.50	16.14	14.63	12.14

There were 269 shareholders of record for our ordinary shares on May 11, 2012. In addition, the last reported sale price of our ordinary shares as reported on the NASDAQ Global Select Stock Market on May 11, 2012 was $18.09.

Dividends

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

Securities authorized for issuance under equity compensation plans

For information regarding securities authorized for issuance under equity compensation plans, see Part III, Item 12, "Security Ownership of Certain Beneficial Owners and Management," which incorporates by reference to the Proxy Statement relating to our 2012 Annual Meeting of Shareholders (the "2012 Proxy Statement").

Repurchase of equity securities

On September 16, 2011, our board of directors authorized the continuation of the Alkermes, Inc. program to repurchase up to $215.0 million of our ordinary shares at the discretion of management from time to time in the open market or through privately negotiated transactions. We did not purchase any shares under this program during the quarter ended March 31, 2012. As of March 31, 2012, we had purchased a total of 8,866,342 shares at a cost of $114.0 million.

Irish Taxes Applicable to U.S. Holders

The following is a general summary of the main Irish tax considerations applicable to the purchase, ownership and disposition of our ordinary shares by U.S. holders. It is based on existing Irish law and practices in effect on 30 April 2012 and on discussions and correspondence with the Irish Revenue Commissioners. Legislative, administrative or judicial changes may modify the tax consequences described below.

The statements do not constitute tax advice and are intended only as a general guide. Furthermore, this information applies only to ordinary shares held as capital assets and does not apply to all categories of shareholders, such as dealers in securities, trustees, insurance companies, collective investment schemes and shareholders who acquire, or who are deemed to acquire their ordinary shares by virtue of an office or employment. This summary is not exhaustive and shareholders should consult their own tax advisers as to the tax consequences in Ireland, or other relevant jurisdictions where we operate, including the acquisition, ownership and disposition of ordinary shares.

Withholding and Income Tax on Dividends.

While we have no current plans to pay dividends, dividends on our ordinary shares would generally be subject to Irish dividend withholding tax ("DWT") at the standard rate of income tax, which is currently 20%, unless an exemption applies. Dividends on our ordinary shares that are owned by residents of the U.S. and held beneficially through the Depositary Trust Company ("DTC") will not be subject to DWT provided that the address of the beneficial owner of the ordinary shares in the records of the broker is in the U.S.

Dividends on our ordinary shares that are owned by residents of the U.S. and held directly would be paid on or before one year after the "relevant date," as defined below without any DWT if the shareholder held shares of Alkermes, Inc. common stock on September 8, 2011, the date on which it was publicly announced that the last Alkermes, Inc. stockholder vote approving the merger had passed, which is referred to as the "relevant date," and has provided a valid Form W-9 showing a U.S. address or a valid U.S. taxpayer identification number to our transfer agent or if the shareholder did not hold shares of Alkermes, Inc. common stock on the relevant date and has provided the appropriate Irish dividend withholding tax forms to our transfer agent, in either case, by the due date to be determined by us before the record date for the first dividend to which the shareholder is entitled.

In addition, all shareholders who hold their ordinary shares directly and who are residents of the U.S., regardless of when such shareholders acquired their ordinary shares must complete the appropriate Irish DWT forms in order to receive dividends paid later than one year after the relevant date without DWT. Such shareholders must provide the appropriate Irish forms to their brokers so that such brokers can further transmit the relevant information to our qualifying intermediary before the record date for the first dividend paid later than one year after the relevant date, in the case of ordinary shares held beneficially, or to our transfer agent by the due date to be determined by us before such record date, in the case of ordinary shares held directly.

If any shareholder who is resident in the U.S. receives a dividend subject to DWT, he or she should generally be able to make an application for a refund from the Irish Revenue Commissioners on the prescribed form.

Irish income tax, if any, may arise in respect of dividends paid by us. However, a shareholder who is neither resident nor ordinarily resident in Ireland and who is entitled to an exemption from DWT, generally has no liability for Irish income tax or to the universal social charge on a dividend from us unless he or she holds his or her ordinary shares through a branch or agency in Ireland which carries out a trade on his or her behalf.

While the U.S./Ireland Double Tax Treaty contains provisions regarding withholding, due to the wide scope of the exemptions from DWT available under Irish domestic law, it would generally be unnecessary for a U.S. resident shareholder to rely on the treaty provisions.

