

Alkermes plc.
Form 10-K
May 18, 2012

[QuickLinks](#) -- Click here to rapidly navigate through this document

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

Form 10-K

(Mark One)

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

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

(State or other jurisdiction of
incorporation or organization)

98-1007018

(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 No

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Exchange Act. Yes No

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes No

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

Edgar Filing: Alkermes plc. - Form 10-K

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.

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

Large accelerated filer

Accelerated filer

Non-accelerated filer

Smaller Reporting company

(Do not check if a
smaller reporting company)

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

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

INDEX

PART I		5
Item 1.	Business	5
Item 1A.	Risk Factors	32
Item 1B.	Unresolved Staff Comments	54
Item 2.	Properties	54
Item 3.	Legal Proceedings	55
Item 4.	Mine Safety Disclosures	55
PART II		
Item 5.	Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities	56
Item 6.	Selected Financial Data	60
Item 7.	Management's Discussion and Analysis of Financial Condition and Results of Operations	62
Item 7A.	Quantitative and Qualitative Disclosures about Market Risk	82
Item 8.	Financial Statements and Supplementary Data	84
Item 9.	Changes in and Disagreements With Accountants on Accounting and Financial Disclosures	85
Item 9A.	Controls and Procedures	85
Item 9B.	Other Information	86
PART III		
Item 10.	Directors, Executive Officers and Corporate Governance	87
Item 11.	Executive Compensation	87
Item 12.	Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters	87
Item 13.	Certain Relationships and Related Transactions, and Director Independence	87
Item 14.	Principal Accounting Fees and Services	87
PART IV		
Item 15.	Exhibits and Financial Statement Schedules	87
SIGNATURES		88

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;

Edgar Filing: Alkermes plc. - Form 10-K

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

Edgar Filing: Alkermes plc. - Form 10-K

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

Edgar Filing: Alkermes plc. - Form 10-K

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

Edgar Filing: Alkermes plc. - Form 10-K

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
<i>RISPERDAL</i> <i>CONSTA</i>	Schizophrenia Bipolar I Disorder	Extended-release microsphere	Worldwide	Manufacturing and Royalty	Janssen
<i>INVEGA</i> <i>SUSTENNA</i> <i>XEPLION</i>	Schizophrenia	NanoCrystal®	Worldwide	Royalty	Janssen
<i>AMPRYA</i> <i>FAMPYRA</i>	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)
<i>BYDUREON</i>	Type 2 diabetes	Extended-release microsphere	U.S. European Union U.A.E.	Royalty	Amylin
<i>VIVITROL</i>	Alcohol dependence Opioid dependence	Extended-release microsphere	U.S. Russia and Commonwealth of Independent States ("CIS")	Product sales Manufacturing and Royalty	Alkermes plc Janssen
<i>TRICOR®</i> <i>LIPANTHYL®</i> <i>LIPIDIL®</i> <i>SUPRALIP®</i>	Cholesterol lowering	NanoCrystal	Worldwide	Royalty	Abbott
<i>ZANAFLEX®</i> <i>CAPSULES®</i> <i>ZANAFLEX®</i> <i>TABLETS</i>	Muscle spasticity	OCR (SODAS®)	U.S.	Manufacturing and Royalty	Acorda
<i>AVINZA®</i>	Chronic moderate to severe pain	OCR (SODAS)	U.S.	Manufacturing and Royalty	Pfizer
<i>EMEND®</i>	Nausea associated with chemotherapy and surgery	NanoCrystal	Worldwide	Royalty	Merck
<i>FOCALIN® XR</i> <i>RITALIN LA®</i>	Attention Deficit Hyperactivity Disorder	OCR (SODAS)	Worldwide	Manufacturing and Royalty	Novartis
<i>MEGACE® ES</i>	Cachexia associated with AIDS	NanoCrystal	U.S.	Royalty	Strativa Pharmaceuticals (a business division of Par Pharmaceutical Companies, Inc.)

Edgar Filing: Alkermes plc. - Form 10-K

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

Edgar Filing: Alkermes plc. - Form 10-K

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, remifentanyl, 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.

Edgar Filing: Alkermes plc. - Form 10-K

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.

Edgar Filing: Alkermes plc. - Form 10-K

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.

Edgar Filing: Alkermes plc. - Form 10-K

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[®] (buprenorphine HCl/naloxone HCl dehydrate sublingual tablets), SUBOXONE[®] (buprenorphine/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.

Edgar Filing: Alkermes plc. - Form 10-K

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.

Edgar Filing: Alkermes plc. - Form 10-K

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."

Edgar Filing: Alkermes plc. - Form 10-K

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.

(in thousands)	Year Ended March 31,		
	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.

Edgar Filing: Alkermes plc. - Form 10-K

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

Edgar Filing: Alkermes plc. - Form 10-K

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.

Edgar Filing: Alkermes plc. - Form 10-K

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

Edgar Filing: Alkermes plc. - Form 10-K

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;

Edgar Filing: Alkermes plc. - Form 10-K

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 infringing 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

Edgar Filing: Alkermes plc. - Form 10-K

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.

Edgar Filing: Alkermes plc. - Form 10-K

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

Edgar Filing: Alkermes plc. - Form 10-K

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. RISPEDAL 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. RISPEDAL 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 (buprenorphine HCl/naloxone HCl dehydrate sublingual tablets), SUBOXONE (buprenorphine/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

Edgar Filing: Alkermes plc. - Form 10-K

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;

Edgar Filing: Alkermes plc. - Form 10-K

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

Edgar Filing: Alkermes plc. - Form 10-K

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.

Edgar Filing: Alkermes plc. - Form 10-K

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

Edgar Filing: Alkermes plc. - Form 10-K

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.

Edgar Filing: Alkermes plc. - Form 10-K

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,

Edgar Filing: Alkermes plc. - Form 10-K

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

Edgar Filing: Alkermes plc. - Form 10-K

	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

Edgar Filing: Alkermes plc. - Form 10-K

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

(in millions)	Years Ended March 31,			Change	
	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	
AMPYRA/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

Edgar Filing: Alkermes plc. - Form 10-K

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:

(in millions)	Year Ended March 31, 2012		Year Ended March 31, 2011		Year Ended March 31, 2010	
	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

(in millions)	Years Ended March 31,			Change Favorable/(Unfavorable)	
	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**

(in millions)	Years Ended March 31,			Change Favorable/(Unfavorable)	
	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

(in millions)	Years Ended March 31,			Change Favorable/(Unfavorable)	
	2012	2011	2010	2012 - 2011	2011 - 2010
Research and development	\$ 141.9	\$ 97.2	\$ 95.4	\$ (44.7)	\$ (1.8)

Edgar Filing: Alkermes plc. - Form 10-K

The increase in R&D expense in the year ended March 31, 2012, as compared to the year ended March 31, 2011, was primarily due to the addition of \$15.5 million of R&D expense for the former EDT business, and an increase in the following expenses from the Old Alkermes business: \$13.6 million in clinical study and laboratory expense; \$6.8 million in professional service expense; and \$9.9 million in employee-related expense, partially offset by a \$2.8 million decrease in license and collaboration fees. The increase in clinical study, laboratory and professional service expense was primarily due to increased activity related to our ALKS 37 and ALKS 9070 development programs, and the increase in employee-related expense is primarily due to an increase in headcount within the Old Alkermes business and share-based compensation expense as recent equity grants were awarded with a higher grant-date fair value than older grants. The decrease in license and collaboration fees was primarily due to a decrease in expense under a collaboration agreement with Acceleron Pharma, Inc. ("Acceleron").

The increase in R&D expenses for the year ended March 31, 2011, as compared to the year ended March 31, 2010, was primarily due to an increase of \$11.7 million in internal clinical and preclinical study, laboratory and license and collaboration expenses, a \$7.3 million increase in professional services and a \$7.0 million increase in employee-related expenses. The increase in internal clinical and preclinical study, laboratory and license and collaboration expenses was primarily due to an increase in the number of, and composition of, ongoing clinical and preclinical studies. The increase in professional services was primarily due to activities related to the approval of VIVITROL for opioid dependence, and the increase in employee-related expenses was primarily due to an increase in share-based compensation expense due to recent equity grants awarded with a higher grant date fair value than older grants, as well as the exclusion of certain prior grants that have vested and are no longer included in share-based compensation expense. These increases were partially offset by \$24.0 million in savings in depreciation, relocation and occupancy as a result of the relocation of our corporate headquarters from Cambridge, Massachusetts to Waltham, Massachusetts in fiscal year 2010.

We expect a modest increase in R&D expense in the year ended March 31, 2013 primarily due to increased R&D investment as certain of our key development programs, notably ALKS 9070, ALKS 37 and ALKS 5461 continue to advance through the pipeline and due to the inclusion of a full year of operations from the former EDT business.

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

Selling, General and Administrative Expense

(in millions)	Years Ended March 31,			Change Favorable/(Unfavorable)	
	2012	2011	2010	2012 - 2011	2011 - 2010
Selling, general and administrative	\$ 137.6	\$ 82.8	\$ 76.5	\$ (54.8)	\$ (6.3)

The increase in selling, general and administrative ("SG&A") costs for the year ended March 31, 2012, as compared to the year ended March 31, 2011, was primarily due to an increase of \$24.7 million

Edgar Filing: Alkermes plc. - Form 10-K

in professional service expense, \$8.0 million in employee-related expenses and \$3.0 million in marketing expense from the Old Alkermes business, as well as the addition of \$18.3 million of SG&A expense for the former EDT business. The increase in professional service was primarily due to costs incurred in connection with the Business Combination. The increase in employee-related expense was primarily due to an increase in headcount and share-based compensation expense as recent equity grants were awarded with a higher grant-date fair value than older grants, and the increase in marketing expenses was due to an analysis we performed to determine the marketability of our existing products and product candidates.

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

We expect an increase in SG&A expense in the year ended March 31, 2013 as a result of the inclusion of a full year of operations from the former EDT business.

Amortization and Impairment of Acquired Intangible Assets

(in millions)	Years Ended March 31,			Change Favorable/(Unfavorable)	
	2012	2011	2010	2012 - 2011	2011 - 2010
Amortization and impairment of acquired intangible assets	\$ 71.2	\$	\$	\$ (71.2)	\$

In connection with the Business Combination, we acquired certain amortizable intangible assets with a fair value of \$643.2 million, which are expected to be amortized over 12 to 13 years. We amortize our amortizable intangible assets using the economic use method, which reflects the pattern that the economic benefits of the intangible assets are consumed as revenue is generated from the underlying patent or contract. During the year ended March 31, 2012, we had \$25.4 million of amortization expense related to the intangible assets acquired as part of the Business Combination. Based upon our most recent analysis, amortization of intangible assets included within our consolidated balance sheet at March 31, 2012, is expected to be in the range of approximately \$40.0 million to \$70.0 million annually through fiscal year 2017.

In connection with the Business Combination, we acquired IPR&D of \$45.8 million, which related to three EDT product candidates including Megestrol for use in Europe at a value of \$28.8 million. During the fourth quarter of fiscal year 2012, and after finalization of the purchase accounting for the Business Combination, we identified events and changes in circumstance, such as correspondence from regulatory authorities and further clinical trial results related to three product candidates, including Megestrol for use in Europe, acquired as part of the Business Combination which indicated that the assets may be impaired. Accordingly, we performed an analysis to measure the amount of the impairment loss, if any. We performed the valuation of the IPR&D from the viewpoint of a market participant through the use of a discounted cash flow model. The model contained certain key assumptions including the cost to bring the products through the clinical trial and regulatory approval process; the gross margin a market participant would likely earn if the product were approved for sale; the cost to sell the approved product and a discount factor based on an industry average weighted average cost of capital. Based on the analysis performed, we determined that the IPR&D was impaired

Edgar Filing: Alkermes plc. - Form 10-K

and recorded an impairment charge of \$45.8 million within "Amortization and impairment of acquired intangible assets."

We also acquired \$92.7 million of goodwill in connection with the Business Combination, which is considered an indefinite-lived asset and is not amortized, but is subject to an annual review for impairment or when circumstances indicate the fair value may be below its carrying value. As a result of a qualitative assessment we performed as of October 31, 2011, we determined that it was not more-likely-than-not that the fair value of the reporting unit was less than its carrying amount, and an impairment of our goodwill was not recorded.

Other (Expense) Income

(in millions)	Years Ended March 31,			Change Favorable/(Unfavorable)	
	2012	2011	2010	2012 - 2011	2011 - 2010
Interest income	\$ 1.5	\$ 2.7	\$ 4.7	\$ (1.2)	\$ (2.0)
Interest expense	(28.1)	(3.3)	(6.0)	(24.8)	2.7
Other income (expense), net	0.5	(0.3)	(0.4)	0.8	0.1
Total other expense, net	\$ (26.1)	\$ (0.9)	\$ (1.7)	\$ (25.2)	\$ 0.8

The increase in interest expense for the year ended March 31, 2012, as compared to the year ended March 31, 2011, was primarily due to our entry into \$450.0 million of term loan financing in July 2011. The \$310.0 million First Lien Term Loan has a principal amount of \$310.0 million and an interest rate of three-month LIBOR plus 5.25%, and the \$140.0 million Second Lien Term Loan has a principal amount of \$140.0 million and an interest rate of three-month LIBOR plus 8.00%. Under the Term Loans, three-month LIBOR is subject to an interest rate floor of 1.50%. The Term Loans became effective upon the closing of the Business Combination in September 2011. Included in interest expense during the year ended March 31, 2012 are commitment fees of \$5.9 million which were incurred during the period from when we priced the Term Loans to when the Term Loans were funded.

We expect interest expense to increase in fiscal year 2013, as fiscal year 2013 will include a full year of interest expense on the \$450.0 million principal balance of the Term Loans. Beyond fiscal year 2013, we anticipate that interest expense will decrease as the Term Loans are paid down, assuming a consistent LIBOR rate.

The decrease in interest expense for the year ended March 31, 2011, as compared to the year ended March 31, 2010, was primarily due to the early redemption of our non-recourse 7% Notes on July 1, 2010. As a result of this transaction, we recorded charges of \$1.4 million relating to the write-off of the unamortized portion of deferred financing costs and \$0.8 million primarily related to the premium paid on the redemption of the non-recourse 7% Notes.

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

Provision for Income Taxes

(in millions)	Years Ended March 31,			Change Favorable/(Unfavorable)	
	2012	2011	2010	2012 - 2011	2011 - 2010
Income tax benefit	\$ (0.7)	\$ (1.0)	\$ (5.1)	\$ (0.3)	\$ (4.1)

Edgar Filing: Alkermes plc. - Form 10-K

Our income tax benefit for the year ended March 31, 2012 consists of a current income tax provision of \$14.0 million and a deferred income tax benefit of \$14.7 million. The current income tax provision is primarily due to a provision of \$13.1 million on the taxable transfer of the BYDUREON intellectual property from the U.S. to Ireland. The deferred tax benefit is primarily due to a benefit of \$4.6 million from the partial release of the Irish deferred tax liability relating to acquired intellectual property that was established in connection with the Business Combination and a benefit of \$9.9 million due to the partial release of an existing U.S. Federal valuation allowance as a consequence of the Business Combination. In connection with the Business Combination, we were incorporated, and are headquartered, in Dublin, Ireland. As a result, our statutory tax rate decreased from 34% in the U.S. to 12.5% in Ireland.

The income tax benefit of \$1.0 million for the year ended March 31, 2011 was primarily related to a \$0.8 million current tax benefit for bonus depreciation pursuant to the *U.S. Small Business Jobs Act of 2010*. The income tax benefit of \$5.1 million for the year ended March 31, 2010 primarily consisted of a current federal income tax benefit of \$3.3 million and a deferred federal and state tax benefit of \$1.8 million. The current federal income tax benefit was the result of a carryback of our 2010 alternative minimum tax ("AMT") NOL pursuant to the *U.S. Worker, Homeownership and Business Act of 2009*. This law increased the carryback period for certain NOLs from two years to five years. Prior to the adoption of this law, we had recorded a full valuation allowance against the credits that were established in prior periods when we were subject to AMT provisions. The deferred federal and state tax benefit was due to our recognition of a \$1.8 million income tax expense associated with the increase in the value of certain securities that we carried at fair market value during the year ended March 31, 2010. This income tax expense was recorded in other comprehensive (loss) income.

As of March 31, 2012, we had \$441.4 million of Irish NOL carryforwards, \$107.3 million of U.S. federal NOL carryforwards, \$15.4 million of state NOL carryforwards, and \$18.7 million of other foreign NOL and capital loss carryforwards, which either expire on various dates through 2032 or can be carried forward indefinitely. These loss carryforwards are available to reduce certain future Irish, U.S. and foreign taxable income, if any. These loss carryforwards are subject to review and possible adjustment by the appropriate taxing authorities. These loss carryforwards, which may be utilized in any future period, may be subject to limitations based upon changes in the ownership of our stock. We have performed a review of ownership changes in accordance with the U.S. Internal Revenue Code and have determined that it is more likely than not that, as a result of the Business Combination, we have experienced a change of ownership. As a consequence, our U.S. federal NOL carryforwards and tax credit carryforwards are subject to an annual limitation of \$127.0 million.

Liquidity and Capital Resources

Our financial condition is summarized as follows:

(in millions)	March 31, 2012	March 31, 2011
Cash and cash equivalents	\$ 83.6	\$ 38.4
Investments short-term	106.8	162.9
Investments long-term	55.7	93.4
 Total cash, cash equivalents and investments	 \$ 246.1	 \$ 294.7
 Working capital	 \$ 250.0	 \$ 204.9
Outstanding borrowings current and long-term	\$ 444.5	\$

Edgar Filing: Alkermes plc. - Form 10-K

Our cash flows for the years ended March 31, 2012, 2011 and 2010 were as follows:

(in millions)	Years Ended March 31,		
	2012	2011	2010
Cash and cash equivalents, beginning of period	\$ 38.4	\$ 79.3	\$ 86.9
Cash (used in) operating activities	(2.5)	(5.9)	(12.3)
Cash (used in) provided by investing activities	(417.1)	5.6	28.0
Cash provided by (used in) financing activities	464.8	(40.6)	(23.3)
Cash and cash equivalents, end of period	\$ 83.6	\$ 38.4	\$ 79.3

The decrease in cash used in operating activities during the year ended March 31, 2012, as compared to the year ended March 31, 2011 was due to an increase in the amount of cash received from our customers, partially offset by an increase in the amount of cash paid to our employees and suppliers. Both the increase in cash from our customers and cash payments to our suppliers and employees is primarily due to the Business Combination. The increase in cash used by investing activities in the year ended March 31, 2012, as compared to the year ended March 31, 2011, was primarily due to the \$500.0 million of cash we paid to acquire EDT and a \$7.6 million increase in cash used to acquire property, plant and equipment, partially offset by a \$79.7 million increase in the net sales of investments. The increase in cash provided by financing activities during the year ended March 31, 2012, as compared to the year ended March 31, 2011, was primarily due to our entry into the Term Loans and an increase of \$12.4 million in the amount of cash received related to the issuance of ordinary shares related to our share-based arrangements.

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

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

The increase in cash used in financing activities during the year ended March 31, 2011, as compared to the year ended March 31, 2010, was primarily due to the early redemption of our non-recourse 7% Notes, as discussed above.

Edgar Filing: Alkermes plc. - Form 10-K

At March 31, 2012, our investments consisted of the following:

(in millions)	Amortized Cost	Gross Unrealized		Estimated Fair Value
		Gains	Losses	
Investments short-term	\$ 106.7	\$ 0.1	\$	\$ 106.8
Investments long-term available-for-sale	54.5	0.8	(0.8)	54.5
Investments long-term held-to-maturity	1.2			1.2
Total	\$ 162.4	\$ 0.9	\$ (0.8)	\$ 162.5

Our investment objectives are, first, to preserve liquidity and conservation of capital and, second, to obtain investment income. Our available-for-sale investments consist primarily of short and long-term U.S. government and agency debt securities, debt securities issued by foreign agencies and backed by foreign governments, corporate debt securities and strategic equity investments, which include the common stock of public companies we have or had a collaborative arrangement with. Our held-to-maturity investments consist of investments that are restricted and held as collateral under certain letters of credit related to certain of our lease agreements. Our primary sources of liquidity are cash provided by past operating activities, payments we have received under R&D arrangements and other arrangements with collaborators and private placements of debt securities.

We classify available-for-sale investments in an unrealized loss position which do not mature within the upcoming 12 months as long-term investments. We have the intent and ability to hold these investments until recovery, which may be at maturity, and it is more likely than not that we would not be required to sell these securities before recovery of their amortized cost. At March 31, 2012, we performed an analysis of our investments with unrealized losses for impairment and determined that they were temporarily impaired. At March 31, 2012, 7% of our investments were valued using unobservable, or Level 3, inputs to determine fair value as they were not actively trading and fair values could not be derived from quoted market prices. The illiquidity of our Level 3 investments does not have a material impact on our overall liquidity, operations, financial flexibility or stability.

We expect to incur significant additional R&D costs and other costs as we expand the development of our proprietary product candidates, including costs related to preclinical studies and clinical trials. Our costs, including R&D costs for our product candidates, manufacturing, and sales, marketing and promotional expenses for any current or future products marketed by us or our collaborators, if any, may exceed revenues in the future, which may result in losses from operations. We believe that our current cash and cash equivalents and short and long-term investments, combined with anticipated revenues and anticipated interest income, will generate sufficient cash flows to meet our current anticipated liquidity and capital requirements for the foreseeable future.

We expect to spend approximately \$25.0 million during the year ended March 31, 2013 for capital expenditures. Our capital expenditures were higher in the year ended March 31, 2012, as compared to the year ended March 31, 2011, due to the addition of the former EDT business. Our capital expenditures were higher in the year ended March 31, 2010, as compared to the years ended March 31, 2011, due to the relocation of our corporate headquarters from Cambridge, Massachusetts to Waltham, Massachusetts, which occurred during the fourth quarter of the year ended March 31, 2010.