Capital Acquisitions Tax

Irish capital acquisitions tax ("CAT") is comprised principally of gift tax and inheritance tax. CAT could apply to a gift or inheritance of our ordinary shares irrespective of the place of residence,

ordinary residence or domicile of the parties. This is because our ordinary shares are regarded as property situated in Ireland as our share register must be held in Ireland. The person who receives the gift or inheritance has primary liability for CAT.

CAT is levied at a rate of 30% above certain tax-free thresholds. The appropriate tax-free threshold is dependent upon (i) the relationship between the donor and the recipient and (ii) the aggregation of the values of previous gifts and inheritances received by the recipient from persons within the same category of relationship for CAT purposes. Gifts and inheritances passing between spouses are exempt from CAT. Our shareholders should consult their own tax advisers as to whether CAT is creditable or deductible in computing any domestic tax liabilities.

Stamp Duty

Irish stamp duty, if any, may become payable in respect of ordinary share transfers. However, a transfer of our ordinary shares from a seller who holds shares through DTC to a buyer who holds the acquired shares through DTC will not be subject to Irish stamp duty. A transfer of our ordinary shares (i) by a seller who holds ordinary shares outside of DTC to any buyer, or (ii) by a seller who holds the ordinary shares through DTC to a buyer who holds the acquired ordinary shares outside of DTC, may be subject to Irish stamp duty, which is currently at the rate of 1% of the price paid or the market value of the ordinary shares acquired, if greater. The person accountable for payment of stamp duty is the buyer or, in the case of a transfer by way of a gift or for less than market value, all parties to the transfer.

A shareholder who holds ordinary shares outside of DTC may transfer those ordinary shares into DTC without giving rise to Irish stamp duty provided that the shareholder would be the beneficial owner of the related book-entry interest in those ordinary shares recorded in the systems of DTC, and in exactly the same proportions, as a result of the transfer and at the time of the transfer into DTC there is no sale of those book-entry interests to a third party being contemplated by the shareholder. Similarly, a shareholder who holds ordinary shares through DTC may transfer those ordinary shares out of DTC without giving rise to Irish stamp duty provided that the shareholder would be the beneficial owner of the ordinary shares, and in exactly the same proportions, as a result of the transfer, and at the time of the transfer out of DTC there is no sale of those ordinary shares to a third party being contemplated by the shareholder. In order for the share registrar to be satisfied as to the application of this Irish stamp duty treatment where relevant, the shareholder must confirm to us that the shareholder would be the beneficial owner of the related book-entry interest in those ordinary shares recorded in the systems of DTC, and in exactly the same proportions or vice-versa, as a result of the transfer and there is no agreement for the sale of the related book-entry interest or the ordinary shares or an interest in the ordinary shares, as the case may be, by the shareholder to a third party being contemplated.

Stock Performance Graph

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

The following graph compares the yearly percentage change in the cumulative total shareholder return on our ordinary shares for the last five fiscal years, with the cumulative total return on the Nasdaq Stock Market (U.S. and Foreign) Index and the Nasdaq Biotechnology Index. It is important to note that information set forth in the graph below with respect to the time period prior to September 16, 2011 refers to the common stock performance of Old Alkermes, while that information with respect to the time period after September 16, 2011 refers to the ordinary share performance of Alkermes plc. The comparison assumes $100 was invested on March 31, 2007 in our common stock and in each of the foregoing indices and further assumes reinvestment of any dividends. We did not declare or pay any dividends on our common stock during the comparison period.

Comparison of Cumulative Total Returns

Comparison of Cumulative Total Returns

	2007	2008	2009	2010	2011	2012
Alkermes, Inc. (until September 16, 2011) and Alkermes plc (as of September 17, 2011)	100	77	79	84	84	120
NASDAQ Stock Market (U.S. and Foreign) Index	100	95	64	102	119	134
NASDAQ Biotechnology Index	100	101	88	121	134	165

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

The selected historical financial data set forth below at March 31, 2012 and 2011 and for the years ended March 31, 2012, 2011 and 2010 are derived from our audited consolidated financial statements, which are included elsewhere in this Annual Report. On September 16, 2011, the business of Old Alkermes and EDT were combined under Alkermes. The selected historical financial data set forth below at March 31, 2009, 2008 and 2007 and for the years ended March 31, 2009 and 2008 are derived from audited consolidated financial statements, which are not included in this Annual Report. The selected historical financial data for the period prior to September 16, 2011 is that of Old Alkermes, while the selected historical financial data for the period after September 16, 2011 is that of Alkermes.