Amounts included as construction in progress in the consolidated balance sheets primarily include costs incurred for the expansion of our manufacturing facilities in Ohio. We continue to evaluate our manufacturing capacity based on expectations of demand for our products and will continue to record such amounts within construction in progress until such time as the underlying assets are placed into service, or we determine we have sufficient existing capacity and the assets are no longer required, at which time we would recognize an impairment charge. We continue to periodically evaluate whether

Edgar Filing: Alkermes plc. - Form 10-K

facts and circumstances indicate that the carrying value of these long-lived assets to be held and used may not be recoverable.

Borrowings

At March 31, 2012, our borrowings consisted of \$450.0 million of term loan financing under the Term Loans. Please refer to Note 10, *Long-Term Debt*, in the accompanying Notes to Consolidated Financial Statements for a discussion of our outstanding term loans.

Contractual Obligations

The following table summarizes our obligations to make future payments under our current contracts at March 31, 2012:

Contractual Obligations	Total	Less Than	One to	Three to	More than	
		One Year (Fiscal 2013)	Three Years (Fiscal 2014 - 2015)	Five Years (Fiscal 2016 - 2017)	Five Years (After Fiscal 2018)	
			(in thousands)			
Term Loans Principal	\$ 449,225	\$ 3,100	\$ 6,200	\$ 6,200	\$ 433,725	
Term Loans Interest	198,228	34,094	67,561	66,723	29,850	
Operating lease obligations	33,473	6,190	7,841	7,442	12,000	
Purchase obligations	109,738	91,761	17,977			
Capital expansion programs	5,034	5,034				
Total contractual cash obligations	\$ 795,698	\$ 140,179	\$ 99,579	\$ 80,365	\$ 475,575	

As the interest rate on our Term Loans is based on three-month LIBOR, we assumed LIBOR to be 1.5%, which is the LIBOR rate floor under the Term Loans for the purposes of this table. This table excludes any liabilities pertaining to uncertain tax positions as we cannot make a reliable estimate of the period of cash settlement with the respective taxing authorities. We have \$0.8 million of liabilities associated with uncertain tax positions at March 31, 2012 and we expect a net reduction in our unrecognized tax benefits in the amount of \$0.5 million due to the expected resolution of certain matters over the next twelve months.

In September 2006, we entered into a license agreement with RPI which granted us exclusive rights to a family of opioid receptor compounds discovered at RPI. Under the terms of the agreement, RPI granted us an exclusive worldwide license to certain patents and patent applications relating to its compounds designed to modulate opioid receptors. We are responsible for the continued research and development of any resulting product candidates. We are obligated to pay annual fees of up to \$0.2 million, and tiered royalty payments of between 1% and 4% of annual net sales in the event any products developed under the agreement are commercialized. In addition, we are obligated to make milestone payments in the aggregate of up to \$9.1 million upon certain agreed-upon development events. All amounts paid to RPI to date under this license agreement have been expensed and are included in R&D expense.

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

mid-single digits on annual net sales in the event any products developed under the agreement are commercialized. Since our initial investment in December 2009, we invested an additional \$0.7 million in Acceleron. All amounts paid to Acceleron to date under this license and collaboration agreement have been expensed and are included in R&D expense, except for our \$8.7 million equity investment which is included in other assets in our consolidated balance sheet at March 31, 2012.

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

Off-Balance Sheet Arrangements

At March 31, 2012, we were not a party to any off-balance sheet arrangements that have, or are reasonably likely to have, a current or future effect on our financial condition, changes in financial condition, revenue or expenses, results of operations, liquidity, capital expenditures or capital resources.

Critical Accounting Estimates

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

Operating Revenues

We have entered into a number of collaboration agreements with pharmaceutical companies including Janssen for RISPERDAL CONSTA and INVEGA SUSTENNA/XEPLION, Acorda for AMPYRA/FAMPYRA, Amylin for BYDUREON and Cilag for the resale of VIVITROL in Russia and the other countries in the CIS. These collaborative arrangements typically include funding of R&D, payments based upon achievement of clinical and pre-clinical development milestones, manufacturing services, sales milestones and royalties on product sales.

On April 1, 2011, we adopted new authoritative guidance on revenue recognition for multiple element arrangements. The guidance, which applies to multiple element arrangements entered into or materially modified on or after April 1, 2011, amends the criteria for separating and allocating consideration in a multiple element arrangement by modifying the fair value requirements for revenue recognition and eliminating the use of the residual method. The fair value of deliverables under the arrangement may be derived using a "best estimate of selling price" if vendor specific objective evidence and third-party evidence are not available. Deliverables under the arrangement will be separate units of accounting provided that (i) a delivered item has value to the customer on a stand-alone basis and (ii) if the arrangement includes a general right of return relative to the delivered item, delivery or performance of the undelivered item is considered probable and substantially in the control of the vendor. We did not enter into any significant multiple element arrangements or materially modify any of our existing multiple element arrangements during the year ended March 31, 2012. Our existing collaboration agreements continue to be accounted for under previously issued revenue recognition guidance for multiple element arrangements, as described below.

Whenever we determine that an arrangement should be accounted for as a single unit of accounting, we determine the period over which the performance obligations will be performed and revenue will be recognized. Revenue will be recognized using either a proportional performance or straight-line method. We recognize revenue using the proportional performance method when the level of effort required to complete our performance obligations under an arrangement can be reasonably estimated and such performance obligations are provided on a best-efforts basis. Earned arrangement

consideration is typically used as the measure of performance. The amount of revenue recognized under the proportional performance method is determined by multiplying the total expected payments under the contract, excluding royalties and payments contingent upon achievement of substantive milestones, by the ratio of earned arrangement consideration to estimated total arrangement consideration to be earned under the arrangement. Revenue is limited to the lesser of the cumulative amount of payments received or the cumulative amount of revenue earned, as determined using the proportional performance method, as of the period ending date.

If we cannot reasonably estimate the total arrangement consideration to be earned under an arrangement, we recognize revenue under the arrangement on a straight-line basis over the period we are expected to complete our performance obligations. Revenue is limited to the lesser of the cumulative amount of payments received or the cumulative amount of revenue earned, as determined using the straight-line method, as of the period ending date.

Significant management judgment is required in determining the consideration to be earned under an arrangement and the period over which we are expected to complete our performance obligations under an arrangement. Steering committee services that are not inconsequential or perfunctory and that are determined to be performance obligations are combined with other research services or performance obligations required under an arrangement, if any, in determining the level of effort required in an arrangement and the period over which we expect to complete our aggregate performance obligations.

Many of our collaboration agreements entitle us to additional payments upon the achievement of performance-based milestones. If the achievement of a milestone is considered probable at the inception of the collaboration, the related milestone payment is included with other collaboration consideration, such as upfront fees and research funding, in our revenue model. Milestones that involve substantial effort on our part and the achievement of which are not considered probable at the inception of the collaboration are considered "substantive milestones."

On April 1, 2011, we prospectively adopted the accounting guidance related to the milestone method of revenue recognition for R&D arrangements. Under the milestone method, contingent consideration received from the achievement of a substantive milestone is recognized in its entirety in the period in which the milestone is achieved, which we believe is more consistent with the substance of our performance under our various collaboration agreements. A milestone is defined as an event (i) that can only be achieved based in whole or in part on either the entity's performance or on the occurrence of a specific outcome resulting from the entity's performance, (ii) for which there is substantive uncertainty at the date the arrangement is entered into that the event will be achieved, and (iii) that would result in additional payments being due to us. A milestone is substantive if the consideration earned from the achievement of the milestone is consistent with our performance required to achieve the milestone, or the increase in value to the collaboration resulting from our performance, relates solely to our past performance, and is reasonable relative to all of the other deliverables and payments within the arrangement. Our collaboration agreements with our partners provide for payments to us upon the achievement of development milestones, such as the completion of clinical trials or regulatory approval for drug candidates. As of April 1, 2011, our agreements with partners included potential future payments for development milestones aggregating \$17.0 million. Given the challenges inherent in developing and obtaining approval for pharmaceutical and biologic products, there was substantial uncertainty as to whether any such milestones would be achieved at the time these collaboration agreements were entered into. In addition, we evaluated whether the development milestones met the remaining criteria to be considered substantive. As a result of our analysis, we considered \$3.0 million of our development milestones to be substantive and, accordingly, we expect to recognize as revenue future payments received from such milestones as we achieve each milestone. The election to adopt the milestone method did not impact our historical financial position at April 1, 2011. This policy election may result in revenue recognition patterns for future milestones

that are materially different from those recognized for milestones received prior to adoption. During the year ended March 31, 2012, we recognized into revenue \$3.0 million upon the achievement of developmental milestones and an aggregate of \$14.0 million upon the achievement of milestones existing at April 1, 2011 where there were no remaining performance obligations under the collaborative arrangements.

Milestone payments received prior to April 1, 2011 from arrangements where we have continuing performance obligations have been deferred and are recognized through the application of a proportional performance model where the milestone payment is recognized over the related performance period or, in full, when there are no remaining performance obligations. We make our best estimate of the period of time for the performance period. We will continue to recognize milestone payments received prior to April 1, 2011 in this manner. As of March 31, 2012, we have deferred revenue of \$4.8 million from milestone payments received prior to April 1, 2011 that will be recognized through the use of a proportional performance model through 2018.

Amounts received prior to satisfying the above revenue recognition criteria are recorded as deferred revenue in the accompanying consolidated balance sheets. Although we follow detailed guidelines in measuring revenue, certain judgments affect the application of our revenue policy. For example, in connection with our existing collaboration agreements, we have recorded on our balance sheet short-term and long-term deferred revenue based on our best estimate of when such revenue will be recognized. Short-term deferred revenue consists of amounts that are expected to be recognized as revenue in the next 12 months. Amounts that we expect will not be recognized within the next 12 months are classified as long-term deferred revenue. However, this estimate is based on our current operating plan and, if our operating plan should change in the future, we may recognize a different amount of deferred revenue over the next 12-month period.

The estimate of deferred revenue also reflects management's estimate of the periods of our involvement in certain of our collaborations. Our performance obligations under these collaborations consist of participation on steering committees, the performance of other R&D and manufacturing services. In certain instances, the timing of satisfying these obligations can be difficult to estimate. Accordingly, our estimates may change in the future. Such changes to estimates would result in a change in revenue recognition amounts. If these estimates and judgments change over the course of these agreements, it may affect the timing and amount of revenue that we recognize and record in future periods. At March 31, 2012, we had short-term and long-term deferred revenue of \$3.1 million and \$7.6 million, respectively, related to our collaborations.

Our manufacturing revenues are earned from the sale of products we manufacture for resale by our collaborative partners. Manufacturing revenues are recognized when persuasive evidence of an arrangement exists, delivery has occurred and title to the product and associated risk of loss has passed to the customer, the sales price is fixed or determinable and collectability is reasonably assured. Certain of our manufacturing revenues are recognized based on information supplied to us by our collaborative partners and require estimates to be made. Differences between the actual manufacturing revenues and estimated manufacturing revenues are reconciled and adjusted for in the period in which they become known.

Our royalty revenues are related to the sale of products by our collaborative partners that incorporate our technology. Royalties are earned under the terms of a license agreement in the period the products are sold by our collaborative partner, and the royalty earned can be reliably measured and collectability is reasonably assured. Sales information is provided to us by our collaborative partners and may require estimates to be made. Differences between actual royalty revenues and estimated royalty revenues are reconciled and adjusted for in the period in which they become known.

We recognize revenue from product sales of VIVITROL when persuasive evidence of an arrangement exists, and title to the product and associated risk of loss has passed to the customer,

Edgar Filing: Alkermes plc. - Form 10-K

which is considered to have occurred when the product has been received by the customer, the sales price is fixed or determinable and collectability is reasonably assured. We sell VIVITROL to pharmaceutical wholesalers, specialty distributors and specialty pharmacies.

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

Medicaid Rebates we record accruals for rebates to states under the Medicaid Drug Rebate Program as a reduction of sales when the product is shipped into the distribution channel. We rebate individual states for all eligible units purchased under the Medicaid program based on a rebate per unit calculation, which is based on our Average Manufacturer Price ("AMP"). We estimate expected unit sales and rebates per unit under the Medicaid program and adjust our rebate estimates based on actual unit sales and rebates per unit. To date, actual Medicaid rebates have not differed materially from our estimates;

Chargebacks wholesaler and specialty pharmacy chargebacks are discounts that occur when contracted customers purchase directly from an intermediary wholesale purchaser. Contracted customers, which consist primarily of federal government agencies purchasing under the federal supply schedule, generally purchase the product at its contracted price, plus a mark-up from the wholesaler. The wholesaler, in-turn, charges back to us the difference between the price initially paid by the wholesaler and the contracted price paid to the wholesaler by the customer. The allowance for wholesaler chargebacks is based on actual and expected utilization of these programs. Wholesaler chargebacks could exceed historical experience and our estimates of future participation in these programs. To date, actual wholesaler chargebacks have not differed materially from our estimates;

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

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

Edgar Filing: Alkermes plc. - Form 10-K

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

(In millions)	Medicaid		Wholesaler		Inventory in		Other		Total	
	Rebates	Chargebacks	Fees	the Channel	Fees	the Channel	Fees	Fees	Fees	Fees
Balance, April 1, 2010	\$ 0.4	\$ 0.1	\$ 0.2	\$ 1.8	\$ 0.1	\$ 2.6				
Provision:										
Current Period	3.2	2.4	2.2	2.5	1.9	12.2				
Prior Period	(0.1)					(0.1)				
Total	3.1	2.4	2.2	2.5	1.9	12.1				
Actual:										
Current Period	(1.9)	(2.3)	(1.8)		(1.1)	(7.1)				
Prior Period	(0.3)	(0.1)	(0.2)	(1.8)	(0.1)	(2.5)				
Total	(2.2)	(2.4)	(2.0)	(1.8)	(1.2)	(9.6)				
Balance, March 31, 2011	\$ 1.3	\$ 0.1	\$ 0.4	\$ 2.5	\$ 0.8	\$ 5.1				
Provision:										
Current Period	4.6	4.2	3.9	3.8	3.3	19.8				
Prior Period										
Total	4.6	4.2	3.9	3.8	3.3	19.8				
Actual:										
Current Period	(3.3)	(4.1)	(3.2)		(3.2)	(13.8)				
Prior Period	(1.1)	(0.1)	(0.4)	(2.5)	(0.7)	(4.8)				
Total	(4.4)	(4.2)	(3.6)	(2.5)	(3.9)	(18.6)				
Balance, March 31, 2012	\$ 1.5	\$ 0.1	\$ 0.7	\$ 3.8	\$ 0.2	\$ 6.3				

Investments

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

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

Edgar Filing: Alkermes plc. - Form 10-K

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

We classify our financial assets and liabilities as Level 1, 2 or 3 within the fair value hierarchy. Fair values determined by Level 1 inputs utilize quoted prices (unadjusted) in active markets for identical assets or liabilities. Fair values determined by Level 2 inputs are based on a market approach using quoted prices obtained from brokers or dealers for similar securities or for securities for which we have limited visibility into their trading volumes. Valuations of these financial instruments do not require a significant degree of judgment. Fair values determined by Level 3 inputs utilize unobservable data points for the asset. Our Level 3 investments are valued using discounted cash flow models that include assumptions such as estimates for interest rates, the timing of cash flows, expected holding periods and risk adjusted discount rates, which include provisions for default and liquidity risk. We also consider assumptions market participants would use in their estimate of fair value, such as collateral underlying the securities, the creditworthiness of the issuers, associated guarantees, bid and ask prices and callability features. While we believe the valuation methodologies are appropriate, the use of valuation methodologies is highly judgmental and changes in methodologies can have a material impact on our results of operations.

Share-Based Compensation

In connection with valuing stock options, we utilize the Black-Scholes option-pricing model, which requires us to estimate certain subjective assumptions. These assumptions include the expected option term, which takes into account both the contractual term of the option and the effect of our employees' expected exercise and post-vesting termination behavior, expected volatility of our ordinary shares over the option's expected term, which is developed using both the historical volatility of our ordinary shares and implied volatility from our publicly traded options, the risk-free interest rate over the option's expected term, and an expected annual dividend yield. Due to the differing exercise and post-vesting termination behavior of our employees and non-employee directors, we establish separate Black-Scholes input assumptions for three distinct employee populations: our senior management; our non-employee directors; and all other employees. For the year ended March 31, 2012, the ranges in weighted-average assumptions were as follows:

Expected option term	5 - 7 years
Expected stock volatility	47% - 51%
Risk-free interest rate	0.82% - 2.50%
Expected annual dividend yield	

In addition to the above, we apply judgment in developing estimates of award forfeitures. For the year ended March 31, 2012, we used an estimated forfeiture rate of zero for our non-employee directors, 5% for members of senior management and 8.25% for all other employees.

For all of the assumptions used in valuing stock options and estimating award forfeitures, our historical experience is generally the starting point for developing our assumptions, which may be modified to reflect information available at the time of grant that would indicate that the future is reasonably expected to differ from the past.

Impairment of Long-Lived Assets

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

Included in our impairment assessment is a review of goodwill. In connection with the acquisition of EDT, we recorded goodwill of \$92.7 million, which represented the excess cost of our investment in the net assets of acquired companies over the fair value of the underlying identifiable net assets at the date of acquisition. Our goodwill balance solely relates to the EDT acquisition in fiscal year 2012. We assess our goodwill balance within our single reporting unit annually and whenever events or changes in circumstances indicate the carrying value of goodwill may not be recoverable to determine whether any impairment in this asset may exist and, if so, the extent of such impairment. In performing our annual goodwill impairment assessment, we first assess qualitative factors to determine whether it is necessary to perform the current two-step test. If we believe, as a result of our qualitative assessment, that it is more-likely-than-not that the fair value of the reporting unit is less than its carrying amount, the quantitative impairment test is required. Otherwise, no further testing is required. If, based on our qualitative assessment, we are required to proceed to the quantitative assessment; we first compare the fair value of our reporting unit to its carrying value. If the carrying value of the net assets assigned to our reporting unit exceeds the fair value of our reporting unit, then the second step of the impairment test is performed in order to determine the implied fair value of our reporting unit's goodwill. If the carrying value of our reporting unit's goodwill exceeds its implied fair value, then the company records an impairment loss equal to the difference. We performed our required annual goodwill impairment assessment during the third quarter of fiscal year 2012.

Our amortizable intangible assets include technology and collaborative arrangements that were acquired as part of the Business Combination. These intangible assets are being amortized as revenue is generated from these products, which we refer to as the economic benefit amortization model. This amortization methodology involves calculating a ratio of actual current period sales to total anticipated sales for the life of the product and applying this ratio to the carrying amount of the intangible asset. An analysis of the anticipated product sales generated from our amortizable intangible assets is performed at least annually during our planning cycle, and this analysis serves as the basis for the calculation of our economic benefit amortization model. This analysis is based upon certain assumptions that we evaluate on a periodic basis, such as the anticipated product sales and expected impact of competitor products and our own pipeline product candidates, as well as the issuance of new patents or the extension of existing patents. Although we believe this process allows us to reliably determine the best estimate of the pattern in which we will consume the economic benefits of our amortizable intangible assets, the model could result in deferring amortization charges to future periods in certain instances, due to continued sales of a product at a nominal level after patent expiration or otherwise. Our initial model was completed as part of the Business Combination and based upon this analysis, amortization of our amortizable intangible assets is expected to be in the range of approximately \$40.0 million to \$70.0 million annually through fiscal year 2017.

We monitor events and expectations regarding product performance. If there are any indications that the assumptions underlying our most recent analysis would be different than those utilized within our current estimates, our analysis would be updated and may result in a significant change in the anticipated lifetime revenue of the products associated with our amortizable intangible assets. For example, the occurrence of an adverse event could substantially increase the amount of amortization

Edgar Filing: Alkermes plc. - Form 10-K

expense associated with our acquired intangible assets as compared to previous periods or our current expectations, which may result in a significant negative impact on our future results of operations.

We review amounts capitalized as IPR&D for impairment at least annually and whenever events or changes in circumstances indicate that the carrying value of the assets might not be recoverable. In the event the carrying value of the assets are not expected to be recovered, the assets are written down to their estimated fair values.

During the fourth quarter of fiscal year 2012, and after finalization of the purchase accounting for the Business Combination, we identified events and changes in circumstance, such as correspondence from regulatory authorities and further clinical trial results related to three product candidates, including Megestrol for use in Europe, acquired as part of the Business Combination which indicated that the assets may be impaired. Accordingly, we recorded an impairment charge of \$45.8 million within "Amortization and impairment of acquired intangible assets" in the accompanying statement of operations and comprehensive loss.

Valuation of Intangible Assets

Our intangible assets consist primarily of collaboration agreements, technology associated with human therapeutic products and IPR&D product candidates that we acquired as part of the Business Combination. When significant identifiable intangible assets are acquired, we engage an independent third-party valuation firm to assist in determining the fair values of these assets as of the acquisition date. Discounted cash flow models are typically used in these valuations, which require the use of significant estimates and assumptions, including but not limited to:

estimating the timing of and expected costs to complete the in-process projects;

projecting regulatory approvals;

estimating future cash flows from product sales resulting from completed products and in-process projects; and

developing appropriate discount rates and probability rates by project.

We believe the fair values assigned to the intangible assets acquired are based upon reasonable estimates and assumptions given available facts and circumstances as of the acquisition dates. If these projects are not successfully developed, the sales and profitability of the company may be adversely affected in future periods. Additionally, the value of the acquired intangible assets may become impaired. We believe that the foregoing assumptions used in the IPR&D analysis were reasonable at the time of the respective acquisition. No assurance can be given, however, that the underlying assumptions used to estimate expected product sales, development costs or profitability, or the events associated with such products, will transpire as estimated.