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

	Year Ended March 31,				
	2012(1)	2011	2010	2009	2008
	(In thousands, except per share data)				
Consolidated Statements of Operations Data:					
REVENUES:					
Manufacturing and royalty revenues	$ 326,444	$ 156,840	$ 149,917	$ 150,091	$ 131,157
Product sales, net	41,184	28,920	20,245	4,467	
Research and development revenue	22,349	880	3,117	42,087	89,510
Net collaborative profit(2)			5,002	130,194	20,050
Total revenues	389,977	186,640	178,281	326,839	240,717
EXPENSES:					
Cost of goods manufactured and sold	127,578	52,185	49,438	43,396	40,677
Research and development	141,893	97,239	95,363	89,478	125,268
Selling, general and administrative(3)	137,632	82,847	76,514	59,008	59,508
Amortization and impairment of acquired intangible assets(4)	71,155				
Impairment of long-lived assets(5)					11,630
Restructuring(5)					6,423
Total expenses	478,258	232,271	221,315	191,882	243,506
OPERATING (LOSS) INCOME	(88,281)	(45,631)	(43,034)	134,957	(2,789)
OTHER (EXPENSE) INCOME(6)	(26,111)	(860)	(1,667)	(3,945)	175,619
(LOSS) INCOME BEFORE INCOME TAXES	(114,392)	(46,491)	(44,701)	131,012	172,830
INCOME TAX (BENEFIT) PROVISION	(714)	(951)	(5,075)	507	5,851
NET (LOSS) INCOME	$ (113,678)	$ (45,540)	$ (39,626)	$ 130,505	$ 166,979
(LOSS) EARNINGS PER COMMON SHARE:					
BASIC	$ (0.99)	$ (0.48)	$ (0.42)	$ 1.37	$ 1.66
DILUTED	$ (0.99)	$ (0.48)	$ (0.42)	$ 1.36	$ 1.62
WEIGHTED AVERAGE NUMBER OF COMMON SHARES OUTSTANDING:					
BASIC	114,702	95,610	94,839	95,161	100,742
DILUTED	114,702	95,610	94,839	96,252	102,923

	Year Ended March 31,				
	2012(1)	2011	2010	2009	2008
	(In thousands, except per share data)				
Consolidated Balance Sheet Data:					
Cash, cash equivalents and investments	$ 246,138	$ 294,730	$ 350,193	$ 404,482	$ 460,361
Total assets	1,435,217	452,448	515,600	566,486	656,311
Long-term debt(7)	444,460			75,888	160,371
Unearned milestone revenue current and long-term					117,657
Shareholders' equity	853,852	392,018	412,616	434,888	305,314

(1) On September 16, 2011, the business of Old Alkermes and EDT were combined under Alkermes. We paid Elan $500.0 million in cash and issued Elan 31.9 million ordinary shares of the Company, which had a fair value of approximately $525.1 million on the closing date, for the EDT business. Alkermes are included for all periods being presented, whereas the operating results of the acquiree, EDT, are included only after the date of acquisition, September 16, 2011, through the end of the period.

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

(3) Includes $29.1 million and $1.1 million of expenses in the years ended March 31, 2012 and 2011, respectively, related to the acquisition of EDT, which consists primarily of banking, legal and accounting expenses.

(4) Includes $25.4 million of amortization of intangibles in the year ended March 31, 2012, acquired in connection with the Business Combination and the impairment of $45.8 million of IPR&D.

(5) Represents charges in connection with the termination of the AIR Insulin development program and our March 2008 restructuring of operations. In connection with the termination of the AIR Insulin development program, we determined that the carrying value of the assets at our AIR commercial manufacturing facility exceeded their fair value and recorded an impairment charge. The March 2008 restructuring program was substantially completed during fiscal 2009. Certain closure costs related to the leased facilities exited in connection with the March 2008 restructuring of operations will continue to be paid through December 2015.