Income Taxes

We use the asset and liability method of accounting for deferred income taxes. Our most significant tax jurisdictions are the Irish and U.S. federal governments and states. Significant estimates are required in determining our provision for income taxes. Some of these estimates are based on management's interpretations of jurisdiction-specific tax laws or regulations and the likelihood of settlement related to tax audit issues. Various internal and external factors may have favorable or unfavorable effects on our future effective income tax rate. These factors include, but are not limited to, changes in tax laws, regulations and/or rates, changing interpretations of existing tax laws or regulations, changes in estimates of prior years' items, likelihood of settlement, and changes in overall levels of income before taxes. In evaluating our ability to recover our deferred tax assets, we consider all available positive and negative evidence including our past operating results, the existence of

cumulative income in the most recent fiscal years, changes in the business in which we operate and our forecast of future taxable income. In determining future taxable income, we are responsible for assumptions utilized including the amount of state, federal and international pre-tax operating income, the reversal of temporary differences and the implementation of feasible and prudent tax planning strategies. These assumptions require significant judgment about the forecasts of future taxable income and are consistent with the plans and estimates that we are using to manage the underlying businesses. At March 31, 2012, we determined, on a jurisdiction by jurisdiction basis, that it is more likely than not that a significant portion of the net deferred tax assets will not be realized, and a valuation allowance has been recorded.

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

Recent Accounting Pronouncements

Please refer to Note 2, *Summary of Significant Accounting Policies*, "New Accounting Pronouncements" in our Consolidated Financial Statements for a discussion of new accounting standards.

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

We hold securities in our investment portfolio that are sensitive to market risks. Our securities with fixed interest rates may have their market value adversely impacted by a rise in interest rates, while floating rate securities may produce less income than expected if interest rates fall. Due in part to these factors, our future investment income may fall short of expectation due to a fall in interest rates or we may suffer losses in principal if we are forced to sell securities that decline in market value due to changes in interest rates. However, because we classify our investments in debt securities as available-for-sale, no gains or losses are recognized due to changes in interest rates unless such securities are sold prior to maturity or declines in fair value are determined to be other-than-temporary. Should interest rates fluctuate by 10%, our interest income would change by approximately \$0.2 million over an annual period. Due to the conservative nature of our short-term and long-term investments and our investment policy, we do not believe that we have a material exposure to interest rate risk as our investment policies specify credit quality standards for our investments and limit the amount of credit exposure from any single issue, issuer or type of investment.

We do not believe that inflation and changing prices have had a material impact on our results of operations, and as over 83% of our investments are in debt securities issued by the U.S. government and/or agencies of developed countries, our exposure to liquidity and credit risk is not believed to be significant.

Edgar Filing: Alkermes plc. - Form 10-K

In September 2011, we and certain of our subsidiaries, as guarantors, entered into the Term Loans with MSSF as administrative agent and as collateral agent, MSSF and HSBC as co-syndication agents, joint lead arrangers and joint bookrunners, and various other financial institutions, as lenders. The initial applicable margin for borrowings under the First Lien Term Loan is three-month LIBOR plus 5.25% and three-month LIBOR plus 8.00% under the Second Lien Term Loan. Under each of the Term Loans, LIBOR is subject to an interest rate floor of 1.50%. Commencing with completion of our first fiscal quarter ending after the Business Combination, the applicable margin under the First Lien Term Loan is subject to adjustment each fiscal quarter, based upon meeting a certain consolidated leverage ratio during the preceding quarter. The applicable margin under the Second Lien Term Loan is not subject to adjustment.

In accordance with the terms of the Term Loans, we entered into two interest rate cap agreements and an interest rate swap agreement to mitigate the interest rate risk on \$225.0 million principal amount of the Term Loans. One interest rate cap, with a notional amount of \$65.0 million protects us if three-month LIBOR were to reach 1.78% from the date of issuance through December 3, 2012. The second interest rate cap, with a notional amount of \$160.0 million protects us if three-month LIBOR were to reach 3% from the date of issuance through December 13, 2013. The interest rate swap protects us if three-month LIBOR were to reach 2.057% from December 3, 2012 through September 3, 2014. As the three-month LIBOR rate was 0.47% at March 31, 2012, the LIBOR floor under the agreement is 1.50%; and as our interest rate cap fixes our interest rate at 1.78% for \$65.0 million principal amount and 3.0% for \$160.0 million principal amount of our term loans, we do not expect changes in the three-month LIBOR to have a material effect on our financial statements through March 31, 2013.

We do not use derivative financial instruments for speculative trading purposes. The counterparties to our interest rate cap and interest rate swap contracts are multinational commercial banks. We believe the risk of counterparty nonperformance is remote.

Currency Exchange Rate Risk

The manufacturing and royalty revenues we receive on RISPERDAL CONSTA, FAMPYRA, INVEGA SUSTENNA, TRICORE 145 and RITALIN LA are a percentage of the net sales made by our collaborative partners. A significant portion of these sales are made in countries outside the U.S. and are denominated in currencies in which the product is sold, which is predominantly the Euro. The manufacturing and royalty payments on these non-U.S. sales are calculated initially in the currency in which the sale is made and is then converted into USD to determine the amount that our partners pay us for manufacturing and royalty revenues. Fluctuations in the exchange ratio of the USD and these non-U.S. currencies will have the effect of increasing or decreasing our manufacturing and royalty revenues even if there is a constant amount of sales in non-U.S. currencies. For example, if the USD weakens against a non-U.S. currency, then our manufacturing and royalty revenues will increase given a constant amount of sales in such non-U.S. currency. For the year ended March 31, 2012, an average 10% strengthening of the USD relative to the currencies in which these products are sold would have resulted in our manufacturing and royalty revenues being reduced by approximately \$11.5 million. For the year ended March 31, 2011, an average 10% strengthening of the USD relative to the currencies in which RISPERDAL CONSTA are sold would have resulted in our manufacturing and royalty revenues being reduced by approximately \$8.1 million.

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

Edgar Filing: Alkermes plc. - Form 10-K

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.

Item 8. *Financial Statements and Supplementary Data*

Selected Quarterly Financial Data

	First Quarter	Second Quarter	Third Quarter	Fourth Quarter
(In thousands, except per share data)				
Year Ended March 31, 2012				
REVENUES:				
Manufacturing and royalty revenues	\$ 48,940	54,039	112,780	110,685
Product sales, net	9,686	9,887	10,597	11,014
Research and development revenue	3,257	8,052	2,266	8,774
Total revenues	61,883	71,978	125,643	130,473
EXPENSES:				
Cost of goods manufactured and sold	16,219	17,530	42,752	51,077
Research and development	28,050	28,160	40,493	45,190
Selling, general and administrative	31,497	36,234	35,469	34,432
Amortization and impairment of acquired intangible assets(1)		1,817	11,896	57,442
Total expenses	75,766	83,741	130,610	188,141
OPERATING LOSS	(13,883)	(11,763)	(4,967)	(57,668)
OTHER INCOME (EXPENSE), NET	591	(6,842)	(9,763)	(10,097)
LOSS BEFORE INCOME TAXES	(13,292)	(18,605)	(14,730)	(67,765)
INCOME TAX (BENEFIT) PROVISION	(54)	3,650	98	(4,408)
NET LOSS	\$ (13,238)	\$ (22,255)	\$ (14,828)	\$ (63,357)
BASIC AND DILUTED NET LOSS PER SHARE	\$ (0.14)	\$ (0.22)	\$ (0.11)	\$ (0.49)
Year Ended March 31, 2011				
REVENUES:				
Manufacturing and royalty revenues	\$ 35,808	\$ 42,623	\$ 35,932	\$ 42,477
Product sales, net	6,204	6,469	7,729	8,518
Research and development revenue	268	155	314	143
Total revenues	42,280	49,247	43,975	51,138

Edgar Filing: Alkermes plc. - Form 10-K

	First Quarter	Second Quarter	Third Quarter	Fourth Quarter
(In thousands, except per share data)				
EXPENSES:				
Cost of goods manufactured and sold	12,665	13,911	12,860	12,749
Research and development	22,977	23,932	22,503	27,827
Selling, general and administrative	19,726	18,436	20,521	24,164
Total expenses	55,368	56,279	55,884	64,740
OPERATING LOSS	(13,088)	(7,032)	(11,909)	(13,602)
OTHER (EXPENSE) INCOME, NET	(379)	(1,577)	567	529
LOSS BEFORE INCOME TAXES	(13,467)	(8,609)	(11,342)	(13,073)
INCOME TAX (BENEFIT) PROVISION	(58)	(943)	41	9
NET LOSS	\$ (13,409)	\$ (7,666)	\$ (11,383)	\$ (13,082)
BASIC AND DILUTED NET LOSS PER SHARE	\$ (0.14)	\$ (0.08)	\$ (0.12)	\$ (0.14)

(1) Includes an impairment charge of \$45.8 million related to IPR&D acquired as part of the Business Combination during the fourth quarter of fiscal year 2012.

All financial statements, other than the quarterly financial data as required by Item 302 of Regulation S-K summarized above, required to be filed hereunder, are filed as an exhibit hereto, are listed under Item 15(a) (1) and (2), and are incorporated herein by reference.

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

Not applicable.

Item 9A. Controls and Procedures

Disclosure Controls and Procedures and Internal Control over Financial Reporting

Controls and Procedures

Our management has evaluated, with the participation of our principal executive officer and principal financial officer, the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended), as of March 31, 2012. Based upon that evaluation, our principal executive officer and principal financial officer concluded that, as of the end of the period covered by this report, our disclosure controls and procedures were effective to provide reasonable assurance that (a) the information required to be disclosed by us in the reports that we file or submit under the Securities Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms, and (b) such information is accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate to allow timely decisions regarding required disclosure. In designing and evaluating our disclosure controls and procedures, our management recognized that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives, and our management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting during the quarter ended March 31, 2012 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Management's Annual Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over our financial reporting as defined in Rules 13a-15(f) and 15d-15(f). Internal control over financial reporting is defined in Rules 13a-15(f) and 15d-15(f) under the Securities Exchange Act as a process designed by, or under the supervision of, the issuer's principal executive and principal financial officers, or persons performing similar functions, and effected by the issuer's board of directors, management and other personnel to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with GAAP and includes those policies and procedures that:

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

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

provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of the issuer's assets that could have a material effect on the financial statements.

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

Our management assessed the effectiveness of our internal control over financial reporting as of March 31, 2012. In making this assessment, management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission ("COSO") in Internal Control Integrated Framework.

Based on this assessment, our management has concluded that, as of March 31, 2012, our internal control over financial reporting was effective.

The effectiveness of our internal control over financial reporting as of March 31, 2012 has been audited by PricewaterhouseCoopers LLP, an independent registered public accounting firm, as stated in their report, which is included herein.

Item 9B. *Other Information*

None.

PART III

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

The information required by this item is incorporated herein by reference to the 2012 Proxy Statement.

Item 11. *Executive Compensation*

The information required by this item is incorporated herein by reference to the 2012 Proxy Statement.

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

The information required by this item is incorporated herein by reference to the 2012 Proxy Statement.

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

The information required by this item is incorporated herein by reference to the 2012 Proxy Statement.

Item 14. *Principal Accounting Fees and Services*

The information required by this item is incorporated herein by reference to the 2012 Proxy Statement.

PART IV

Item 15. *Exhibits and Financial Statement Schedules*

- (a)(1) Consolidated Financial Statements The consolidated financial statements of Alkermes plc, required by this item are submitted in a separate section beginning on page F-1 of this Form 10-K.
- (2) Financial Statement Schedules All schedules have been omitted because the absence of conditions under which they are required or because the required information is included in the consolidated financial statements or notes thereto.

POWER OF ATTORNEY

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

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

Signature	Title	Date
<u>/s/ RICHARD F. POPS</u> Richard F. Pops	Chairman and Chief Executive Officer (Principal Executive Officer)	May 18, 2012
<u>/s/ JAMES M. FRATES</u> James M. Frates	Senior Vice President and Chief Financial Officer (Principal Financial and Accounting Officer)	May 18, 2012
<u>/s/ DAVID W. ANSTICE</u> David W. Anstice	Director	May 18, 2012
<u>/s/ FLOYD E. BLOOM</u> Floyd E. Bloom	Director	May 18, 2012
<u>/s/ ROBERT A. BREYER</u> Robert A. Breyer	Director	May 18, 2012
<u>/s/ GERALDINE HENWOOD</u> Geraldine Henwood	Director	May 18, 2012
<u>/s/ PAUL J. MITCHELL</u> Paul J. Mitchell	Director	May 18, 2012
<u>/s/ WENDY L. DIXON</u> Wendy L. Dixon	Director	May 18, 2012
<u>/s/ MARK B. SKALETSKY</u> Mark B. Skaletsky	Director	May 18, 2012

EXHIBIT INDEX

Exhibit No.	Description of Exhibit
1.1++	Form of Underwriting Agreement entered into by and among Citigroup Global Markets Inc., Jefferies & Company, Inc. and Morgan Stanley & Co. LLC as Representatives of the several Underwriters; Elan Science Three Limited, as the Selling Shareholder; and Alkermes plc, as the Company, dated as of March 8, 2012 (Incorporated by reference to Exhibit 1.1 of the Registration Statement on Form S-1, as amended (Registration No. 333-179550), which was declared effective by the Securities and Exchange Commission on March 2, 2012).
2.1++	Business Combination Agreement and Plan of Merger, dated as of May 9, 2011, by and among Elan, Alkermes, Inc., Alkermes plc and certain other parties (Incorporated by reference to Annex A to the proxy statement/prospectus forming a part of the Registration Statement on Form S-4, as amended (Registration No. 333-175078), which was declared effective by the Securities and Exchange Commission on August 4, 2011.)
3.1++	Amended and Restated Memorandum and Articles of Association of Alkermes plc (Incorporated by reference to Exhibit 3.1 to the Alkermes plc Current Report on Form 8-K filed on September 16, 2011.)
4.1++	Shareholder's Agreement by and among Elan, Elan Science Three Limited and Alkermes plc (Incorporated by reference to Exhibit 4.1 to the Alkermes plc Current Report on Form 8-K filed on September 16, 2011.)
10.1++	Lease, dated as of October 26, 2000, between FC88 Sidney, Inc. and Alkermes, Inc. (Incorporated by reference to Exhibit 10.3 to the Alkermes, Inc. Quarterly Report on Form 10-Q for the quarter ended December 31, 2000 (File No. 001-14131).)
10.2++	Lease, dated as of October 26, 2000, between Forest City 64 Sidney Street, Inc. and Alkermes, Inc. (Incorporated by reference to Exhibit 10.4 to the Alkermes, Inc. Quarterly Report on Form 10-Q for the quarter ended December 31, 2000 (File No. 001-14131).)
10.3++	Lease Agreement, dated as of April 22, 2009 between PDM Unit 850, LLC, and Alkermes, Inc. (Incorporated by reference to Exhibit 10.5 to the Alkermes, Inc. Annual Report on Form 10-K for the fiscal year ended March 31, 2009 (File No. 001-14131).)
10.4++	First Amendment to Lease Agreement between Alkermes, Inc. and PDM Unit 850, LLC, dated as of June 18, 2009 (Incorporated by reference to Exhibit 10.2 to the Alkermes, Inc. Quarterly Report on Form 10-Q for the quarter ended June 30, 2009 (File No. 001-14131).)
10.5++ *	License Agreement, dated as of February 13, 1996, between Medisorb Technologies International L.P. and Janssen Pharmaceutica Inc. (U.S.) (assigned to Alkermes, Inc. in July 2006). (Incorporated by reference to Exhibit 10.19 to the Alkermes, Inc. Annual Report on Form 10-K for the fiscal year ended March 31, 1996 (File No. 000-19267).)
10.6++ *	License Agreement, dated as of February 21, 1996, between Medisorb Technologies International L.P. and Janssen Pharmaceutica International (worldwide except United States) (assigned to Alkermes, Inc. in July 2006). (Incorporated by reference to Exhibit 10.20 to the Alkermes, Inc. Annual Report on Form 10-K for the fiscal year ended March 31, 1996 (File No. 000-19267).)

Edgar Filing: Alkermes plc. - Form 10-K

Exhibit No.	Description of Exhibit
10.7++ **	Manufacturing and Supply Agreement, dated August 6, 1997, by and among Alkermes Controlled Therapeutics Inc. II, Janssen Pharmaceutica International and Janssen Pharmaceutica, Inc. (assigned to Alkermes, Inc. in July 2006). (Incorporated by reference to Exhibit 10.19 to the Alkermes, Inc. Annual Report on Form 10-K for the fiscal year ended March 31, 2002 (File No. 001-14131).)
10.8++ ***	Third Amendment To Development Agreement, Second Amendment To Manufacturing and Supply Agreement and First Amendment To License Agreements by and between Janssen Pharmaceutica International Inc. and Alkermes Controlled Therapeutics Inc. II, dated April 1, 2000 (assigned to Alkermes, Inc. in July 2006) (with certain confidential information deleted). (Incorporated by reference to Exhibit 10.5 to the Alkermes, Inc. Quarterly Report on Form 10-Q for the quarter ended December 31, 2004 (File No. 001-14131).)
10.9++ ***	Fourth Amendment To Development Agreement and First Amendment To Manufacturing and Supply Agreement by and between Janssen Pharmaceutica International Inc. and Alkermes Controlled Therapeutics Inc. II, dated December 20, 2000 (assigned to Alkermes, Inc. in July 2006) (with certain confidential information deleted). (Incorporated by reference to Exhibit 10.4 to the Alkermes, Inc. Quarterly Report on Form 10-Q for the quarter ended December 31, 2004 (File No. 001-14131).)
10.10++ **	Addendum to Manufacturing and Supply Agreement, dated August 2001, by and among Alkermes Controlled Therapeutics Inc. II, Janssen Pharmaceutica International and Janssen Pharmaceutica, Inc. (assigned to Alkermes, Inc. in July 2006). (Incorporated by reference to Exhibit 10.19(b) to the Alkermes, Inc. Annual Report on Form 10-K for the fiscal year ended March 31, 2002 (File No. 001-14131).)
10.11++ **	Letter Agreement and Exhibits to Manufacturing and Supply Agreement, dated February 1, 2002, by and among Alkermes Controlled Therapeutics Inc. II, Janssen Pharmaceutica International and Janssen Pharmaceutica, Inc. (assigned to Alkermes, Inc. in July 2006). (Incorporated by reference to Exhibit 10.19(a) to the Alkermes, Inc. Annual Report on Form 10-K for the fiscal year ended March 31, 2002 (File No. 001-14131).)
10.12++ ***	Amendment to Manufacturing and Supply Agreement by and between JPI Pharmaceutica International, Janssen Pharmaceutica Inc. and Alkermes Controlled Therapeutics Inc. II, dated December 22, 2003 (assigned to Alkermes, Inc. in July 2006) (with certain confidential information deleted). (Incorporated by reference to Exhibit 10.8 to the Alkermes, Inc. Quarterly Report on Form 10-Q for the quarter ended December 31, 2004 (File No. 001-14131).)
10.13++ ***	Fourth Amendment To Manufacturing and Supply Agreement by and between JPI Pharmaceutica International, Janssen Pharmaceutica Inc. and Alkermes Controlled Therapeutics Inc. II, dated January 10, 2005 (assigned to Alkermes, Inc. in July 2006) (with certain confidential information deleted). (Incorporated by reference to Exhibit 10.9 to the Alkermes, Inc. Quarterly Report on Form 10-Q for the quarter ended December 31, 2004 (File No. 001-14131).)
10.14++ ***	Agreement by and between JPI Pharmaceutica International, Janssen Pharmaceutica Inc. and Alkermes Controlled Therapeutics Inc. II, dated December 21, 2002 (assigned to Alkermes, Inc. in July 2006) (with certain confidential information deleted). (Incorporated by reference to Exhibit 10.6 to the Alkermes, Inc. Quarterly Report on Form 10-Q for the quarter ended December 31, 2004 (File No. 001-14131).)

Edgar Filing: Alkermes plc. - Form 10-K

Exhibit No.	Description of Exhibit
10.15++ ***	Amendment to Agreement by and between JPI Pharmaceutica International, Janssen Pharmaceutica Inc. and Alkermes Controlled Therapeutics Inc. II, dated December 16, 2003 (assigned to Alkermes, Inc. in July 2006) (with certain confidential information deleted). (Incorporated by reference to Exhibit 10.7 to the Alkermes, Inc. Quarterly Report on Form 10-Q for the quarter ended December 31, 2004 (File No. 001-14131).)
10.16+ ++	Employment agreement, dated as of December 12, 2007, by and between Richard F. Pops and Alkermes, Inc. (Incorporated by reference to Exhibit 10.1 to the Alkermes, Inc. Quarterly Report on Form 10-Q for the quarter ended December 31, 2007 (File No. 001-14131).)
10.17+ ++	Amendment to Employment Agreement by and between Alkermes, Inc. and Richard F. Pops. (Incorporated by reference to Exhibit 10.5 to the Alkermes, Inc. Current Report on Form 8-K filed on October 7, 2008 (File No. 001-14131).)
10.18+ ++	Amendment No. 2 to Employment Agreement by and between Alkermes, Inc. and Richard F. Pops, dated September 10, 2009. (Incorporated by reference to Exhibit 10.2 to the Alkermes, Inc. Current Report on Form 8-K filed on September 11, 2009 (File No. 001-14131).)
10.19+ ++	Form of Employment Agreement, dated as of December 12, 2007, by and between Alkermes, Inc. and each of Kathryn L. Biberstein, Elliot W. Ehrich, M.D., James M. Frates, Michael J. Landine, Gordon G. Pugh. (Incorporated by reference to Exhibit 10.3 to the Alkermes, Inc. Quarterly Report on Form 10-Q for the quarter ended December 31, 2007 (File No. 001-14131).)
10.20+ ++	Form of Amendment to Employment Agreement by and between Alkermes, Inc. and each of each of Kathryn L. Biberstein, Elliot W. Ehrich, M.D., James M. Frates, Michael J. Landine, Gordon G. Pugh. (Incorporated by reference to Exhibit 10.7 to the Alkermes, Inc. Current Report on Form 8-K filed on October 7, 2008 (File No. 001-14131).)
10.21+ ++	Form of Covenant Not to Compete, of various dates, by and between Alkermes, Inc. and each of Kathryn L. Biberstein and James M. Frates. (Incorporated by reference to Exhibit 10.15 to the Alkermes, Inc. Annual Report on Form 10-K for the year ended March 31, 2008 (File No. 001-14131).)
10.22+ ++	Form of Covenant Not to Compete, of various dates, by and between Alkermes, Inc. and each of Elliot W. Ehrich, M.D., Michael J. Landine, and Gordon G. Pugh. (Incorporated by reference to Exhibit 10.15(a) to the Alkermes, Inc. Annual Report on Form 10-K for the year ended March 31, 2008 (File No. 001-14131).)
10.23+ ++	Form of Indemnification Agreement by and between Alkermes, Inc. and each of its directors and executive officers (Incorporated by reference to Exhibit 10.1 to the Alkermes, Inc. Current Report on Form 8-K filed on March 25, 2010 (File No. 001-14131).)
10.24+ ++	Alkermes, Inc. 1998 Equity Incentive Plan as Amended and Approved on November 2, 2006. (Incorporated by reference to Exhibit 10.1 to the Alkermes, Inc. Quarterly Report on Form 10-Q for the fiscal quarter ended December 31, 2006 (File No. 001-14131).)
10.25+ ++	Form of Stock Option Certificate pursuant to Alkermes, Inc. 1998 Equity Incentive Plan. (Incorporated by reference to Exhibit 10.37 to the Alkermes, Inc. Annual Report on Form 10-K for the fiscal year ended March 31, 2006 (File No. 001-14131).)