(6) Includes a gain on the sale of our Series C convertible, redeemable preferred stock of Reliant Pharmaceuticals, Inc. ("Reliant") during the year ended March 31, 2008 of $174.6 million. This gain was recorded upon the acquisition of Reliant by GlaxoSmithKline in November 2007. We purchased the Series C convertible, redeemable preferred stock of Reliant for $100.0 million in December 2001, and our investment in Reliant had been written down to zero prior to the time of the sale.

(7) At March 31, 2012, long-term debt includes both the current and long-term portion of the $310.0 million first lien term loan facility (the "First Lien Term Loan") and the $140.0 million second lien term loan facility (the "Second Lien Term Loan" and, together with the First Lien Term Loan, the "Term Loans"). The Term Loans were issued on September 16, 2011. At March 31, 2009 and 2008, long-term debt included both the current and long-term portion of the Non-Recourse RISPERDAL CONSTA secured 7% Notes (the "non-recourse 7% Notes"). The non-recourse 7% Notes were issued by RC Royalty Sub LLC, a wholly-owned subsidiary of Old Alkermes ("Royalty Sub") on February 1, 2005 and were non-recourse to Alkermes. These notes were fully redeemed on July 1, 2010 in advance of the previously scheduled maturity date of January 1, 2012. Royalty Sub was dissolved during the year ended March 31, 2012.

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

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

Overview

We develop medicines that address the unmet needs and challenges of people living with chronic disease. A fully integrated global biopharmaceutical company, we apply proven scientific expertise, proprietary technologies and global development capabilities to the creation of innovative treatments for major clinical conditions with a focus on CNS disorders, such as schizophrenia, addiction and depression. We create new, proprietary pharmaceutical products for our own account, and we collaborate with other pharmaceutical and biotechnology companies. We are increasingly focused on maintaining rights to commercialize our leading product candidates in certain markets.

On September 16, 2011, the business of Old Alkermes and EDT were combined under Alkermes. As part of the Business Combination, a wholly owned subsidiary of the Company merged with and into Old Alkermes, with Old Alkermes surviving as a wholly owned subsidiary of the Company. At the effective time of the Business Combination, (i) each share of Old Alkermes common stock then issued and outstanding and all associated rights were canceled and automatically converted into and became the right to receive one ordinary share of Alkermes and (ii) all issued and outstanding options and stock awards to purchase Old Alkermes common stock granted under any equity compensation plan were converted into options and stock awards to purchase on substantially the same terms and conditions the same number of Alkermes ordinary shares at the same exercise price. We paid Elan $500.0 million in cash and issued Elan 31.9 million ordinary shares of the Company, which had a fair value of approximately $525.1 million on the closing date, for the EDT business. Upon consummation of the Business Combination, the former shareholders of Old Alkermes owned approximately 75% of the Company, with the remaining approximately 25% of the Company owned by a subsidiary of Elan.

On March 13, 2012, Alkermes plc completed an underwritten public offering of 24,150,000 of the ordinary shares of Alkermes plc held by Elan. After completion of the offering, Elan, through its subsidiary, owned 7,750,000 of our ordinary shares, equivalent to 6% of the outstanding equity of the Company as of March 31, 2012.

For a more detailed discussion of the Business Combination, refer to the notes to our condensed consolidated financial statements, including Note 1, *The Company*, and Note 3, *Acquisitions*, in the accompanying Notes to Consolidated Financial Statements for the year ended March 31, 2012.

The Business Combination is being accounted for using the acquisition method of accounting for business combinations with Old Alkermes being treated as the accounting acquirer under U.S. GAAP, which means that the operating results of Old Alkermes are included for all periods being presented, whereas the operating results of the acquiree, EDT, are included only after the date of acquisition, September 16, 2011, through the end of the period.

Executive Summary

We and our pharmaceutical and biotechnology partners have more than 20 commercialized products sold worldwide, including in the U.S. We earn manufacturing and/or royalty revenues on net sales of products commercialized by our partners and earn revenue on net sales of VIVITROL, which is a proprietary product that we manufacture, market and sell in the U.S. Our five key products are

expected to generate significant revenues for us in the near- and medium-term, as they possess long patent lives, are singular or competitively advantaged products in their class and are generally in the launch phases of their commercial lives. These five key products are: RISPERDAL CONSTA and INVEGA SUSTENNA/XEPLION; AMPYRA/FAMPYRA; BYDUREON; and VIVITROL.