Edgar Filing: Alkermes plc. - Form 10-K

Exhibit No.	Description of Exhibit
10.26+ ++	Alkermes, Inc. Amended and Restated 1999 Stock Option Plan. (Incorporated by reference to Appendix A to the Alkermes, Inc. Definitive Proxy Statement on Form DEF 14/A filed on July 27, 2007 (File No. 001-14131).)
10.27+ ++	Form of Incentive Stock Option Certificate pursuant to the 1999 Stock Option Plan, as amended. (Incorporated by reference to Exhibit 10.35 to the Alkermes, Inc. Annual Report on Form 10-K for the fiscal year ended March 31, 2006 (File No. 001-14131).)
10.28+ ++	Form of Non-Qualified Stock Option Certificate pursuant to the 1999 Stock Option Plan, as amended. (Incorporated by reference to Exhibit 10.36 to the Alkermes, Inc. Annual Report on Form 10-K for the fiscal year ended March 31, 2006 (File No. 001-14131).)
10.29+ ++	Alkermes, Inc. 2002 Restricted Stock Award Plan as Amended and Approved on November 2, 2006. (Incorporated by reference to Exhibit 10.3 to the Alkermes, Inc. Quarterly Report on Form 10-Q for the fiscal quarter ended December 31, 2006 (File No. 001-14131).)
10.30+ ++	Amendment to Alkermes, Inc. 2002 Restricted Stock Award Plan. (Incorporated by reference to Appendix B to the Alkermes, Inc. Definitive Proxy Statement on Form DEF 14/A filed on July 27, 2007 (File No. 001-14131).)
10.31+ ++	2006 Stock Option Plan for Non-Employee Directors. (Incorporated by reference to Exhibit 10.4 to the Alkermes, Inc. Quarterly Report on Form 10-Q for the fiscal quarter ended September 30, 2006 (File No. 001-14131).)
10.32+ ++	Amendment to 2006 Stock Option Plan for Non-Employee Directors. (Incorporated by reference to Appendix C to the Alkermes, Inc. Definitive Proxy Statement on Form DEF 14/A filed on July 27, 2007 (File No. 001-14131).)
10.33+ ++	Alkermes Fiscal 2012 Reporting Officer Performance Pay Plan. (Incorporated by reference to Exhibit 10.1 to the Alkermes, Inc. Current Report on Form 8-K filed on March 24, 2011 (File No. 001-14131).)
10.34+ ++	Amended and Restated Alkermes Fiscal 2012 Reporting Officer Performance Pay Plan. (Incorporated by reference to Exhibit 10.1 to the Alkermes, Inc. Current Report on Form 8-K filed on May 19, 2011 (File No. 001-14131).)
10.35+ ++	Amendment to Amended and Restated Alkermes Fiscal 2012 Reporting Officer Performance Pay Plan (Incorporated by reference to the Alkermes plc Current Report on Form 8-K filed on October 7, 2011 (File No. 001-35299).)
10.36+ ++	Alkermes, Inc. 2008 Stock Option and Incentive Plan (Incorporated by reference to Exhibit 10.1 to the Alkermes, Inc. Current Report on Form 8-K filed on October 7, 2008 (File No. 001-14131).)
10.37+ ++	Alkermes, Inc. 2008 Stock Option and Incentive Plan, Stock Option Award Certificate (Incentive Stock Option), as amended (Incorporated by reference to Exhibit 10.27(a) to the Alkermes, Inc. Annual Report on Form 10-K for the fiscal year ended March 31, 2010 (File No. 001-14131).)
10.38+ ++	Alkermes, Inc. 2008 Stock Option and Incentive Plan, Stock Option Award Certificate (Non-Qualified Option), as amended (Incorporated by reference to Exhibit 10.27(b) to the Alkermes, Inc. Annual Report on Form 10-K for the fiscal year ended March 31, 2010 (File No. 001-14131).)

Edgar Filing: Alkermes plc. - Form 10-K

Exhibit No.	Description of Exhibit
10.39+ ++	Alkermes, Inc. 2008 Stock Option and Incentive Plan, Stock Option Award Certificate (Non-Employee Director) (Incorporated by reference to Exhibit 10.4 to the Alkermes, Inc. Current Report on Form 8-K filed on October 7, 2008 (File No. 001-14131).)
10.40+ ++	Alkermes, Inc. 2008 Stock Option and Incentive Plan, Restricted Stock Unit Award Certificate (Time Vesting Only). (Incorporated by reference to Exhibit 10.1 to the Alkermes, Inc. Current Report on Form 8-K filed on May 22, 2009 (File No. 001-14131).)
10.41+ ++	Alkermes, Inc. 2008 Stock Option and Incentive Plan, Restricted Stock Unit Award Certificate (Performance Vesting Only). (Incorporated by reference to Exhibit 10.2 to the Alkermes, Inc. Current Report on Form 8-K filed on May 22, 2009 (File No. 001-14131).)
10.42++ ****	Development and License Agreement, dated as of May 15, 2000, by and between Alkermes Controlled Therapeutics Inc. II and Amylin Pharmaceuticals, Inc., as amended on October 24, 2005 and July 17, 2006 (assigned, as amended, to Alkermes, Inc. in July 2006). (Incorporated by reference to Exhibit 10.28 to the Alkermes, Inc. Annual Report on Form 10-K for the fiscal year ended March 31, 2010 (File No. 001-14131).)
10.43++	First Lien Term Loan Credit Agreement, dated as of September 16, 2011, among Alkermes, Inc., the guarantors party thereto, the lenders party thereto, Morgan Stanley Senior Funding, Inc. as Administrative Agent and Collateral Agent and the arrangers and agents party thereto (Incorporated by reference to Exhibit 10.1 to the Alkermes plc Current Report on Form 8-K filed on September 16, 2011.)
10.44++	Second Lien Term Loan Credit Agreement, dated as of September 16, 2011, among Alkermes, Inc., the guarantors party thereto, the lenders party thereto, Morgan Stanley Senior Funding, Inc. as Administrative Agent and Collateral Agent and the arrangers and agents party thereto (Incorporated by reference to Exhibit 10.2 to the Alkermes plc Current Report on Form 8-K filed on September 16, 2011.)
10.45++	Intellectual Property Transfer Agreement, dated as of September 15, 2011 between Alkermes, Inc., Alkermes Controlled Therapeutics, Inc. and Alkermes Pharma Holdings Limited (Incorporated by reference to Exhibit 10.3 to the Alkermes plc Current Report on Form 8-K filed on September 16, 2011.)
10.46+ ++	Form of Deed of Indemnification for Alkermes plc Officers (Incorporated by reference to Exhibit 10.1 to the Alkermes plc Current Report on Form 8-K filed on September 20, 2011.)
10.47+ ++	Form of Deed of Indemnification for Alkermes plc Directors/Secretary (Incorporated by reference to Exhibit 10.2 to the Alkermes plc Current Report on Form 8-K filed on September 20, 2011.)
10.48+ ++	Form of Deed of Indemnification for Alkermes, Inc. and Subsidiaries Directors/Secretary (Incorporated by reference to Exhibit 10.3 to the Alkermes plc Current Report on Form 8-K filed on September 20, 2011.)
10.49+ ++	Fiscal 2012 Alkermes plc Affiliated Company Reporting Officer Performance Pay Plan (Incorporated by reference to Exhibit 10.4 to the Alkermes plc Current Report on Form 8-K filed on September 20, 2011.)

Edgar Filing: Alkermes plc. - Form 10-K

Exhibit No.	Description of Exhibit
10.50+ ++	Shane Cooke Offer Letter, dated as of September 15, 2011 (Incorporated by reference to Exhibit 10.5 to the Alkermes plc Current Report on Form 8-K filed on September 20, 2011.)
10.51+ ++	Employment Agreement by and between Alkermes Pharma Ireland Limited and Shane Cooke, dated as of September 16, 2011 (Incorporated by reference to Exhibit 10.6 to the Alkermes plc Current Report on Form 8-K filed on September 20, 2011.)
10.52+ ++	James L. Botkin Offer Letter, dated as of September 15, 2011 (Incorporated by reference to Exhibit 10.7 to the Alkermes plc Current Report on Form 8-K filed on September 20, 2011.)
10.53+ ++	Employment Agreement by and between Alkermes Gainesville LLC and James L. Botkin, dated as of September 16, 2011 (Incorporated by reference to Exhibit 10.8 to the Alkermes plc Current Report on Form 8-K filed on September 20, 2011.)
10.54+ ++	Alkermes plc 2011 Stock Option and Incentive Plan (Incorporated by reference to Exhibit 10.1 to the Alkermes plc Current Report on Form 8-K filed on December 8, 2011 (File No. 001-35299)).
10.55+ ++	Employment Agreement by and between Alkermes, Inc. and Mark P. Stejbach, dated as of February 29, 2012 (Incorporated by reference to Exhibit 10.1 to the Alkermes plc Current Report on Form 8-K filed on March 5, 2012 (File No. 001-35299)).
10.56+ ++	Offer Letter between Alkermes, Inc. and Mark P. Stejbach, effective as of February 15, 2012 (Incorporated by reference to Exhibit 10.2 to the Alkermes plc Current Report on Form 8-K filed on March 5, 2012 (File No. 001-35299)).
10.57#	Waiver and Consent, dated March 7, 2012.
10.58#	Second Waiver and Consent, dated March 8, 2012.
10.59+ ++	Fiscal 2013 Alkermes plc Affiliated Company Reporting Officer Performance Plan (Incorporated by reference to Exhibit 10.1 to the Alkermes plc Current Report on Form 8-K filed on March 30, 2012 (File No. 001-35299)).
21.1#	List of subsidiaries
23.1#	Consent of PricewaterhouseCoopers LLP
24.1	Power of Attorney (included on the signature pages hereto)
31.1#	Certification Pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934
31.2#	Certification Pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934
32.1#	Certification Pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
101.INS**	XBRL Instance Document
101.SCH+++	XBRL Taxonomy Extension Schema Document
101.CAL+++	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF+++	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB+++	XBRL Taxonomy Extension Label Linkbase Document

Edgar Filing: Alkermes plc. - Form 10-K

Exhibit No.	Description of Exhibit
101.PRE+++	XBRL Taxonomy Extension Presentation Linkbase Document

- + Indicates a management contract or any compensatory plan, contract or arrangement.
- ++ Previously filed.
- +++ XBRL (Extensible Business Reporting Language) information is furnished and not filed or a part of a registration statement or prospectus for purposes of Sections 11 or 12 of the Securities Act of 1933, is deemed not filed for purposes of Section 18 of the Securities Exchange Act of 1934, and is not otherwise subject to liability under these Sections.
- # Filed herewith.
- * Confidential status has been granted for certain portions thereof pursuant to a Commission Order granted September 3, 1996. Such provisions have been filed separately with the Commission.
- ** Confidential status has been granted for certain portions thereof pursuant to a Commission Order granted September 16, 2002. Such provisions have been separately filed with the Commission.
- *** Confidential status has been granted for certain portions thereof pursuant to a Commission Order granted September 26, 2005. Such provisions have been filed separately with the Commission.
- **** Confidential status has been granted for certain portions thereof pursuant to a Commission Order granted June 28, 2010. Such provisions have been filed separately with the Commission.

Report of Independent Registered Public Accounting Firm

To the Board of Directors and Stockholders of Alkermes plc.:

In our opinion, the accompanying consolidated balance sheets and the related consolidated statements of operations and comprehensive (loss) income, of shareholder's equity and of cash flows present fairly, in all material respects, the financial position of Alkermes plc. and its subsidiaries at March 31, 2012 and 2011, and the results of their operations and their cash flows for each of the three years in the period ended March 31, 2012 in conformity with accounting principles generally accepted in the United States of America. Also in our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of March 31, 2012, based on criteria established in *Internal Control Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). The Company's management is responsible for these financial statements, for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting, included in Management's Annual Report on Internal Control over Financial Reporting under Item 9A. Our responsibility is to express opinions on these financial statements and on the Company's internal control over financial reporting based on our integrated audits. We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the financial statements are free of material misstatement and whether effective internal control over financial reporting was maintained in all material respects. Our audits of the financial statements included examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. Our audit of internal control over financial reporting included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audits also included performing such other procedures as we considered necessary in the circumstances. We believe that our audits provide a reasonable basis for our opinions.

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

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

Boston, Massachusetts
May 18, 2012

ALKERMES PLC AND SUBSIDIARIES

CONSOLIDATED BALANCE SHEETS

March 31, 2012 AND 2011

	2012 (In thousands, except share and per share amounts)	2011
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	\$ 83,601	\$ 38,394
Investments short-term	106,846	162,928
Receivables	96,381	22,969
Inventory	39,759	20,425
Prepaid expenses and other current assets	12,566	8,244
Total current assets	339,153	252,960
PROPERTY, PLANT AND EQUIPMENT, NET	302,995	95,020
INTANGIBLE ASSETS NET	617,845	
GOODWILL	92,740	
INVESTMENTS LONG-TERM	55,691	93,408
OTHER ASSETS	26,793	11,060
TOTAL ASSETS	\$ 1,435,217	\$ 452,448
LIABILITIES AND SHAREHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Accounts payable and accrued expenses	\$ 79,154	\$ 44,934
Deferred revenue current	6,910	3,123
Long-term debt current	3,100	
Total current liabilities	89,164	48,057
LONG-TERM DEBT	441,360	
DEFERRED REVENUE LONG-TERM	7,578	4,837
DEFERRED TAX LIABILITIES LONG-TERM	34,512	
OTHER LONG-TERM LIABILITIES	8,751	7,536
Total liabilities	581,365	60,430
COMMITMENTS AND CONTINGENCIES (Note 17)		
SHAREHOLDERS' EQUITY:		
Preferred stock, par value, \$0.01 per share; 50,000,000 and zero shares authorized; none issued and outstanding at March 31, 2012 and 2011, respectively		
Ordinary shares, par value, \$0.01 per share; 450,000,000 and 160,000,000 shares authorized; 130,212,530 and 105,771,507 shares issued; 130,177,452 and 95,702,299 shares outstanding at March 31, 2012 and 2011, respectively	1,300	1,055
Non-voting common stock, par value, \$0.01 per share; zero and 450,000 shares authorized; zero and 382,632 shares issued and outstanding at March 31, 2012 and 2011, respectively		4
Treasury stock, at cost (35,078 and 10,069,208 shares at March 31, 2012 and 2011, respectively)	(571)	(131,095)
Additional paid-in capital	1,380,742	936,295
Accumulated other comprehensive loss	(2,713)	(3,013)
Accumulated deficit	(524,906)	(411,228)
Total shareholders' equity	853,852	392,018

Edgar Filing: Alkermes plc. - Form 10-K

TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY

\$ 1,435,217 \$ 452,448

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

F-2

ALKERMES PLC AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

Years Ended March 31, 2012, 2011 AND 2010

	2012	2011	2010
	(In thousands, except per share amounts)		
REVENUES:			
Manufacturing and royalty revenues	\$ 326,444	\$ 156,840	\$ 149,917
Product sales, net	41,184	28,920	20,245
Research and development revenue	22,349	880	3,117
Other			5,002
Total revenues	389,977	186,640	178,281
EXPENSES:			
Cost of goods manufactured and sold	127,578	52,185	49,438
Research and development	141,893	97,239	95,363
Selling, general and administrative	137,632	82,847	76,514
Amortization and impairment of acquired intangible assets	71,155		
Total expenses	478,258	232,271	221,315
OPERATING LOSS	(88,281)	(45,631)	(43,034)
OTHER EXPENSE, NET:			
Interest income	1,516	2,728	4,667
Interest expense	(28,111)	(3,298)	(5,974)
Other income (expense), net	484	(290)	(360)
Total other expense, net	(26,111)	(860)	(1,667)
LOSS BEFORE INCOME TAXES	(114,392)	(46,491)	(44,701)
PROVISION (BENEFIT) FOR INCOME TAXES	(714)	(951)	(5,075)
NET LOSS	\$ (113,678)	\$ (45,540)	\$ (39,626)
LOSS PER COMMON SHARE:			
Basic	\$ (0.99)	\$ (0.48)	\$ (0.42)
Diluted	\$ (0.99)	\$ (0.48)	\$ (0.42)
WEIGHTED AVERAGE NUMBER OF COMMON SHARES OUTSTANDING:			
Basic	114,702	95,610	94,839
Diluted	114,702	95,610	94,839
COMPREHENSIVE LOSS:			
Net loss	\$ (113,678)	\$ (45,540)	\$ (39,626)
Unrealized losses on marketable securities:			
Holding gains (losses), net of tax	627	379	2,998
Less: Reclassification adjustment for losses included in net (loss) income			94
Unrealized gains (losses) on marketable securities	627	379	3,092

Edgar Filing: Alkermes plc. - Form 10-K

Unrealized losses on derivative contracts, net of tax

(327)

COMPREHENSIVE LOSS	\$ (113,378)	\$ (45,161)	\$ (36,534)
--------------------	--------------	-------------	-------------

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

F-3

Edgar Filing: Alkermes plc. - Form 10-K

ALKERMES PLC AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF SHAREHOLDERS' EQUITY
Years Ended March 31, 2012, 2011 AND 2010

	Ordinary Shares		Non-voting Common Stock		Accumulated Other Comprehensive Paid-In Loss Accumulated Capital (Income) Deficit			Treasury Stock		Total
	Shares	Amount	Shares	Amount	Capital	(Income)	Deficit	Shares	Amount	
(In thousands, except share data)										
BALANCE March 31, 2009	104,044,663	\$ 1,040	382,632	\$ 4	\$ 892,415	\$ (6,484)	\$ (326,062)	(9,508,451)	\$ (126,025)	\$ 434,888
Issuance of common stock under employee stock plans	770,665	7			2,586					2,593
Receipt of Alkermes' stock for the purchase of stock options or to satisfy minimum tax withholding obligations related to stock based awards					972			(108,410)	(972)	
Repurchase of common stock for treasury, at cost								(328,404)	(2,684)	(2,684)
Share-based compensation					14,107					14,107
Excess tax benefit from share-based compensation					246					246
Unrealized gain on marketable securities, net of tax of \$1,831						3,092				3,092
Net loss							(39,626)			(39,626)
BALANCE March 31, 2010	104,815,328	\$ 1,047	382,632	\$ 4	\$ 910,326	\$ (3,392)	\$ (365,688)	(9,945,265)	\$ (129,681)	\$ 412,616
Issuance of common stock under employee stock plans	956,179	8			4,736					4,744
Receipt of Alkermes' stock for the purchase of stock options or to satisfy minimum tax withholding obligations related to stock based awards					1,414			(123,943)	(1,414)	
Share-based compensation					19,819					19,819
Unrealized gain on marketable securities, net of tax of \$225						379				379
Net loss							(45,540)			(45,540)
BALANCE March 31, 2011	105,771,507	\$ 1,055	382,632	\$ 4	\$ 936,295	\$ (3,013)	\$ (411,228)	(10,069,208)	\$ (131,095)	\$ 392,018
Issuance of common stock to Elan Corporation, plc in connection with the purchase of Elan Drug Technologies	31,900,000	319			524,755					525,074
Issuance of ordinary shares under employee stock plans	2,398,422	24			17,164					17,188
Receipt of Alkermes' stock for the purchase of stock options or to satisfy minimum tax withholding obligations related to stock based awards					3,676			(205,901)	(3,676)	
Share-based compensation					28,615					28,615
Excess tax benefit from share-based compensation					4,335					4,335
Conversion of non-voting common stock to common stock	382,632	4	(382,632)	(4)						
Cancellation of treasury stock	(10,240,031)	(102)			(134,098)			10,240,031	134,200	
Unrealized gains on marketable securities, net of tax of \$372						627				627
Unrealized loss on cash flow hedge, net of tax of \$(194)						(327)				(327)
Net loss							(113,678)			(113,678)
BALANCE March 31, 2012	130,212,530	\$ 1,300		\$	\$ 1,380,742	\$ (2,713)	\$ (524,906)	(35,078)	\$ (571)	\$ 853,852

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

ALKERMES PLC AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF CASH FLOWS
Years Ended March 31, 2012, 2011 AND 2010