For the year ended March 31, 2012, we reported $390.0 million in revenues, which included the revenues generated from products associated with the former EDT business, and represented an increase of more than 109% over the year ended March 31, 2011 compared to those for Old Alkermes. Revenues from our five key products accounted for 60% of our total consolidated revenues for the year ended March 31, 2012.

For the year ended March 31, 2012, total expenses increased by $246.0 million, as compared to the year ended March 31, 2011, due primarily to the addition of EDT. Expenses from the EDT business were $175.0 million for the year ended March 31, 2012, and we incurred $29.1 million during the year ended March 31, 2012 related to the EDT acquisition, which consisted primarily of banking, legal and accounting services.

On September 16, 2011, we entered into the Term Loans with MSSF and HSBC. The $310.0 million First Lien Term Loan has an initial applicable margin for borrowings of three-month LIBOR plus 5.25%, was issued with an original issue discount of $3.1 million and has a term of six years. The $140.0 million Second Lien Term Loan has an initial applicable margin for borrowings of three-month LIBOR plus 8.00%, was issued with an original issue discount of $2.8 million, and has a term of seven years. Under each of the Term Loans, LIBOR is subject to an interest rate floor of 1.50%. Required quarterly principal payments of $0.8 million on the First Lien Term Loan began during the three months ended March 31, 2012. In addition, beginning in fiscal year 2013, we are required to make principal payments on the First Lien Term Loan for amounts up to 50% of excess cash flows as defined in the First Lien Term Loan credit agreement. The principal amount of the Second Lien Term Loan is due and payable in full on the maturity date. If prepayments are made prior to September 16, 2012, we may be subject to prepayment premium of 1% of the amount of the term loans being repaid if the prepayment is made in connection with a refinancing transaction or 1% of the amount of the outstanding term loans if the prepayment is made in connection with an amendment to the agreement resulting in a refinancing transaction.

Results of Operations

Manufacturing and Royalty Revenues

	Years Ended March 31,			Change Favorable/(Unfavorable)	
(in millions)	**2012**	**2011**	**2010**	**2012 - 2011**	**2011 - 2010**
Manufacturing and royalty revenues:					
RISPERDAL CONSTA	$ 168.3	$ 154.3	$ 146.0	$ 14.0	$ 8.3
TRICOR 145	27.8			27.8	
AMYPRA/FAMPYRA	24.6			24.6	
RITALIN LA/FOCALIN XR	23.1			23.1	
INVEGA SUSTENNA/XEPLION	18.0			18.0	
VERELAN	14.2			14.2	
BYDUREON	1.5			1.5	
Other	48.9	2.5	3.9	46.4	(1.4)
Manufacturing and royalty revenues	$ 326.4	$ 156.8	$ 149.9	$ 169.6	$ 6.9

Manufacturing revenues are earned from the sale of products we manufacture for resale by our collaborative partners. Royalty revenues are earned on our collaborators' sales of products that incorporate our technologies. Royalties are generally recognized in the period the products are sold by our collaborators.

Under our RISPERDAL CONSTA supply and license agreements with Janssen, we earned manufacturing revenues at 7.5% of Janssen's unit net sales price of RISPERDAL CONSTA and royalty revenues at 2.5% Janssen's net sales of RISPERDAL CONSTA in the fiscal years ending March 31, 2012, 2011 and 2010. The increase in RISPERDAL CONSTA manufacturing and royalty revenues for the year ended March 31, 2012, as compared to the year ended March 31, 2011, was primarily due to an 8% increase in the number of units shipped to Janssen and a 1% increase in royalties. The increase in royalties was due to an increase in Janssen's end-market sales of RISPERDAL CONSTA from $1,525.6 million during the year ended March 31, 2011 to $1,540.3 million during the year ended March 31, 2012. The increase in RISPERDAL CONSTA manufacturing and royalty revenues for the year ended March 31, 2011, as compared to the year ended March 31, 2010, was primarily due to a 16% increase in the number of units shipped to Janssen and a 3% increase in royalties, partially offset by a 5% decrease in the net unit sales price due to currency fluctuations and a 1% decrease in the net unit sales price due in part to the effect from the U.S. healthcare reform law. The increase in royalties was due to an increase in Janssen's end-market sales of RISPERDAL CONSTA from $1,477.6 million during the year ended March 31, 2010 to $1,525.6 million during the year ended March 31, 2011. Units sold in countries outside the U.S. by Janssen in the years ended March 31, 2012, 2011 and 2010 accounted for 83%, 83% and 79% of the total units sold, respectively. See "Item 7A. Quantitative and Qualitative Disclosures about Market Risk" for information on currency exchange rate risk related to RISPERDAL CONSTA revenues.