	2012	2011	2010
	(In thousands)		
CASH FLOWS FROM OPERATING ACTIVITIES:			
Net loss	\$ (113,678)	\$ (45,540)	\$ (39,626)
Adjustments to reconcile net loss to cash flows from operating activities:			
Share-based compensation expense	28,826	19,832	13,921
Depreciation and amortization	93,684	8,652	25,026
Deferred income taxes	(14,556)		
Loss on purchase of non-recourse RISPERDAL CONSTA secured 7% Notes		841	
Other non-cash charges	4,342	1,861	3,833
Changes in assets and liabilities, excluding the effect of acquisitions:			
Receivables	(14,014)	2,347	(728)
Inventory, prepaid expenses and other assets	(4,879)	5,211	(4,037)
Accounts payable and accrued expenses	11,217	6,954	(2,064)
Deferred revenue	6,068	635	(4,753)
Other long-term liabilities	508	(88)	(1,638)
Payment or purchase of non-recourse RISPERDAL CONSTA secured 7% notes attributable to original issue discount		(6,611)	(2,181)
Cash flows used in operating activities	(2,482)	(5,906)	(12,247)
CASH FLOWS FROM INVESTING ACTIVITIES:			
Additions to property, plant and equipment	(16,988)	(9,401)	(15,787)
Proceeds from the sale of equipment	35	395	248
Acquisition of Elan Drug Technologies, net of cash acquired	(494,774)		
Investment in Acceleron Pharmaceuticals, Inc.	(231)	(501)	(8,000)
Purchases of investments	(228,229)	(370,375)	(465,387)
Sales and maturities of investments	323,028	385,511	516,935
Cash flows (used in) provided by investing activities	(417,159)	5,629	28,009
CASH FLOWS FROM FINANCING ACTIVITIES:			
Proceeds from the issuance of ordinary shares for share-based compensation arrangements	17,188	4,744	2,593
Excess tax benefit from share-based compensation	4,335		246
Proceeds from the issuance of long-term debt	444,100		
Principal payments of long-term debt	(775)		
Payment or purchase of non-recourse RISPERDAL CONSTA secured 7% notes		(45,397)	(23,486)
Purchase of ordinary shares for treasury			(2,684)
Cash flows provided by (used in) financing activities	464,848	(40,653)	(23,331)
NET DECREASE IN CASH AND CASH EQUIVALENTS	45,207	(40,930)	(7,569)
CASH AND CASH EQUIVALENTS Beginning of period	38,394	79,324	86,893
CASH AND CASH EQUIVALENTS End of period	\$ 83,601	\$ 38,394	\$ 79,324
SUPPLEMENTAL CASH FLOW DISCLOSURE:			
Cash paid for interest	\$ 21,658	\$ 1,684	\$ 4,918
Cash paid for taxes	\$ 10,068	\$ 60	\$ 114
Non-cash investing and financing activities:			
Purchased capital expenditures included in accounts payable and accrued expenses	\$ 3,416	\$ 424	\$ 2,798
Investment in Civitas Therapeutics, Inc.	\$ 1,547	\$ 1,320	\$

Edgar Filing: Alkermes plc. - Form 10-K

Issuance of common stock used in the acquisition of Elan Drug Technologies	\$ 525,074	\$	\$
--	------------	----	----

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

F-5

ALKERMES PLC AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

1. THE COMPANY

Alkermes plc is a fully integrated, global biopharmaceutical company that applies its scientific expertise and proprietary technologies to develop innovative medicines that improve patient outcomes. The Company has a diversified portfolio of more than 20 commercial drug products and a substantial clinical pipeline of product candidates that address central nervous system ("CNS") disorders such as addiction, schizophrenia and depression. Headquartered in Dublin, Ireland, Alkermes plc has a research and development ("R&D") center and corporate offices in Waltham, Massachusetts and manufacturing facilities in Athlone, Ireland; Gainesville, Georgia; and Wilmington, Ohio.

On September 16, 2011, the business of Alkermes, Inc. 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") in a transaction accounted for as a reverse acquisition with Alkermes, Inc. treated as the accounting acquirer. As a result, the historical financial statements of Alkermes, Inc. are included in the comparative prior periods. As part of the Business Combination, Antler Acquisition Corp., a wholly owned subsidiary of the Company, merged with and into Alkermes, Inc. (the "Merger"), with Alkermes, Inc. surviving as a wholly owned subsidiary of the Company. Prior to the Merger, EDT was carved-out of Elan and reorganized under the Company. At the effective time of the Merger, (i) each share of Alkermes, Inc. common stock then issued and outstanding and all associated rights were canceled and automatically converted into the right to receive one ordinary share of the Company; (ii) all then-issued and outstanding options to purchase Alkermes, Inc. common stock granted under any stock option plan were converted into options to purchase, on substantially the same terms and conditions, the same number of ordinary shares of the Company at the same exercise price; and (iii) all then-issued and outstanding awards of Alkermes, Inc. common stock were converted into awards of the same number, on substantially the same terms and conditions, of ordinary shares of the Company. As a result, upon consummation of the Merger and the issuance of the ordinary shares of the Company in exchange for the canceled shares of Alkermes, Inc. common stock, the former shareholders of Alkermes, Inc. owned approximately 75% of the Company, with the remaining approximately 25% of the Company owned by a subsidiary of Elan pursuant to the terms of a shareholder's agreement.

Use of the terms such as "us," "we," "our," "Alkermes" or the "Company" in this Annual Report on Form 10-K is meant to refer to Alkermes plc and its 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 Alkermes, Inc. Prior to September 16, 2011, Alkermes, Inc. was an independent pharmaceutical company incorporated in the Commonwealth of Pennsylvania and traded on the NASDAQ Global Select Stock Market under the symbol "ALKS."

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Principles of Consolidation

The consolidated financial statements include the accounts of Alkermes plc and its wholly-owned subsidiaries: Alkermes Ireland Holdings Limited, Alkermes Pharma Ireland Limited, Alkermes U.S. Holdings, Inc., Alkermes, Inc., Eagle Holdings USA, Inc., Alkermes Gainesville LLC, Alkermes Controlled Therapeutics, Inc., Alkermes Europe, Ltd., Alkermes Finance Ireland Limited, Alkermes Finance S.A R.L. and Alkermes Finance Ireland (No. 2) Limited. Intercompany accounts and transactions have been eliminated.

ALKERMES PLC AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

Use of Estimates

The preparation of the Company's consolidated financial statements in accordance with accounting principles generally accepted in the United States ("U.S.") ("GAAP") requires management to make estimates, judgments and assumptions that may affect the reported amounts of assets, liabilities, revenues and expenses, and related disclosure of contingent assets and liabilities. On an on-going basis, the Company evaluates its estimates and judgments and methodologies, including those related to revenue recognition and related allowances, its collaborative relationships, clinical trial expenses, the valuation of inventory, impairment and amortization of intangibles and long-lived assets, share-based compensation, income taxes including the valuation allowance for deferred tax assets, valuation of investments and derivative instruments, litigation and restructuring charges. The Company bases its estimates on historical experience and on various other assumptions that are believed to be reasonable, the results of which form the basis for making judgments about the carrying values of assets and liabilities. Actual results may differ from these estimates under different assumptions or conditions.

Cash and Cash Equivalents

The Company values its cash and cash equivalents at cost plus accrued interest, which the Company believes approximates their market value. The Company considers only those investments which are highly liquid, readily convertible into cash and that mature within three months from the date of purchase to be cash equivalents.

Investments

The Company has investments in various types of securities including U.S. government and agency obligations, debt securities issued by foreign agencies and backed by foreign governments and corporate debt securities. The Company also has strategic equity investments which includes the common stock of a public company with which the Company has a collaborative arrangement. The Company generally holds its interest-bearing investments with major financial institutions and in accordance with documented investment policies. The Company limits the amount of credit exposure to any one financial institution or corporate issuer. At March 31, 2012, substantially all these investments are classified as available-for-sale and are recorded at fair value. Holding gains and losses on these investments are considered "unrealized" and are reported within "Accumulated other comprehensive (loss) income," a component of shareholders' equity. The Company uses the specific identification method for reclassifying unrealized gains and losses into earnings when investments are sold. Certain of the Company's money market funds and held-to-maturity investments are restricted investments held as collateral under letters of credit related to certain of the Company's service provider agreements and lease agreements, respectively, and are included in "Investments short-term" and "Investments long-term", respectively, in the consolidated balance sheets.

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

ALKERMES PLC AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

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

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

Fair Value of Financial Instruments

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

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

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

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

The carrying amounts reflected in the consolidated balance sheets for cash and cash equivalents, accounts receivable, other current assets, accounts payable and accrued expenses approximate fair value due to their short-term nature.

ALKERMES PLC AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

Inventory

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

Property, Plant and Equipment

Property, plant and equipment are recorded at cost, subject to review for impairment whenever events or changes in circumstances indicate that the carrying amount of the assets may not be recoverable. Expenditures for repairs and maintenance are charged to expense as incurred and major renewals and improvements are capitalized. Depreciation is calculated using the straight-line method over the following estimated useful lives of the assets:

Asset group	Term
Buildings and improvements	15 - 40 years
Furniture, fixtures and equipment	3 - 10 years
Leasehold improvements	Shorter of useful life or lease term

Business Acquisitions

The Company's consolidated financial statements include the operations of an acquired business after the completion of the acquisition. The Company accounts for acquired businesses using the acquisition method of accounting. The acquisition method of accounting for acquired businesses requires, among other things, that most assets acquired and liabilities assumed be recognized at their estimated fair values as of the acquisition date, and that the fair value of acquired in-process research and development ("IPR&D") be recorded on the balance sheet. Also, transaction costs are expensed as incurred. Any excess of the purchase price over the assigned values of the net assets acquired is recorded as goodwill. Contingent consideration, if any, is included within the acquisition cost and is recognized at its fair value on the acquisition date. A liability resulting from contingent consideration is remeasured to fair value at each reporting date until the contingency is resolved. Changes in fair value are recognized in earnings.

Goodwill and Intangible Assets

Goodwill represents the excess cost of the Company's investment in the net assets of acquired companies over the fair value of the underlying identifiable net assets at the date of acquisition. The Company's goodwill balance solely relates to the EDT acquisition in the fiscal year ended March 31, 2012, as described in Note 3, *Acquisitions*. Goodwill is not amortized but is tested for impairment annually or when events or circumstances indicate the fair value of a reporting unit may be below its carrying value. A reporting unit is an operating segment or sub-segment to which goodwill is assigned when initially recorded.

In September 2011, the Financial Accounting Standards Board ("FASB") issued guidance related to testing goodwill for impairment. This accounting standard allows an entity to first assess qualitative

ALKERMES PLC AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

factors to determine whether it is necessary to perform the current two-step test. If an entity believes, as a result of its qualitative assessment, that it is more-likely-than-not that the fair value of a reporting unit is less than its carrying amount, the quantitative impairment test is required. Otherwise, no further testing is required. An entity can choose to perform the qualitative assessment on none, some or all of its reporting units. Moreover, an entity can bypass the qualitative assessment for any reporting unit in any period and proceed directly to step one of the impairment test, and then resume performing the qualitative assessment in any subsequent period. This standard is effective for annual and interim goodwill impairment tests performed for fiscal years beginning after December 15, 2011. However, an entity can choose to early adopt the standard if its annual test date is before the issuance of the final standard, provided that the entity has not yet performed its 2011 annual impairment test or issued its financial statements. The Company chose to early adopt the provisions of this standard as it had not yet performed its annual impairment test, which the Company performs as of October 31 each year. The adoption of this standard did not impact the Company's financial position or results of operations. As a result of the qualitative assessment performed as of October 31, 2011, the Company determined that it was not more-likely-than-not that the fair value of the reporting unit was less than its carrying amount, and an impairment of the Company's goodwill was not recorded.

The Company's finite-lived intangible assets consist of core developed technology and collaboration agreements and are recorded at fair value at the time of their acquisition and are stated within its consolidated balance sheets net of accumulated amortization and impairments. The finite-lived intangible assets are amortized over their estimated useful life using the economic use method, which reflects the pattern that the economic benefits of the intangible assets are consumed as revenue is generated from the underlying patent or contract. The useful lives of the Company's intangible assets are primarily based on the legal or contractual life of the underlying patent or contract, which does not include additional years for the potential extension or renewal of the contract or patent. IPR&D represents the fair value assigned to R&D assets that were acquired prior to their completion. IPR&D is considered an indefinite-lived asset and is not amortized but is tested for impairment annually or when events or circumstances indicate the fair value may be below its carrying value. If and when development is complete, which generally occurs when regulatory approval to market a product is obtained, the associated assets would be deemed finite-lived and would then be amortized based on their respective estimated useful lives at that point in time. The Company's intangible assets were all acquired as part of the EDT acquisition in the fiscal year ended March 31, 2012, as described in Note 3, *Acquisitions*.

Impairment of Long-Lived Assets

The Company reviews long-lived assets to be held and used for impairment whenever events or changes in circumstances indicate that the carrying amount of the assets may not be recoverable. Conditions that would necessitate an impairment assessment include a significant decline in the observable market value of an asset, a significant change in the extent or manner in which an asset is used, or a significant adverse change that would indicate that the carrying amount of an asset or group of assets is not recoverable. Determination of recoverability is based on an estimate of undiscounted future cash flows resulting from the use of the asset and its eventual disposition. In the event that such cash flows are not expected to be sufficient to recover the carrying amount of the assets, the assets are written-down to their estimated fair values. Long-lived assets to be disposed of are carried at fair value less costs to sell them.

ALKERMES PLC AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

Asset Retirement Obligations

The Company recognized an asset retirement obligation for an obligation to remove leasehold improvements and other related activities at the conclusion of the Company's lease for its AIR[®] manufacturing facility located in Chelsea, Massachusetts, which it presently subleases. The carrying amount of the asset retirement obligation at March 31, 2012 and 2011, was \$1.9 million and \$1.7 million, respectively, and is included within "Other Long-Term Liabilities" in the accompanying consolidated balance sheets.

The following table shows changes in the carrying amount of the Company's asset retirement obligation for the years ended March 31, 2012 and 2011:

(In thousands)	Carrying Amount
Balance, April 1, 2010	\$ 1,537
Accretion expense	155
Balance, March 31, 2011	\$ 1,692
Accretion expense	170
Balance, March 31, 2012	\$ 1,862

*Revenue Recognition*Collaborative Arrangements

The Company has entered into a number of collaboration agreements with pharmaceutical companies including Ortho-McNeil-Janssen Pharmaceuticals, Inc. and Janssen Pharmaceutica International, a division of Cilag International AG ("Janssen") for RISPERDAL[®] CONSTA[®] and INVEGA[®] SUSTENNA[®]/XEPLION[®], Acorda Therapeutics, Inc. ("Acorda") for AMPYRA[®]/FAMPYRA[®], Amylin Pharmaceuticals, Inc. ("Amylin") for BYDUREON[™] and Cilag GmbH International ("Cilag") for the resale of VIVITROL in Russia and the other countries in the Commonwealth of Independent States ("CIS"). These collaborative arrangements typically include upfront payments, funding of R&D, payments based upon achievement of pre-clinical and clinical development milestones, manufacturing services, sales milestones and royalties on product sales.

On April 1, 2011, the Company adopted new authoritative guidance on revenue recognition for multiple element arrangements. The guidance, which applies to multiple element arrangements entered into or materially modified on or after April 1, 2011, amends the criteria for separating and allocating consideration in a multiple element arrangement by modifying the fair value requirements for revenue recognition and eliminating the use of the residual method. The fair value of deliverables under the arrangement may be derived using a "best estimate of selling price" if vendor specific objective evidence and third-party evidence is not available. Deliverables under the arrangement will be separate units of accounting provided that (i) a delivered item has value to the customer on a stand-alone basis and (ii) if the arrangement includes a general right of return relative to the delivered item, delivery or performance of the undelivered item is considered probable and substantially in the control of the vendor. The Company did not enter into any significant multiple element arrangements or materially modify any of its existing multiple element arrangements during the year ended March 31, 2012. The

ALKERMES PLC AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

Company's existing collaboration agreements continue to be accounted for under previously issued revenue recognition guidance for multiple element arrangements, as described below.

Whenever the Company determines that an arrangement should be accounted for as a single unit of accounting, the Company determines the period over which the performance obligations will be performed and revenue will be recognized. Revenue will be recognized using either a proportional performance or straight-line method. The Company recognizes revenue using the proportional performance method when the level of effort required to complete its performance obligations under an arrangement can be reasonably estimated and such performance obligations are provided on a best-efforts basis. Earned arrangement consideration is typically used as the measure of performance. The amount of revenue recognized under the proportional performance method is determined by multiplying the total expected payments under the contract, excluding royalties and payments contingent upon achievement of substantive milestones, by the ratio of earned arrangement consideration to estimated total arrangement consideration to be earned under the arrangement. Revenue is limited to the lesser of the cumulative amount of payments received or the cumulative amount of revenue earned, as determined using the proportional performance method, as of the period ending date.

If the Company cannot reasonably estimate the total arrangement consideration to be earned under an arrangement, the Company recognizes revenue under the arrangement on a straight-line basis over the period the Company is expected to complete its performance obligations. Revenue is limited to the lesser of the cumulative amount of payments received or the cumulative amount of revenue earned, as determined using the straight-line method, as of the period ending date.

Significant management judgment is required in determining the consideration to be earned under an arrangement and the period over which the Company is expected to complete its performance obligations under an arrangement. Steering committee services that are not inconsequential or perfunctory and that are determined to be performance obligations are combined with other research services or performance obligations required under an arrangement, if any, in determining the level of effort required in an arrangement and the period over which the Company expects to complete its aggregate performance obligations.

Many of the Company's collaboration agreements entitle it to additional payments upon the achievement of performance-based milestones. If the achievement of a milestone is considered probable at the inception of the collaboration, the related milestone payment is included with other collaboration consideration, such as upfront payments and research funding, in the Company's revenue model. Milestones that involve substantial effort on the Company's part and the achievement of which are not considered probable at the inception of the collaboration are considered "substantive milestones."

On April 1, 2011, the Company prospectively adopted the accounting guidance related to the milestone method of revenue recognition for R&D arrangements. Under the milestone method, contingent consideration received from the achievement of a substantive milestone is recognized in its entirety in the period in which the milestone is achieved, which the Company believes is more consistent with the substance of its performance under its various collaboration agreements. A milestone is defined as an event (i) that can only be achieved based in whole or in part on either the entity's performance or on the occurrence of a specific outcome resulting from the entity's performance, (ii) for which there is substantive uncertainty at the date the arrangement is entered into that the event will be achieved, and (iii) that would result in additional payments being due to the

ALKERMES PLC AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

entity. A milestone is substantive if the consideration earned from the achievement of the milestone is consistent with the Company's performance required to achieve the milestone, or the increase in value to the collaboration resulting from the Company's performance, relates solely to the Company's past performance, and is reasonable relative to all of the other deliverables and payments within the arrangement. The Company's collaboration agreements with its partners provide for payments to the Company upon the achievement of development milestones, such as the completion of clinical trials or regulatory approval for drug candidates. As of April 1, 2011, the Company's agreements with partners included potential future payments for development milestones aggregating \$17.0 million. Given the challenges inherent in developing and obtaining approval for pharmaceutical and biologic products, there was substantial uncertainty as to whether any such milestones would be achieved at the time these collaboration agreements were entered into. In addition, the Company evaluated whether the development milestones met the remaining criteria to be considered substantive. As a result of the Company's analysis, the Company considers \$3.0 million of its development milestones to be substantive and, accordingly, the Company expects to recognize as revenue future payments received from such milestones as it achieves each milestone. The election to adopt the milestone method did not impact the Company's historical financial position at April 1, 2011. This policy election may result in revenue recognition patterns for future milestones that are materially different from those recognized for milestones received prior to adoption. During the year ended March 31, 2012, the Company recognized into revenue \$3.0 million upon the achievement of developmental milestones and an aggregate of \$14.0 million upon the achievement of milestones existing at April 1, 2011, where there were no remaining performance obligations under the collaborative arrangements.

Milestone payments received prior to April 1, 2011 from arrangements where the Company has continuing performance obligations have been deferred and are recognized through the application of a proportional performance model where the milestone payment is recognized over the related performance period or, in full, when there are no remaining performance obligations. The Company makes its best estimate of the period of time for the performance period. The Company will continue to recognize milestone payments received prior to April 1, 2011 in this manner. As of March 31, 2012, the Company has deferred revenue of \$4.8 million from milestone payments received prior to April 1, 2011 that will be recognized through the use of a proportional performance model through 2018.

Amounts received prior to satisfying the above revenue recognition criteria are recorded as deferred revenue in the accompanying consolidated balance sheets. Although the Company follows detailed guidelines in measuring revenue, certain judgments affect the application of its revenue policy. For example, in connection with the Company's existing collaboration agreements, the Company has recorded on its balance sheet short-term and long-term deferred revenue based on its best estimate of when such revenue will be recognized. Short-term deferred revenue consists of amounts that are expected to be recognized as revenue in the next 12 months. Amounts that the Company expects will not be recognized within the next 12 months are classified as long-term deferred revenue. However, this estimate is based on the Company's current operating plan and, if its operating plan should change in the future, the Company may recognize a different amount of deferred revenue over the next 12-month period.

ALKERMES PLC AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

The estimate of deferred revenue also reflects management's estimate of the periods of the Company's involvement in certain of its collaborations. The Company's performance obligations under these collaborations consist of participation on steering committees and the performance of other research and development services. In certain instances, the timing of satisfying these obligations can be difficult to estimate. Accordingly, the Company's estimates may change in the future. Such changes to estimates would result in a change in revenue recognition amounts. If these estimates and judgments change over the course of these agreements, it may affect the timing and amount of revenue that the Company recognizes and records in future periods. At March 31, 2012, the Company had short-term and long-term deferred revenue of \$3.1 million and \$7.6 million, respectively, related to its collaborations.

Manufacturing revenues The Company recognizes manufacturing revenues from the sale of products it manufactures for resale by its collaborative partners. Manufacturing revenues are recognized when persuasive evidence of an arrangement exists, delivery has occurred and title to the product and associated risk of loss has passed to the customer, the sales price is fixed or determinable and collectability is reasonably assured. Certain of the Company's manufacturing revenues are recognized by the Company based on information supplied to the Company by its collaborative partners and require estimates to be made. Differences between the actual manufacturing revenues and estimated manufacturing revenues are reconciled and adjusted for in the period in which they become known.

Royalty revenue The Company recognizes royalty revenues related to the sale of products by its collaborative partners that incorporates the Company's technology. Royalties are earned under the terms of a license agreement in the period the products are sold by the Company's collaborative partner and collectability is reasonably assured. Certain of the Company's royalty revenues are recognized by the Company based on information supplied to the Company by its collaborative partners and require estimates to be made. Differences between the actual royalty revenues and estimated royalty revenues are reconciled and adjusted for in the period in which they become known.

Research and development revenue R&D revenue consists of funding that compensates the Company for formulation, pre-clinical and clinical testing under R&D arrangements. The Company generally bills its partners under R&D arrangements using a single full-time equivalent ("FTE") or hourly rate, plus direct external costs, if any.

Product Sales, net

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

ALKERMES PLC AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

The Company records its product sales net of the following significant categories of sales discounts and allowances as a reduction of product sales at the time VIVITROL is shipped into the distribution channel, and are adjusted for inventory in the distribution channel:

Medicaid Rebates the Company records accruals for rebates to states under the Medicaid Drug Rebate Program as a reduction of sales when the product is shipped into the distribution channel. The Company rebates individual states for all eligible units purchased under the Medicaid program based on a rebate per unit calculation, which is based on its Average Manufacturer Price ("AMP"). The Company estimates expected unit sales and rebates per unit under the Medicaid program and adjusts its rebate estimates based on actual unit sales and rebates per unit.

Chargebacks wholesaler, specialty pharmacy and distributor, or intermediary, chargebacks are discounts that occur when contracted customers purchase directly from an intermediary. Contracted customers, which include federal government agencies purchasing under the federal supply schedule, generally purchase the product at its contracted price, plus a mark-up from the intermediary. The intermediary, in-turn, charges back to the Company the difference between the price initially paid by the intermediary and the contracted price paid to the intermediary by the customer. The allowance for chargebacks is based on actual and expected utilization of these programs. Chargebacks could exceed historical experience and the Company's estimates of future participation in these programs. To date, actual chargebacks have not differed materially from the Company's estimates.

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

Risk-management instruments

On September 16, 2011, the Company entered into a \$310.0 million first lien term loan facility (the "First Lien Term Loan") and a \$140.0 million second lien term loan facility (the "Second Lien Term Loan" and, together with the First Lien Term Loan, the "Term Loans"). Interest on the Term Loans is at a rate equal to an applicable margin plus three-month LIBOR. The Company addressed its risk to exposure to fluctuations in interest rates by entering into certain derivative financial instruments, the objective of which is to limit the impact of fluctuations in interest rates on earnings. The Company's derivative activities are initiated within the guidelines of documented corporate risk management policies and do not create additional risk because gains and losses on derivative contracts offset losses and gains on the liabilities being hedged.

During the year ended March 31, 2012, the Company entered into an interest rate swap contract that was designated and qualified as a cash flow hedge. The Company reviews the effectiveness of its derivatives on a quarterly basis. The effective portion of gains or losses on the Company's cash flow hedge is reported as a component of accumulated other comprehensive loss and reclassified into earnings in the same period the hedged transaction affects earnings. Hedge ineffectiveness is immediately recognized in earnings.

ALKERMES PLC AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

During the year ended March 31, 2012, the Company entered into two interest rate cap contracts that were not designated as hedging instruments. The interest rate caps are recorded at fair value with associated gains or losses recognized in other income/(expense) during the period of change.

Foreign Currency

The Company's functional and reporting currency is the U.S. dollar. Transactions in foreign currencies are recorded at the exchange rate prevailing on the date of the transaction. The resulting monetary assets and liabilities are translated into U.S. dollars at exchange rates prevailing on the subsequent balance sheet date. Gains and losses as a result of translation adjustments are recorded within "Other income (expense)" in the accompanying consolidated statement of operations and comprehensive loss. During the years ended March 31, 2012, 2011 and 2010, the Company recorded a gain on foreign currency translation of \$0.5 million, none and none, respectively.

Concentrations

Financial instruments that potentially subject the Company to concentrations of credit risk are accounts receivable and marketable securities. Billings to large pharmaceutical and biotechnology companies account for the majority of the Company's accounts receivable, and collateral is generally not required from these customers. To mitigate credit risk, the Company monitors the financial performance and credit worthiness of its customers. The following represents revenue and receivables from the Company's customers exceeding 10% of the total in each category as of, and for the years ended, March 31:

Customer	2012		2011		2010	
	Receivables	Revenue	Receivables	Revenue	Receivables	Revenue
Janssen	30%	48%	75%	83%	86%	83%
Acorda	11%					

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

ALKERMES PLC AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

Geographic Information

Company revenues by geographic location, as determined by the location of the customer, and the location of its long-term assets, excluding financial instruments and deferred taxes, are as follows:

(in thousands)	Year Ended March 31,		
	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			

Research and Development Expenses

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

A significant portion of the Company's internally generated R&D expenses (including laboratory supplies, travel, dues and subscriptions, recruiting costs, temporary help costs, consulting costs and allocable costs such as occupancy and depreciation) are not tracked by project as they benefit multiple projects or the Company's technologies in general. Externally generated R&D expenses are tracked by project and certain of these expenses are reimbursed to the Company by its partners. The Company accounts for its R&D expenses on a departmental and functional basis in accordance with its budget and management practices. All such costs are expensed as incurred.

Share-Based Compensation

The Company's share-based compensation programs grant awards which include stock options and restricted stock units ("RSU"), which vest with the passage of time and, to a limited extent, vest based on the achievement of certain performance or market criteria. Certain of the Company's employees are retirement eligible under the terms of the Company's stock option plans (the "Plans") and stock option awards to these employees generally vest in full upon retirement. Since there are no effective future service requirements for these employees, the fair value of these awards is expensed in full on the grant date.

ALKERMES PLC AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

Stock Options

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

The fair value of stock option grants is based on estimates as of the date of grant using a Black-Scholes option valuation model. The Company uses historical data as the basis for estimating option terms and forfeitures. Separate groups of employees that have similar historical stock option exercise and forfeiture behavior are considered separately for valuation purposes. The ranges of expected terms disclosed below reflect different expected behavior among certain groups of employees. Expected stock volatility factors are based on a weighted average of implied volatilities from traded options on the Company's ordinary shares and historical stock price volatility of the Company's ordinary shares, which is determined based on a review of the weighted average of historical daily price changes of the Company's ordinary shares. The risk-free interest rate for periods commensurate with the expected term of the share option is based on the U.S. treasury yield curve in effect at the time of grants. The dividend yield on the Company's ordinary shares is estimated to be zero as the Company has not paid and does not expect to pay dividends. The exercise price of options granted prior to October 7, 2008 equals the average of the high and low of the Company's ordinary shares traded on the NASDAQ Select Stock Global Market on the date of grant. Beginning with the adoption of the Alkermes, Inc. 2008 Stock Option and Incentive Plan (the "2008 Plan"), the exercise price of option grants made after October 7, 2008 is equal to the closing price of the Company's ordinary shares traded on the NASDAQ Select Stock Global Market on the date of grant.

The fair value of each stock option grant was estimated on the grant date with the following weighted-average assumptions:

	Year Ended March 31,		
	2012	2011	2010
Expected option term	5 - 7 years	5 - 7 years	5 - 7 years
Expected stock volatility	47% - 51%	46% - 51%	38% - 49%
Risk-free interest rate	0.82% - 2.50%	1.11% - 3.42%	1.83% - 3.05%
Expected annual dividend yield			

Time-Vested Restricted Stock Units

Time-vested RSUs awarded to employees generally vest one-fourth per year over four years from the anniversary of the date of grant, provided the employee remains continuously employed with the Company. Shares of the Company's ordinary shares are delivered to the employee upon vesting, subject to payment of applicable withholding taxes. The fair value of time-vested RSUs is based on the market

ALKERMES PLC AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

value of the Company's stock on the date of grant. Compensation expense, including the effect of forfeitures, is recognized over the applicable service period.

Performance-Based Restricted Stock Units

The Company had RSUs that vested upon the achievement of certain performance criteria and RSUs that vested upon the achievement of a market condition. Shares of the Company's ordinary shares were delivered to the employee upon vesting, subject to payment of applicable withholding taxes. The estimated fair value of the RSUs that vested upon the achievement of certain performance criteria was based on the market value of the Company's stock on the date of grant. The estimated fair value of the RSUs that vested upon the achievement of a market condition was determined through the use of a Monte Carlo simulation model, which utilizes input variables that determine the probability of satisfying the market condition stipulated in the award and calculates the fair market value for the performance award.

Compensation expense for RSUs that vest upon the achievement of performance criteria is recognized from the moment the Company determines the performance criteria will be met to the date the Company deems the event is likely to occur. Cumulative adjustments are recorded quarterly to reflect subsequent changes in the estimated outcome of performance-related conditions until the date results are determined. Compensation expense for RSUs that vest upon the achievement of a market condition is recognized over a derived service period as determined by the Monte Carlo simulation model. The vesting of these awards is subject to the respective employees' continued employment. Both of these awards had been fully expensed prior to the beginning of the year ended March 31, 2012 and both awards vested during the year ended March 31, 2012.

Income Taxes

The Company recognizes income taxes under the asset and liability method. Deferred income taxes are recognized for differences between the financial reporting and tax bases of assets and liabilities at enacted statutory tax rates in effect for the years in which the differences are expected to reverse. The effect on deferred taxes of a change in tax rates is recognized in income in the period that includes the enactment date. The Company accounts for uncertain tax positions using a "more-likely-than-not" threshold for recognizing and resolving uncertain tax positions. The evaluation of uncertain tax positions is based on factors including, but not limited to, changes in tax law, the measurement of tax positions taken or expected to be taken in tax returns, the effective settlement of matters subject to audit, new audit activity and changes in facts or circumstances related to a tax position. The Company evaluates this tax position on a quarterly basis. The Company also accrues for potential interest and penalties related to unrecognized tax benefits in income tax expense.

Comprehensive Loss

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

ALKERMES PLC AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

Loss per Share

Basic loss per share is calculated based upon net loss available to holders of common shares divided by the weighted average number of shares outstanding. For the calculation of diluted loss per share, the Company uses the weighted average number of shares outstanding, as adjusted for the effect of potential dilutive securities, including stock options and RSUs.

Segment Information

The Company operates as one business segment, which is the business of developing, manufacturing and commercializing medicines designed to yield better therapeutic outcomes and improve the lives of patients with serious diseases. The Company's chief decision maker, the Chairman and Chief Executive Officer, reviews the Company's operating results on an aggregate basis and manages the Company's operations as a single operating unit.

Employee Benefit Plans

401(K) Plan

The Company maintains a 401(k) retirement savings plan (the "401(k) Plan"), which covers substantially all of its U.S. based employees. Eligible employees may contribute up to 100% of their eligible compensation, subject to certain Internal Revenue Service limitations. Through March 31, 2012, the Company matched 50% of the first 6% of employee pay and beginning April 1, 2012, the Company matches 100% of employee contributions up to the first 5% of employee pay, up to IRS limits. Employee and Company contributions are fully vested when made. During the years ended March 31, 2012, 2011 and 2010, the Company contributed \$2.5 million, \$2.0 million and \$1.8 million, respectively, to match employee deferrals under the 401(k) Plan.

Defined Contribution Plan

The Company maintains a defined contribution plan for its Ireland based employees (the "defined contribution plan"). The defined contribution plan provides for eligible employees to contribute up to the maximum of 40% of their total taxable earnings, depending upon their age, or €115,000. The Company provides a match of up to 18% of taxable earnings depending upon an individual's contribution level. During the years ended March 31, 2012, 2011 and 2010, the Company contributed \$1.8 million, none and none, respectively, in contributions to the defined contribution plan.

New Accounting Pronouncements

In January 2010, the Company adopted accounting guidance issued by the FASB related to fair value measurements that requires additional disclosure related to transfers in and out of Levels 1 and 2 of the fair value hierarchy. In addition, effective for the Company beginning on April 1, 2011, this standard further requires an entity to present disaggregated information about activity in Level 3 fair value measurements on a gross basis, rather than as one net amount. As this accounting standard only requires enhanced disclosure, the adoption of this newly issued accounting standard did not impact the Company's financial position or results of operations.

ALKERMES PLC AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

In May 2011, the FASB issued accounting guidance that clarifies the application of certain existing fair value measurement guidance and expands the disclosures for fair value measurements that are estimated using significant unobservable (Level 3) inputs. This standard was effective on a prospective basis for the Company on January 1, 2012. The adoption of this standard did not have a material impact on the Company's financial position or results of operations.

In June 2011, the FASB issued guidance related to the presentation of comprehensive income. This accounting standard (1) eliminates the option to present the components of other comprehensive income as part of the statement of changes in stockholders' equity; (2) requires the consecutive presentation of the statement of net income and other comprehensive income; and (3) requires an entity to present reclassification adjustments on the face of the financial statements from other comprehensive income to net income. The amendments in this accounting standard do not change the items that must be reported in other comprehensive income or when an item of other comprehensive income must be reclassified to net income nor do the amendments affect how earnings per share is calculated or presented. This standard is required to be applied retrospectively and is effective for fiscal years and interim periods within those years beginning after December 15, 2011. As this accounting standard only requires enhanced disclosure, the adoption of this standard is not expected to have an impact on the Company's financial position or results of operations.

In December 2011, the FASB issued accounting guidance that requires an entity to disclose both gross and net information about instruments and transactions eligible for offset in the statement of financial position as well as instruments and transactions executed under a master netting or similar arrangement. The standard was issued to enable users of financial statements to understand the effects or potential effects of those arrangements on its financial position. This standard is required to be applied retrospectively and is effective for fiscal years, and interim periods within those years, beginning on or after January 1, 2013. As this accounting standard only requires enhanced disclosure, the adoption of this standard is not expected to have an impact on the Company's financial position or results of operations.

3. ACQUISITIONS

On September 16, 2011, the Company acquired EDT from Elan in a transaction accounted for under the acquisition method of accounting for business combinations, in exchange for \$500.0 million in cash and 31.9 million ordinary shares of Alkermes, valued at \$525.1 million, based on a stock price of \$16.46 per share on the acquisition date. Under the acquisition method of accounting, the assets acquired and liabilities assumed were recorded as of the acquisition date, at their respective fair values. The reported consolidated financial condition and results of operations after completion of the acquisition reflect these fair values. EDT's results of operations are included in the consolidated financial statements from the date of acquisition.

Prior to the acquisition, EDT, which was a division of Elan, developed and manufactured pharmaceutical products that deliver clinical benefits to patients using EDT's experience and proprietary drug technologies in collaboration with other pharmaceutical companies worldwide. EDT's two principal drug technology platforms are the oral controlled release platform ("OCR") and the bioavailability enhancement platform, including EDT's NanoCrystal® technology. The Company acquired EDT to diversify its commercialized product portfolio and pipeline candidates, enhance its

ALKERMES PLC AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

3. ACQUISITIONS (Continued)

financial resources in order to invest in its proprietary drug candidates, pursue additional growth opportunities and reduce its cost of capital.

During the year ended March 31, 2012, the Company incurred approximately \$29.1 million in expenses related to the EDT acquisition, which primarily consist of banking, legal, accounting and valuation-related expenses. These expenses have been recorded within "Selling, general and administrative" expense in the accompanying consolidated statement of operations and comprehensive loss. During the year ended March 31, 2012, the Company's results of operations included revenues of \$165.0 million and net loss of \$6.3 million from the acquired EDT business.

The purchase price of the EDT business was as follows (in thousands):

Upfront payment in accordance with the merger agreement	\$ 500,000
Equity consideration in accordance with the merger agreement	525,074
Total purchase price	\$ 1,025,074

The purchase price allocation resulted in the following amounts being allocated to the assets acquired and liabilities assumed at the acquisition date based upon their respective fair values summarized below (in thousands):

Cash	\$ 5,225
Receivables	59,398
Inventory	29,669
Prepaid expenses and other current assets	1,806
Property plant and equipment	210,558
Acquired identifiable intangible assets	689,000
Goodwill	92,740
Other assets	4,360
Accounts payable and accrued expenses	(18,650)
Deferred tax liabilities	(48,448)
Other long-term liabilities	(584)
Total	\$ 1,025,074

Asset categories acquired in the EDT acquisition included working capital, fixed assets and identifiable intangible assets, including IPR&D.

The intangible assets acquired included the following (in thousands):

Collaboration agreements	\$ 499,700
NanoCrystal technology	74,600
OCR technology	66,300
In-process research and development	45,800
Trademark	2,600
Total	\$ 689,000

ALKERMES PLC AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

3. ACQUISITIONS (Continued)

Intangible assets associated with collaboration agreements relate to the several collaboration agreements EDT has in place with third-party pharmaceutical companies related to the development and commercialization of products or an improvement to existing products based on EDT's experience with drug delivery systems and their technology platforms. The estimated useful life of the collaboration agreements is 12 years. The NanoCrystal and OCR technologies are platform technologies that are used in both currently marketed products and potential future products currently under development. The estimated fair value of these technologies was determined using the relief from royalty method, an approach under which fair value is estimated to be the present value of royalties saved because the Company owns the intangible assets and therefore does not have to pay a royalty for its use. The estimated useful lives of the NanoCrystal and OCR technologies are 13 and 12 years, respectively.

Intangible assets associated with IPR&D relate to three EDT product candidates, including Megestrol for use in Europe, which had a value of \$28.8 million. The estimated fair value for the collaboration agreements and IPR&D was determined using the excess earnings approach. The excess earnings approach includes projecting revenue and costs attributable to the associated collaboration agreement or product candidate and then subtracting the required return related to other contributory assets used in the business to determine any residual excess earnings attributable to the collaboration agreement or product candidate. The after-tax excess earnings are then discounted to present value using an appropriate discount rate. During the fourth quarter of fiscal year 2012, and after finalization of the purchase accounting for the Business Combination, the Company identified events and changes in circumstance, such as correspondence from regulatory authorities and further clinical trial results related to three product candidates, including Megestrol for use in Europe, acquired as part of the Business Combination which indicated that the assets may be impaired. Accordingly, the Company recorded an impairment charge of \$45.8 million within "Amortization and impairment of acquired intangible assets" in the accompanying statement of operations and comprehensive loss. See Note 8, *Goodwill and Intangible Assets* for additional details.

The estimated fair value of the EDT trademark was determined using the relief from royalty method. The Company does not expect to use the EDT trademark beyond March 31, 2012 and, as a result, the Company amortized the full value of the trademark during the year ended March 31, 2012.

The excess of purchase price over the fair value amounts assigned to the assets acquired and liabilities assumed represents the goodwill amount resulting from the acquisition. The Company does not expect any portion of this goodwill to be deductible for tax purposes. The goodwill attributable to the acquisition of EDT has been recorded as a noncurrent asset and is not amortized, but is subject to an annual review for impairment. The factors that contributed to the recognition of goodwill included the synergies that are specific to the Company's business and not available to market participants, including the Company's unique ability to leverage its knowledge in the areas of drug delivery and development of innovative medicines to improve patients' lives, the acquisition of a talented workforce that brings translational medicine expertise to the Company's preclinical compounds and the Company's ability to utilize its research capacity to develop additional compounds using the acquired technologies.

ALKERMES PLC AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

3. ACQUISITIONS (Continued)

Pro forma financial information (unaudited)

The following unaudited pro forma information presents the combined results of operations for years ended March 31, 2012, 2011 and 2010 as if the acquisition of EDT had been completed on April 1, 2009. The unaudited pro forma results do not reflect any material adjustments, operating efficiencies or potential cost savings which may result from the consolidation of operations but do reflect certain adjustments expected to have a continuing impact on the combined results.