We expect revenues from RISPERDAL CONSTA and INVEGA SUSTENNA/XEPLION, our long acting atypical antipsychotic franchise, to continue to grow, as INVEGA SUSTENNA/XEPLION is launched around the world. A number of companies, including us, are working to develop products to treat schizophrenia and/or bipolar disorder that may compete with RISPERDAL CONSTA and INVEGA SUSTENNA/XEPLION. Increased competition may lead to reduced unit sales of RISPERDAL CONSTA and INVEGA SUSTENNA/XEPLION, as well as increasing pricing pressure. RISPERDAL CONSTA is covered by a patent until 2021 in the EU and 2023 in the U.S., and INVEGA SUSTENNA/XEPLION is covered by a patent until 2018 in the EU and 2019 in the U.S., and as such, we do not anticipate any generic versions in the near-term for either of these products.

The increase in royalty revenues from TRICOR 145, AMPYRA/FAMPYRA, RITALIN LA/FOCALIN XR, INVEGA SUSTENNA/XEPLION, VERELAN and the other manufacturing and royalty revenues were primarily due to the addition of the portfolio of commercialized products from the former EDT business on September 16, 2011, which was the closing date of the Business Combination. A number of our mature products, including RITALIN LA and VERELAN, are currently facing generic competition and TRICOR 145 and FOCALIN XR will face generic competition in fiscal year 2013. As a result, we expect sales of these products to decline over the next few fiscal years.

We expect AMPYRA/FAMPYRA sales to continue to grow as Acorda continues to penetrate the U.S. market with AMPYRA and Biogen Idec continues to launch FAMPYRA in the rest of the world. AMPYRA is covered by a patent until 2027 in the U.S. and FAMPYRA is covered by a patent until 2025 in the EU, and as such, we do not anticipate any generic versions of these products in the near-term. A number of companies are working to develop products to treat multiple sclerosis that may compete with AMPYRA/FAMPYRA, which may negatively impact future sales of the products.

Product Sales, Net

Our product sales consist of sales of VIVITROL in the U.S. to wholesalers, specialty distributors and specialty pharmacies. The following table presents the adjustments to arrive at VIVITROL product sales, net for sales of VIVITROL in the U.S. during the years ended March 31, 2012, 2011 and 2010:

	Year Ended March 31, 2012		Year Ended March 31, 2011		Year Ended March 31, 2010	
(in millions)	**Amount**	**% of Sales**	**Amount**	**% of Sales**	**Amount**	**% of Sales**
Product sales, gross	$ 57.6	100.0%	$ 39.3	100.0%	$ 24.7	100.0%
Adjustments to product sales, gross:						
Medicaid rebates	(4.6)	(8.0)%	(3.1)	(8.0)%	(0.9)	(3.6)%
Chargebacks	(4.1)	(7.1)%	(2.4)	(6.1)%	(1.2)	(4.9)%
Wholesaler fees	(3.0)	(5.2)%	(2.2)	(5.6)%	(0.9)	(3.6)%
Reserve for inventory in the channel(1)	(1.3)	(2.3)%	(0.8)	(2.0)%	(0.5)	(2.0)%
Other	(3.4)	(5.9)%	(1.9)	(4.8)%	(1.0)	(4.1)%
Total adjustments	(16.4)	(28.5)%	(10.4)	(26.5)%	(4.5)	(18.2)%
Product sales, net	$ 41.2	71.5%	$ 28.9	73.5%	$ 20.2	81.8%