(In thousands, except per share data)	Year Ended December 31,	
	2012	2011
Revenues	\$ 500,105	\$ 450,222
Net (loss) income	\$ (108,782)	\$ 10,265
Basic and diluted (loss) earnings per common share	\$ (0.84)	\$ 0.08

F-24

ALKERMES PLC AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

4. INVESTMENTS

Investments consist of the following:

(In thousands)	Amortized Cost	Gains	Gross Unrealized Losses		Estimated Fair Value
			Less than One Year	Greater than One Year	
March 31, 2012					
Short-term investments:					
Available-for-sale securities:					
U.S. government and agency debt securities	\$ 62,925	\$ 67	\$ (17)	\$	\$ 62,975
International government agency debt securities	25,646	22	(2)		25,666
Corporate debt securities	12,324	27			12,351
	100,895	116	(19)		100,992
Held-to-maturity securities:					
Certificates of deposit	4,236				4,236
U.S. government obligations	417				417
	4,653				4,653
Money market funds	1,201				1,201
Total short-term investments	106,749	116	(19)		106,846
Long-term investments:					
Available-for-sale securities:					
U.S. government and agency debt securities	35,493		(70)		35,423
International government agency debt securities	10,257		(20)		10,237
Corporate debt securities	8,009			(660)	7,349
Strategic investments	644	838			1,482
	54,403	838	(90)	(660)	54,491
Held-to-maturity securities:					
Certificates of deposit	1,200				1,200
Total long-term investments	55,603	838	(90)	(660)	55,691
Total investments	\$ 162,352	\$ 954	\$ (109)	\$ (660)	\$ 162,537
March 31, 2011					
Short-term investments:					
Available-for-sale securities:					
U.S. government and agency debt securities	\$ 117,298	\$ 129	\$ (1)	\$	\$ 117,426
Corporate debt securities	20,973	48		(4)	21,017
International government agency debt securities	23,048	236			23,284
	161,319	413	(1)	(4)	161,727
Money market funds	1,201				1,201
Total short-term investments	162,520	413	(1)	(4)	162,928

Edgar Filing: Alkermes plc. - Form 10-K

Long-term investments:

Available-for-sale securities:					
U.S. government and agency debt securities	57,709		(804)		56,905
International government agency debt securities	15,281		(93)		15,188
Corporate debt securities	15,140		(29)	(328)	14,783
Strategic investments	644	31			675
	88,774	31	(926)	(328)	87,551
Held-to-maturity securities:					
Certificates of deposit	5,440				5,440
U.S. government obligations	417				417
	5,857				5,857
Total long-term investments	94,631	31	(926)	(328)	93,408
Total investments	\$ 257,151	\$ 444	\$ (927)	\$ (332)	\$ 256,336

F-25

ALKERMES PLC AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

4. INVESTMENTS (Continued)

The proceeds from the sales and maturities of marketable securities, excluding strategic equity investments, which were primarily reinvested and resulted in realized gains and losses, were as follows:

(In thousands)	Year Ended March 31,		
	2012	2011	2010
Proceeds from the sales and maturities of marketable securities	\$ 323,028	\$ 385,511	\$ 516,935
Realized gains	\$ 47	\$ 77	\$ 251
Realized losses	\$ 11	\$ 32	\$ 43

The Company's available-for-sale and held-to-maturity securities at March 31, 2012 have contractual maturities in the following periods:

(In thousands)	Available-for-sale		Held-to-maturity	
	Amortized Cost	Estimated Fair Value	Amortized Cost	Estimated Fair Value
Within 1 year	\$ 60,828	\$ 60,840	\$ 5,853	\$ 5,853
After 1 year through 5 years	93,826	93,161		
Total	\$ 154,654	\$ 154,001	\$ 5,853	\$ 5,853

At March 31, 2012, the Company believes that the unrealized losses on its available-for-sale investments are temporary. The investments with unrealized losses consist primarily of corporate debt securities. In making the determination that the decline in fair value of these securities was temporary, the Company considered various factors, including but not limited to: the length of time each security was in an unrealized loss position; the extent to which fair value was less than cost; financial condition and near-term prospects of the issuers; and the Company's intent not to sell these securities, and the assessment that it is more likely than not that the Company would not be required to sell these securities before the recovery of their amortized cost basis.

The Company's investment in Acceleron Pharma, Inc. ("Acceleron") was \$8.7 million and \$8.5 million at March 31, 2012 and 2011, respectively, which is recorded within "Other assets" in the accompanying consolidated balance sheets. The Company accounts for its investment in Acceleron under the cost method as Acceleron is a privately-held company over which the Company does not exercise significant influence. The Company continues to monitor this investment to evaluate whether any decline in its value has occurred that would be other-than-temporary, based on the implied value from any recent rounds of financing completed by Acceleron, market prices of comparable public companies and general market conditions.

The Company's investment in Civitas Therapeutics, Inc. ("Civitas") was \$2.0 million and \$1.3 million at March 31, 2012 and 2011, respectively, which is recorded within "Other assets" in the accompanying consolidated balance sheets. The Company accounts for its investment in Civitas under the equity method as the Company has an approximately 11% ownership position in Civitas, has a seat on the board of directors and believes it may be able to exercise significant influence over the operating and financial policies of Civitas.

ALKERMES PLC AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

4. INVESTMENTS (Continued)

During the year ended March 31, 2012, Civitas issued 14.3 million shares of Series A preferred stock in exchange for \$12.5 million. The Company did not participate in the financing, however, it received 12.4% of these Series A preferred shares in accordance with the terms of its arrangement with Civitas and recorded an increase to its investment in Civitas of \$1.5 million. The Company has deferred the recognition of the gain on its investment in Civitas and will recognize it into "Other income", ratably over a period of approximately four years, in the Company's consolidated statement of operations and comprehensive loss. In addition, during the year ended March 31, 2012, the Company recorded a reduction in its investment in Civitas of \$0.9 million, which represented the Company's proportionate share of Civitas' net losses for this period.

5. FAIR VALUE

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

(In thousands)	March 31, 2012	Level 1	Level 2	Level 3
Assets:				
Cash equivalents	\$ 1,201	\$ 1,201	\$	\$
U.S. government and agency debt securities	98,398	98,398		
International government agency debt securities	35,903	30,902		5,001
Corporate debt securities	19,700		14,045	5,655
Strategic equity investments	1,482	1,482		
Interest rate cap contracts	20		20	
Total	\$ 156,704	\$ 131,983	\$ 14,065	\$ 10,656
Liabilities:				
Interest rate swap contract	\$ (522)		(522)	
Total	\$ (522)	\$	\$ (522)	\$

(In thousands)	March 31, 2011	Level 1	Level 2	Level 3
Assets:				
Cash equivalents	\$ 1,303	\$ 1,303	\$	\$
U.S. government and agency debt securities	174,331	174,331		
Corporate debt securities	35,801		34,754	1,047
International government agency debt securities	38,471	38,471		
Strategic equity investments	675	675		
Total	\$ 250,581	\$ 214,780	\$ 34,754	\$ 1,047

ALKERMES PLC AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

5. FAIR VALUE (Continued)

The following table is a rollforward of the fair value of the Company's investments whose fair value was determined using Level 3 inputs at March 31, 2012:

(In thousands)	Fair Value
Balance, April 1, 2011	\$ 1,047
Investments transferred into Level 3 from Level 1	4,995
Investments transferred into Level 3 from Level 2	7,586
Investments transferred out of Level 3 to Level 2	(2,762)
Total unrealized losses included in comprehensive loss	(210)
 Balance, March 31, 2012	 \$ 10,656

The Company transfers its financial assets and liabilities measured at fair value on a recurring basis between the fair value hierarchies at the end of each reporting period. During the year ended March 31, 2012, there was one investment in corporate debt securities transferred into Level 3 from Level 2 as trading in this security ceased during the period. Also, during the year ended March 31, 2012, there was one investment in an international government agency debt security transferred into Level 3 from Level 1 as trading in this security ceased during the period. During the period, there were two corporate debt securities that were transferred into Level 2 from Level 3 as trading in these securities resumed during the period. There were no transfers of investments between Level 1 and Level 2 during the year ended March 31, 2012.

In September and December 2011, the Company entered into interest rate cap agreements, and in September 2011, the Company entered into an interest rate swap agreement. These agreements are described in greater detail in Note 11, *Derivative Instruments*. The fair value of the Company's interest rate cap and interest rate swap agreements were based on an income approach, which excludes accrued interest, and takes into consideration then-current interest rates and then-current creditworthiness of the Company or the counterparty, as applicable.

Substantially all of the Company's corporate debt securities have been classified as Level 2. These securities were initially valued at the transaction price and subsequently valued, at the end of each reporting period, utilizing market observable data. The market observable data includes reportable trades, benchmark yields, credit spreads, broker/dealer quotes, bids, offers, current spot rates and other industry and economic events. The Company validates the prices developed using the market observable data by obtaining market values from other pricing sources, analyzing pricing data in certain instances and confirming that the relevant markets are active.

The Company used a discounted cash flow model to determine the estimated fair value of its Level 3 securities. The assumptions used in the discounted cash flow model included estimates for interest rates, timing of cash flows, expected holding periods and risk-adjusted discount rates, which include provisions for default and liquidity risk, which the Company believes to be the most critical assumptions utilized within the analysis. When available, the Company considers bid and ask prices in valuing its Level 3 securities.

The carrying amounts reflected in the condensed consolidated balance sheets for cash and cash equivalents, accounts receivable, other current assets, accounts payable and accrued expenses approximate fair value due to their short-term nature. The fair value of the remaining financial

ALKERMES PLC AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

5. FAIR VALUE (Continued)

instruments not currently recognized at fair value on the Company's consolidated balance sheets consist of the Term Loans. The estimated fair value of the Term Loans, which was based on quoted market price indications, is as follows:

(In thousands)	Carrying Value	Estimated Fair Value
First Lien Term Loan	\$ 306,822	\$ 314,265
Second Lien Term Loan	\$ 137,638	\$ 144,550

6. INVENTORY

Inventory consists of the following:

(In thousands)	March 31,	
	2012	2011
Raw materials	\$ 12,841	\$ 3,100
Work in process	9,569	5,843
Finished goods(1)	16,968	11,127
Consigned-out inventory(2)	381	355
Inventory	\$ 39,759	\$ 20,425

- (1) At March 31, 2012 and 2011, the Company had \$1.3 million and \$2.0 million, respectively, of finished goods inventory located at its third party warehouse and shipping service provider.
- (2) At March 31, 2012 and 2011, consigned-out inventory relates to VIVITROL inventory in the distribution channel for which the Company had not recognized revenue.

7. PROPERTY, PLANT AND EQUIPMENT

Property, plant and equipment consist of the following:

(In thousands)	March 31,	
	2012	2011
Land	\$ 8,891	\$ 301
Building and improvements	127,583	36,792
Furniture, fixture and equipment	189,262	62,660
Leasehold improvements	45,798	44,779
Construction in progress	44,768	42,194
Subtotal	416,302	186,726
Less: accumulated depreciation	(113,307)	(91,706)
Total property, plant and equipment, net	\$ 302,995	\$ 95,020

ALKERMES PLC AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

7. PROPERTY, PLANT AND EQUIPMENT (Continued)

Depreciation expense was \$22.5 million, \$8.7 million and \$25.0 million for the years ended March 31, 2012, 2011 and 2010, respectively. The Company has \$0.5 million of fully depreciated equipment acquired under a capital lease at March 31, 2012 and 2011, respectively.

During the year ended March 31, 2012, the Company wrote off furniture, fixtures and equipment that had a carrying value of less than \$0.1 million at the time of disposition and received proceeds from the sales of furniture, fixtures and equipment of less than \$0.1 million. During the year ended March 31, 2011, the Company wrote off furniture, fixtures and equipment that had a carrying value of \$0.1 million at the time of disposition and received proceeds from the sales of furniture, fixtures and equipment of \$0.4 million.

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

8. GOODWILL AND INTANGIBLE ASSETS

Goodwill and intangible assets consists of the following:

(In thousands)	Weighted Amortizable Life	March 31, 2012		
		Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount
Goodwill		\$ 92,740	\$	\$ 92,740
Finite-lived intangible assets:				
Collaboration agreements	12	\$ 499,700	\$ (17,734)	\$ 481,966
NanoCrystal technology	13	74,600	(1,839)	72,761
OCR technology	12	66,300	(3,182)	63,118
Trademark		2,600	(2,600)	
Total finite-lived intangible assets		643,200	(25,355)	617,845
Indefinite-lived intangible assets:				
IPR&D		45,800	(45,800)	
Total		\$ 689,000	\$ (71,155)	\$ 617,845

The Company's goodwill balance solely relates to the Business Combination. As a result of the qualitative assessment performed as of October 31, 2011, the Company determined that it was not more-likely-than-not that the fair value of the reporting unit was less than its carrying amount, and an impairment of the Company's goodwill was not recorded.

During the fourth quarter of fiscal year 2012 and after finalization of the purchase accounting for the Business Combination, the Company identified events and changes in circumstance, such as correspondence from regulatory authorities and further clinical trial results related to three product

ALKERMES PLC AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

8. GOODWILL AND INTANGIBLE ASSETS (Continued)

candidates, including Megestrol for use in Europe, acquired as part of the Business Combination which indicated that the assets may be impaired. As such, the Company performed an analysis to measure the amount of the impairment loss, if any. The Company performed the valuation of its IPR&D from the viewpoint of a market participant through the use of a discounted cash flow model. The model contained certain key assumptions, including the cost to bring the pre-clinical products through the clinical trial and regulatory approval process, the gross margin a market participant would expect to earn if the products were approved for sale, the cost to sell the approved product and a discount factor based on an industry average weighted average cost of capital. Based on the analysis performed, the Company determined that the IPR&D was impaired and recorded an impairment charge of \$45.8 million within "Amortization and impairment of acquired intangible assets" in the accompanying statement of operations and comprehensive loss.

The Company recorded \$25.4 million of amortization expense related to its finite-lived intangible assets during the year ended March 31, 2012. Based upon the Company's most recent analysis, amortization of intangible assets included within its consolidated balance sheet at March 31, 2012 is expected to be in the range of approximately \$40.0 million to \$70.0 million annually through fiscal year 2017.

9. ACCOUNTS PAYABLE AND ACCRUED EXPENSES

Accounts payable and accrued expenses consist of the following:

(In thousands)	March 31,	
	2012	2011
Accounts payable	\$ 18,400	\$ 9,269
Accrued compensation	25,023	17,481
Accrued interest	2,472	
Accrued other	33,259	18,184
Total accounts payable and accrued expenses	\$ 79,154	\$ 44,934

10. LONG-TERM DEBT

Long-term debt consists of the following:

(In thousands)	March 31,	March 31,
	2012	2011
First Lien Term Loan, due September 16, 2017	\$ 306,822	\$
Second Lien Term Loan, due September 16, 2018	137,638	
Total	444,460	
Less: current portion	(3,100)	
Long-term debt	\$ 441,360	\$

ALKERMES PLC AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

10. LONG-TERM DEBT (Continued)

Term Loans

On September 16, 2011, the Company entered into the Term Loans with certain of its subsidiaries, as guarantors, Morgan Stanley Senior Funding, Inc., ("MSSF") as administrative agent and as collateral agent, MSSF and HSBC Securities (USA) Inc., ("HSBC") as co-syndication agents, joint lead arrangers and joint bookrunners, and various other financial institutions, as lenders. The First Lien Term Loan was issued with an original issue discount of \$3.1 million, has a term of six years and is secured by a first priority lien on substantially all of the assets and properties of the Company and the guarantors. The Second Lien Term Loan was issued with an original issue discount of \$2.8 million, has a term of seven years and is secured by a second priority lien on substantially all of the assets and properties of the Company and the guarantors.

Scheduled maturities with respect to the Term Loans are as follows (in thousands):

Fiscal Year:	
2013	\$ 3,100
2014	3,100
2015	3,100
2016	3,100
2017	3,100
Thereafter	433,725
Total	\$ 449,225

The initial applicable margin for borrowings under the First Lien Term Loan is three-month LIBOR plus 5.25% and three-month LIBOR plus 8.00% under the Second Lien Term Loan. Under each of the Term Loans, LIBOR is subject to an interest rate floor of 1.50%. Commencing upon the completion of the Company's first fiscal quarter ending after the Business Combination, the applicable margin under the First Lien Term Loan is subject to adjustment each fiscal quarter, based upon meeting a certain consolidated leverage ratio during the preceding quarter. The applicable margin under the Second Lien Term Loan is not subject to adjustment.

Required quarterly principal payments of \$0.8 million on the First Lien Term Loan began on March 31, 2012. In addition, beginning in fiscal year 2013, the Company is 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. The Company may make prepayments of principal without penalty; however, no principal payments may be made on the Second Lien Term Loan until the First Lien Term Loan has been repaid in full. If prepayments are made prior to September 16, 2012, the Company 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.

Each of the Term Loans has incremental capacity in an amount of \$50.0 million, plus additional amounts so long as the Company meets certain conditions, including a specified leverage ratio. The agreements governing the Term Loans include a number of restrictive covenants that, among other things, and subject to certain exceptions and baskets, impose operating and financial restrictions on

ALKERMES PLC AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

10. LONG-TERM DEBT (Continued)

Alkermes, Inc., the Company and the restricted subsidiaries. These financing agreements also contain customary affirmative covenants and events of default. The Company was in compliance with its debt covenants at March 31, 2012.

As part of the Term Loans, the Company is required to enter into and thereafter maintain hedge agreements to the extent necessary to provide that at least 50% of the aggregate principal amount of the Term Loans is subject to either a fixed interest rate or interest rate protection for a period of not less than three years. Pursuant to this requirement, the Company entered into an interest rate swap agreement and interest rate cap agreements, which are discussed in greater detail in Note 11, *Derivative Instruments*.

The Company incurred \$11.8 million of offering costs associated with the issuance of the Term Loans which were recorded under the caption "Other assets" in the accompanying consolidated balance sheets. The offering costs and original issue discount related to the Term Loans are being amortized to interest expense over the estimated repayment terms using the effective interest method. During the year ended March 31, 2012, the Company had amortization expense of \$3.5 million related to the offering costs and original issue discount.

Non-Recourse RISPERDAL CONSTA Secured 7% Notes

On February 1, 2005, the Company, pursuant to the terms of a purchase and sale agreement, sold, assigned and contributed to Royalty Sub the rights of the Company to collect certain royalty payments and manufacturing fees earned under the license and manufacturing and supply agreements with Janssen, in exchange for approximately \$144.2 million in cash. Concurrently with the purchase and sale agreement, on February 1, 2005, Royalty Sub issued an aggregate principal amount of \$170.0 million of its non-recourse 7% Notes to certain institutional investors in a private placement, for net proceeds of approximately \$144.2 million, after the original issue discount and offering costs of approximately \$19.7 million and \$6.1 million, respectively. The yield to maturity at the time of the offer was 9.75%. The annual cash coupon rate was 7% and was payable quarterly, beginning on April 1, 2005, however, portions of the principal amount that were not paid off in accordance with the expected principal repayment schedule would have accrued interest at 9.75% per annum. Through January 1, 2009, the holders received only quarterly cash interest payments. Beginning on April 1, 2009, principal payments were made to the holders, subject to certain conditions, and the non-recourse 7% Notes were scheduled to mature on January 1, 2012.

On July 1, 2010, in addition to the scheduled principal payment of \$6.4 million, the Company fully redeemed the balance of the non-recourse 7% Notes for \$39.2 million, representing 101.75% of the outstanding principal balance in accordance with the terms of the Indenture for the non-recourse 7% Notes. As a result of this transaction, the Company recorded charges of \$1.4 million relating to the write-off of the unamortized portion of deferred financing costs and \$0.8 million primarily related to the premium paid on the redemption of the non-recourse 7% Notes within "Interest expense" in the accompanying consolidated statement of operations. During the years ended March 31, 2012, 2011 and 2010, amortization of the original issue discount and offering costs, which were being amortized over the expected principal repayment period ending January 1, 2012, totaled zero, \$1.7 million, and \$1.7 million, respectively.

ALKERMES PLC AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

11. DERIVATIVE INSTRUMENTS

In December 2011, the Company entered into an interest rate cap agreement with Morgan Stanley Capital Services LLC ("MSCS") at a cost of \$0.1 million to mitigate the impact of fluctuations in the three-month LIBOR rate at which the Company's Term Loans bear interest. The interest rate cap agreement expires in December 2013, has a notional value of \$160.0 million and is not designated as a hedging instrument. The Company recorded a loss of \$0.1 million within "Other expense, net" in the accompanying consolidated statements of operations and comprehensive loss due to the decrease in value of this contract during the year ended March 31, 2012.

In July 2011, the Company entered into an interest rate cap agreement with HSBC Bank USA at a cost of less than \$0.1 million to mitigate the impact of fluctuations in the three-month LIBOR rate at which the Company's Term Loans bear interest. The interest rate cap agreement became effective upon the issuance of the Term Loans, expires in December 2012, has a notional value of \$65.0 million and is not designated as a hedging instrument. The Company recorded an immaterial amount of loss within "Other expense, net" in the accompanying consolidated statements of operations and comprehensive loss due to the decline in value of this contract during the year ended March 31, 2012.

In July 2011, the Company entered into an interest rate swap agreement with MSCS to mitigate the impact of fluctuations in the three-month LIBOR rate at which the Company's Term Loans bear interest. The interest rate swap agreement becomes effective in December 2012, expires in December 2014 and has a notional value of \$65.0 million. This contract has been designated as a cash flow hedge and accordingly, to the extent effective, any unrealized gains or losses on this interest rate swap contract is reported in accumulated other comprehensive loss. To the extent the hedge is ineffective, hedge transaction gains and losses are reported in "Other expense, net" when the interest payment on the related debt is recognized.

The following table summarizes the fair value and presentation in the consolidated balance sheets for derivatives designated and not designated as hedging instruments:

(In thousands)	Balance Sheet Location	Fair Value at March 31, 2012
<i>Interest rate swap</i>		
Liability derivative designated as a cash flow hedge	Other long-term liabilities	\$ (522)
<i>Interest rate caps</i>		
Asset derivatives not designated as a hedging instruments	Other long-term assets	\$ 20

The following table summarizes the effect of derivatives designated as hedging instruments on the consolidated statements of operations and comprehensive loss:

(In thousands)	Amount Recognized in Accumulated Other Comprehensive Loss (Effective Portion)	Amount Reclassified from Accumulated Other Comprehensive Loss into Earnings (Effective Portion)	Amount of Loss Recorded (Ineffective Portion)
March 31, 2012	\$ (522)	\$	\$

The cash flow hedge was deemed to be effective at March 31, 2012. Accordingly, the Company included the loss incurred during the year ended March 31, 2012 within accumulated other comprehensive loss. The Company expects that when this contract matures any amounts in accumulated

ALKERMES PLC AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

11. DERIVATIVE INSTRUMENTS (Continued)

other comprehensive loss is to be reported as an adjustment to interest expense. The Company considers the impact of its and MSCS' credit risk on the fair value of the contract as well as the ability of each party to execute its obligations under the contract. At March 31, 2012, credit risk did not materially change the fair value of the Company's interest rate swap contract.

12. LOSS PER SHARE

Basic loss per common share is calculated based upon net loss available to holders of common shares divided by the weighted average number of shares outstanding. Diluted loss per common share is based upon the weighted-average number of common shares outstanding during the period plus additional weighted-average common equivalent shares outstanding during the period when the effect is dilutive. Common equivalent shares result from the assumed exercise of outstanding stock options (the proceeds of which are then assumed to have been used to repurchase outstanding stock using the treasury stock method) and the vesting of unvested restricted stock units. Common equivalent shares have not been included in the net loss per common share calculations because the effect would have been anti-dilutive.