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

The increase in product sales, gross for the year ended March 31, 2012, as compared to the year ended March 31, 2011, was primarily due to a 34% increase in the number of units sold into the distribution channel and a 9% increase in price. The increase in product sales, gross for the year ended March 31, 2011, as compared to the year ended March 31, 2010, was primarily due to a 36% increase in the number of units sold into the distribution channel and a 17% increase in price. The increases in chargebacks during the year ended March 31, 2012, as compared to the year ended March 31, 2011 and the year ended March 31, 2011, as compared to the year ended March 31, 2010, was primarily due to the increase in the price of VIVITROL and increased 340B/PHS pricing discounts. The increases in Medicaid rebates during the year ended March 31, 2011, as compared to the year ended March 31, 2010, was primarily due to higher rebates resulting from a price increase in October 2010 and the impact of increased Medicaid rebate percentage and the extension of Medicaid rebates to Medicaid managed care organizations.

We expect VIVITROL sales to continue to grow as we continue to penetrate the opioid dependence indication market in the U.S. In addition, we anticipate that Janssen-Cilag will increase sales of VIVITROL in Russia and the CIS, which are recorded as manufacturing and royalty revenues, and there exists the potential to launch the product in other countries around the world. A number of companies, including us, are working to develop products to treat addiction, including alcohol and opioid dependence, that may compete with VIVITROL, which may negatively impact future sales of VIVITROL. Increased competition may lead to reduced unit sales of VIVITROL, as well as increasing pricing pressure. VIVITROL is covered by a patent that will expire in the U.S. in 2029 and in Europe in 2021 and, as such, we do not anticipate any generic versions of this product in the near-term.

Research and Development Revenue

	Years Ended March 31,			Change Favorable/(Unfavorable)	
(in millions)	**2012**	**2011**	**2010**	**2012 - 2011**	**2011 - 2010**
Research and development programs:					
BYDUREON	$ 14.1	$ 0.6	$ 0.7	$ 13.5	$ (0.1)
Other	8.2	0.3	0.4	7.9	(0.1)
Research and development revenue	$ 22.3	$ 0.9	$ 1.1	$ 21.4	$ (0.2)

R&D revenue is generally earned for services performed and milestones achieved under arrangements with our collaborators. The increase in R&D revenue for the year ended March 31, 2012, as compared to the year ended March 31, 2011, was primarily due to $14.0 million in BYDUREON milestone payments we received during the year. Under our agreement with Amylin, we received a $7.0 million milestone payment related to the first commercial sale of BYDUREON in the EU and a $7.0 million milestone payment related to the first commercial sale of BYDUREON in the U.S. During the year ended March 31, 2012, we also received a $3.0 million milestone payment upon receipt of regulatory approval for VIVITROL in Russia for the opioid dependence indication.

Costs and Expenses

Cost of Goods Manufactured and Sold

	Years Ended March 31,			Change Favorable/(Unfavorable)	
(in millions)	**2012**	**2011**	**2010**	**2012 - 2011**	**2011 - 2010**
Cost of goods manufactured and sold	$ 127.6	$ 52.2	$ 49.4	$ (75.4)	$ (2.8)

The increase in cost of goods manufactured and sold in the year ended March 31, 2012, as compared to the year ended March 31, 2011, was primarily due to the addition of $70.0 million of cost of goods manufactured from the addition of EDT's portfolio of commercialized products and a $3.0 million increase in VIVITROL cost of goods manufactured and sold primarily due to an increase in the number of units sold.

The increase in cost of goods manufactured and sold in the year ended March 31, 2011, as compared to the year ended March 31, 2010, was primarily due to a 16% increase in the number of units of RISPERDAL CONSTA shipped to Janssen, partially offset by an 11% decrease in the unit cost of RISPERDAL CONSTA. The decrease in the unit cost of RISPERDAL CONSTA was partially due to a $1.7 million decrease in costs incurred for scrap. We expect an increase in cost of goods manufactured and sold in fiscal year 2013, as compared to fiscal year 2012, as a result of the inclusion of a full year of operations from the former EDT business as well as from an increase in production volumes to support higher sales of AMPYRA/FAMPYRA and VIVITROL, as well as various other contract manufacturing activities.

Research and Development Expense

	Years Ended March 31,			Change Favorable/(Unfavorable)	
(in millions)	**2012**	**2011**	**2010**	**2012 - 2011**	**2011 - 2010**
Research and development					