The potential common equivalent shares consisted of the following:

(In thousands)	Year Ended March 31,		
	2012	2011	2010
Denominator:			
Stock options	8,299	13,357	17,675
Restricted stock units	1,205	936	419
Total	9,504	14,293	18,094

13. SHAREHOLDERS' EQUITY

Share Repurchase Programs

On September 16, 2011, the board of directors authorized the continuation of the Alkermes, Inc., share repurchase program to repurchase up to \$215.0 million of the Company's ordinary shares at the discretion of management from time to time in the open market or through privately negotiated transactions. The objective of the repurchase program is to improve shareholders' returns. At March 31, 2012, approximately \$101.0 million was available to repurchase ordinary shares pursuant to the repurchase program. All shares repurchased are recorded as treasury stock. The repurchase program has no set expiration date and may be suspended or discontinued at any time. During the year ended March 31, 2012 and 2011, the Company did not acquire any shares of outstanding ordinary shares under the repurchase program.

During the years ended March 31, 2012, 2011 and 2010, the Company acquired, by means of net share settlements, 205,901, 123,943 and 100,449 shares of Alkermes ordinary shares, at an average price of \$17.85, \$11.41 and \$8.68 per share, respectively, related to the vesting of employee stock awards to satisfy withholding tax obligations. In addition, during the year ended March 31, 2010, the Company acquired 7,961 shares of Alkermes ordinary shares, at an average price of \$12.56 per share, tendered by former and current employees as payment of the exercise price of stock options granted under the Company's equity compensation plans. During the years ended March 31, 2012 and 2011, there were

ALKERMES PLC AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

13. SHAREHOLDERS' EQUITY (Continued)

no shares tendered by former or current employees as payment of the exercise price of stock options granted under the Company's equity compensation plans.

14. SHARE-BASED COMPENSATION

Share-based Compensation Expense

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

(In thousands)	Year Ended March 31,		
	2012	2011	2010
Cost of goods manufactured and sold	\$ 2,962	\$ 1,725	\$ 1,506
Research and development	8,784	6,218	3,489
Selling, general and administrative	17,080	11,889	8,926
Total share-based compensation expense	\$ 28,826	\$ 19,832	\$ 13,921

At March 31, 2012, 2011 and 2010, \$0.4 million, \$0.6 million and \$0.6 million, respectively, of share-based compensation cost was capitalized and recorded as "Inventory" in the consolidated balance sheets.

Share-based Compensation Plans

The Company has two compensation plans pursuant to which awards are currently being made, the 2011 Stock Option and Incentive Plan (the "2011 Plan"), and the 2008 Plan. The Company has five share-based compensation plans pursuant to which outstanding awards have been made, but from which no further awards can or will be made: (i) the 1996 Stock Option Plan for Non-Employee Directors (the "1996 Plan"); (ii) the 1998 Equity Incentive Plan (the "1998 Plan"); (iii) the 1999 Stock Option Plan (the "1999 Plan"); (iv) the 2002 Restricted Stock Award Plan (the "2002 Plan"); and (v) the 2006 Stock Option Plan for Non-Employee Directors (the "2006 Plan"). The 2011 Plan and the 2008 Plan provides for issuance of non-qualified and incentive stock options, restricted stock, restricted stock units, cash-based awards and performance shares to employees, officers and directors of, and consultants to, the Company in such amounts and with such terms and conditions as may be determined by the compensation committee of the Company's board of directors, subject to provisions of the 2011 Plan and the 2008 Plan.

At March 31, 2012, there were 9.4 million shares of ordinary shares available for issuance under the Company's stock plans. The 2011 Plan provides that awards other than stock options will be counted against the total number of shares available under the plan in a 1.8-to-1 ratio and the 2008 Plan provides that awards other than stock options will be counted against the total number of shares available under the plan in a 2-to-1 ratio.

ALKERMES PLC AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

14. SHARE-BASED COMPENSATION (Continued)

Stock Options

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

	Number of Shares	Weighted Average Exercise Price
Outstanding, April 1, 2011	16,985,009	\$ 13.45
Granted	3,802,100	\$ 16.41
Exercised	(1,798,349)	\$ 11.63
Forfeited	(227,025)	\$ 13.50
Expired	(1,401,975)	\$ 21.60
Outstanding, March 31, 2012	17,359,760	\$ 13.68
Exercisable, March 31, 2012	11,018,060	\$ 13.54

The weighted average grant date fair value of stock options granted during the years ended March 31, 2012, 2011 and 2010 was \$8.00, \$5.92 and \$4.46, respectively. The aggregate intrinsic value of stock options exercised during the years ended March 31, 2012, 2011 and 2010 was \$11.1 million, \$2.0 million and \$2.6 million, respectively.

At March 31, 2012, there were 6.1 million stock options expected to vest with a weighted average exercise price of \$13.87 per share, a weighted average contractual remaining life of 8.6 years and an aggregate intrinsic value of \$28.4 million. At March 31, 2012, the aggregate intrinsic value of stock options exercisable was \$56.6 million with a weighted average remaining contractual term of 4.2 years. The number of stock options expected to vest is determined by applying the pre-vesting forfeiture rate to the total outstanding options. The intrinsic value of a stock option is the amount by which the market value of the underlying stock exceeds the exercise price of the stock option.

At March 31, 2012, there was \$23.3 million of unrecognized compensation cost related to unvested stock options, which is expected to be recognized over a weighted average period of approximately 2.1 years. Cash received from option exercises under the Company's award plans during the years ended March 31, 2012 and 2011 was \$17.2 million and \$4.7 million, respectively. The Company issued new shares upon option exercises during the years ended March 31, 2012 and 2011.

ALKERMES PLC AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

14. SHARE-BASED COMPENSATION (Continued)

Time-Vested Restricted Stock Units

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

	Number of Shares	Weighted Average Grant Date Fair Value
Nonvested, April 1, 2011	1,870,515	\$ 10.69
Granted	883,100	\$ 17.91
Vested	(544,989)	\$ 11.17
Forfeited	(94,450)	\$ 13.54
Novested, March 31, 2012	2,114,176	\$ 13.45

The weighted average grant date fair value of time-vested RSUs granted during the years ended March 31, 2012, 2011 and 2010 was \$17.91, \$11.74 and \$8.83, respectively. The total fair value of time-vested RSUs that vested during the years ended March 31, 2012, 2011 and 2010 was \$6.1 million, \$4.0 million and \$2.4 million, respectively.

At March 31, 2012, there was \$12.5 million of total unrecognized compensation cost related to unvested time-vested RSUs, which will be recognized over a weighted average remaining contractual term of 1.9 years.

Performance-Based Restricted Stock Units

In May 2009, the board of directors awarded 45,000 RSUs to certain of the Company's executive officers under the 2006 Plan that vest upon the approval of BYDUREON by the U.S. Food and Drug Administration ("FDA"), provided the approval by the FDA occurs at least one year after the date of grant. During the year ended March 31, 2010, 20,000 RSU's were forfeited upon the resignation of an executive officer. The grant date fair value of the award was \$8.55 per share, which was the market value of the Company's stock on the date of grant. During the year ended March 31, 2012, the performance condition was met and the award vested.

In May 2008, the board of directors awarded 40,000 RSUs to certain of the Company's executive officers under the 2002 Plan that vest upon the achievement of a market condition specified in the award terms. During the year ended March 31, 2010, 10,000 RSU's were forfeited upon the resignation of an executive officer. The grant date fair value of \$9.48 per share was determined through the use of a Monte Carlo simulation model. The compensation cost for the award's grant date fair value of \$0.4 million was recognized over a derived service period of 1.4 years. During the year ended March 31, 2012, the market condition was met and the awards vested.

ALKERMES PLC AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

15. COLLABORATIVE ARRANGEMENTS

The Company's business strategy includes forming collaborations to develop and commercialize its products, and to access technological, financial, marketing, manufacturing and other resources. The Company significant collaborative arrangements are described below:

Janssen

RISPERDAL CONSTA

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

Under license agreements, the Company granted Janssen and an affiliate of Janssen exclusive worldwide licenses to use and sell RISPERDAL CONSTA. Under its license agreements with Janssen, the Company receives 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 the Company. 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 its manufacturing and supply agreement with Janssen, the Company records 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 the Company. In the event that Janssen terminates the manufacturing and supply agreement without terminating the license agreements, the royalty rate payable to the Company on Janssen's net sales of RISPERDAL CONSTA would increase from 2.5% to 5.0%.

INVEGA SUSTENNA/XEPLION

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

Under its license agreement, the Company receives 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

ALKERMES PLC AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

15. COLLABORATIVE ARRANGEMENTS (Continued)

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 the Company. The Company and Janssen have the right to terminate the agreement upon the material breach of the other party, which is not cured within a certain time period or upon the other party's bankruptcy or insolvency.

During the years ended March 31, 2012, 2011 and 2010, the Company recognized \$186.6 million, \$154.4 million, and \$148.8 million, respectively, of revenue from its arrangements with Janssen.

Acorda

Under an amended and restated license agreement, the Company granted Acorda an exclusive worldwide license to use and sell and, solely in accordance with its supply agreement, to make or have made AMPYRA/FAMPYRA. Under its license agreement with Acorda, the Company receives 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. The Company has 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 the Company terminates Acorda's license in any country, the Company is 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 its commercial manufacturing supply agreement with Acorda, the Company manufactures and supplies 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. The Company receives royalties equal to 8% of net selling price for all product manufactured by it and a compensating payment for product manufactured and supplied by a third party. The Company 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.

ALKERMES PLC AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

15. COLLABORATIVE ARRANGEMENTS (Continued)

In January 2011, the Company entered into a development and supplemental agreement to its amended and restated license agreement with Acorda. Under the terms of this agreement, the Company granted Acorda the right, either with it 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 the Company or by a third party for commercialization. If Acorda selects and commercializes a formulation developed by the Company, the Company is entitled to development fees, milestone payments (for new indications if not previously paid), license revenues and royalties in accordance with its amended and restated license agreement, and either manufacturing fees as a percentage of net selling price for product manufactured by the Company or compensating fees for product manufactured by third parties. If Acorda selects a formulation not developed by the Company, then the Company 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 amended and restated 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.

During the years ended March 31, 2012, 2011 and 2010, the Company recognized \$25.8 million, none and none respectively, of revenue from its arrangements with Acorda.

Amylin

In May 2000, the Company entered into a development and license agreement with Amylin for the development of exendin products falling within the scope of its patents, which includes the once-weekly formulation of exenatide, BYDUREON. Pursuant to the development and license agreement, Amylin has an exclusive, worldwide license to the Company's polymer-based microsphere technology for the development and commercialization of injectable extended-release formulations of exendins and other related compounds. The Company receives 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. In October 2005 and in July 2006, the Company amended the development and license agreement. Under the amended agreement, the Company is responsible for formulation and is 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

ALKERMES PLC AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

15. COLLABORATIVE ARRANGEMENTS (Continued)

conducting clinical trials, securing regulatory approvals and marketing any products resulting from the collaboration on a worldwide basis.

In conjunction with the 2005 amendment of the development and license agreement with Amylin, the Company 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 the Company's manufacturing processes was completed in 2009. Amylin will be responsible for the manufacture of BYDUREON and will operate the facility.

Until December 31 of the tenth full calendar year following the year in which the first commercial sale of BYDUREON occurs, the Company will receive royalties equal to 8% of net sales from the first 40 million units of BYDUREON sold in any particular year and 5.5% of net sales from units sold beyond the first 40 million units for that year. Thereafter, during the term of the development and license agreement, the Company will receive royalties equal to 5.5% of net sales of products sold. The Company received a \$7.0 million milestone payment in each of July 2011 and March 2012 upon the first commercial sale of BYDUREON in the EU and U.S., respectively.

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 its 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 the Company. In addition, either party may terminate the development and license agreement upon a material default or breach by the other party that is not cured within 60 days after receipt of written notice specifying the default or breach.

During the years ended March 31, 2012, 2011 and 2010, the Company recognized \$18.8 million, \$2.9 million and \$4.1 million, respectively, of revenue from its arrangements with Amylin.

Cilag

In December 2007, the Company entered into a license and commercialization agreement with Cilag to commercialize VIVITROL for the treatment of alcohol dependence and opioid dependence in Russia and other countries in the CIS. Under the terms of the agreement, Cilag has primary responsibility for securing all necessary regulatory approvals for VIVITROL and Janssen-Cilag, an affiliate of Cilag, commercializes the product. The Company is responsible for the manufacture of VIVITROL and receives manufacturing and royalty revenues based upon product sales.

Cilag has paid the Company \$6.0 million to date in nonrefundable payments, and the Company's agreement provides that it 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 the Company, 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 it 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

ALKERMES PLC AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

15. COLLABORATIVE ARRANGEMENTS (Continued)

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.

During the year ended March 31, 2012, 2011 and 2010, the Company recognized \$5.1 million, \$0.4 million and \$0.8 million of revenue from its arrangement with Cilag, respectively.

16. INCOME TAXES

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

(In thousands)	Year Ended March 31,		
	2012	2011	2010
Current income tax provision (benefit):			
U.S. Federal	\$ 7,321	\$ (756)	\$ (3,318)
U.S. State	6,649	30	75
Rest of world	28		
Deferred income tax (benefit) provision:			
Ireland	(4,551)		
U.S. Federal	(10,024)	(206)	(1,674)
U.S. State	(137)	(19)	(158)
Total tax benefit	\$ (714)	\$ (951)	\$ (5,075)

The current income tax provision for the year ended March 31, 2012 is primarily due to a provision of \$13.1 million on the taxable transfer of the BYDUREON intellectual property from the U.S. to Ireland, partially offset by a \$4.3 million benefit recorded to additional paid-in capital related to the utilization of certain NOL carryforwards resulting from the exercise of employee stock options. The current income tax benefit for the year ended March 31, 2011 is primarily related to a tax benefit for bonus depreciation pursuant to the *Small Business Jobs Act of 2010*. The current income tax benefit for the year ended March 31, 2010 is primarily the result of a carryback of the Company's 2010 AMT NOL pursuant to the *Worker, Homeownership and Business Act of 2009*. This law increased the carryback period for certain NOLs from two years to five years. Prior to the adoption of this law, the Company had recorded a full valuation allowance against the credits that were established in prior periods when the Company was subject to AMT provisions.

The deferred tax provision for the year ended March 31, 2012 is primarily due to a benefit of \$4.6 million from the partial release of the Irish deferred tax liability relating to acquired intellectual property that was established in connection with the Business Combination and a benefit of \$9.9 million due to the partial release of an existing U.S. federal valuation allowance as a consequence of the Business Combination. The deferred tax benefits for the years ended March 31, 2011 and 2010 are primarily due to the recognition of \$0.2 million and \$1.8 million of income tax expense associated with the increase in the value of certain securities that it carried at fair market value during the year ended March 31, 2011 and 2010, respectively.

No provision for income tax has been provided on undistributed earnings of the Company's foreign subsidiaries because the Company considers such earnings to be indefinitely reinvested. Cumulative unremitted earnings of overseas subsidiaries totaled approximately \$10 million at March 31, 2012. In the event of distribution of those earnings in the form of dividends or otherwise, the Company would

ALKERMES PLC AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

16. INCOME TAXES (Continued)

be subject to income taxes, subject to an adjustment, if any, for foreign tax credits, and foreign withholding taxes payable to certain foreign tax authorities. Determination of the amount of income tax liability that would be incurred is not practicable because of the complexities associated with this hypothetical calculation; however, unrecognized foreign tax credit carryforwards may be available to reduce some portion of the tax liability, if any.

The distribution of the Company's net loss before the provision for income taxes by geographical area consisted of the following:

(In thousands)	Year Ended March 31,		
	2012	2011	2010
Ireland	\$ (36,711)	\$	\$
U.S.	(84,858)	(46,491)	(44,701)
Rest of world	7,177		
Loss before provision for income taxes	\$ (114,392)	\$ (46,491)	\$ (44,701)

The components of the Company's net deferred tax liabilities are as follows:

(In thousands)	March 31,	
	2012	2011
Deferred tax assets:		
Irish NOL carryforwards	\$ 55,175	\$
Tax benefit from the exercise of stock options	22,089	35,440
Share-based compensation	21,992	18,137
Tax credit carryforwards	12,294	18,038
U.S. federal and state NOL carryforwards	7,365	54,555
Alkermes Europe, Ltd. NOL carryforward	4,675	5,049
Deferred revenue	1,778	2,016
Other	9,774	6,459
Less: valuation allowance	(107,128)	(133,212)
Total deferred tax assets	28,014	6,482
Deferred tax liabilities:		
Intangible assets	(42,857)	
Property, plant and equipment	(19,049)	(6,482)
Total deferred tax liabilities	(61,906)	(6,482)
Net deferred tax liabilities	\$ (33,892)	\$

As of March 31, 2012, the Company had \$441.4 million of Irish NOL carryforwards, \$107.3 million of U.S. federal NOL carryforwards, \$15.4 million of state NOL carryforwards, and \$18.7 million of other foreign NOL and capital loss carryforwards, which either expire on various dates through 2032 or can be carried forward indefinitely. These loss carryforwards are available to reduce certain future Irish and foreign taxable income, if any. These loss carryforwards are subject to review and possible adjustment by the appropriate taxing authorities. These loss carryforwards, which may be utilized in any future period, may be subject to limitations based upon changes in the ownership of the company's

ALKERMES PLC AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

16. INCOME TAXES (Continued)

stock. The Company has performed a review of ownership changes in accordance with the U.S. Internal Revenue Code and the Company has determined that it is more likely than not that, as a result of the Business Combination, the Company has experienced a change of ownership. As a consequence, the Company's U.S. federal NOL carryforwards and tax credit carryforwards are subject to an annual limitation of \$127.0 million.

The Company records a deferred tax asset or liability based on the difference between the financial statement and tax basis of assets and liabilities, as measured by enacted tax rates assumed to be in effect when these differences reverse. In evaluating the Company's ability to recover its deferred tax assets, the Company considers all available positive and negative evidence including its past operating results, the existence of cumulative income in the most recent fiscal years, changes in the business in which the Company operates and its forecast of future taxable income. In determining future taxable income, the Company is responsible for assumptions utilized including the amount of Irish, U.S. and other foreign pre-tax operating income, the reversal of temporary differences and the implementation of feasible and prudent tax planning strategies. These assumptions require significant judgment about the forecasts of future taxable income and are consistent with the plans and estimates that the Company is using to manage the underlying businesses. As of March 31, 2012, the Company determined that it is more likely than not that a significant portion of the deferred tax assets will not be realized and a valuation allowance has been recorded. The \$26.1 million decrease in the valuation allowance from the year ended March 31, 2011 to the year ended March 31, 2012 was primarily due to the utilization of NOLs. The Company has a \$33.9 million deferred tax liability as of March 31, 2012 which is primarily related to book over tax basis differences in acquired intellectual property.

The tax benefit from stock option exercises included in the table above represents benefits accumulated prior to the adoption of Accounting Standards Codification ("ASC") Topic 718 ("ASC 718") that have not been realized. Subsequent to the adoption of ASC 718 on April 1, 2006, an additional \$17.1 million of tax benefits from stock option exercises, in the form of NOL carryforwards and tax credit carryforwards, have not been recognized in the financial statements and will be once they are realized. In total, the Company has approximately \$39.2 million related to certain NOL carryforwards and tax credit carryforwards resulting from the exercise of employee stock options, the tax benefit of which, when recognized, will be accounted for as a credit to additional paid-in capital rather than a reduction of income tax expense.

ALKERMES PLC AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

16. INCOME TAXES (Continued)

As part of the Business Combination, Alkermes plc was incorporated and is headquartered in Dublin, Ireland. The statutory tax rate for trading income in Ireland is 12.5%. A reconciliation of the Company's statutory tax rate to its effective rate is as follows:

	Year Ended March 31,		
	2012	2011	2010
Statutory rate	12.5%	34.0%	34.0%
U.S. State income taxes, net of U.S. federal benefit	(6.8)%	%	(0.1)%
R&D credit	%	1.4%	0.8%
Share-based compensation	(0.7)%	(2.6)%	(2.9)%
Other permanent items	%	(0.6)%	(0.5)%
Change in valuation allowance	47.3%	(30.1)%	(19.9)%
Foreign rate differential	(51.7)%	%	%
Effective tax rate	0.6%	2.1%	11.4%

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

(In thousands)	Unrecognized Tax Benefits
Balance, April 1, 2009	\$ 1,826
Additions based on tax positions related to prior periods	9
Balance, March 31, 2010	1,835
Additions based on tax positions related to prior periods	49
Balance, March 31, 2011	1,884
Additions based on tax positions related to prior periods	624
Decreases due to lapse of statute of limitations	(68)
Balance, March 31, 2012	\$ 2,440

Included in unrecognized tax benefits at March 31, 2012 is \$2.4 million of tax benefits that, if recognized, would affect the Company's annual effective tax rate. Of this balance, \$1.7 million relates to deferred tax assets for which a full valuation allowance would be recorded, offsetting any tax benefits that would be realized. The Company expects a net reduction in its unrecognized tax benefits in the amount of \$0.5 million due to the expected resolution of certain matters over the next twelve months. The Company has elected to include interest and penalties related to uncertain tax positions as a component of its provision for taxes. For the year ended March 31, 2012, the Company's accrued interest and penalties related to uncertain tax positions was not significant.

Our major taxing jurisdictions include Ireland and the U.S. (federal and state). These jurisdictions have varying statutes of limitations. In the U.S., the 2007 through 2012 fiscal years remain subject to examination by the respective tax authorities. In Ireland, fiscal years 2008 to 2012 remain subject to examination by the Irish tax authorities. Additionally, because of our Irish and U.S. loss carryforwards, certain tax returns from fiscal years 1998 onward may also be examined. These years generally remain open for three to four years after the loss carryforwards have been utilized. Fiscal years, 2007, 2008 and 2010 for Alkermes, Inc., are currently under examination by the U.S. Internal Revenue Service.

ALKERMES PLC AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

17. COMMITMENTS AND CONTINGENCIES

Lease Commitments

The Company leases certain of its offices, research laboratories and manufacturing facilities under operating leases with initial terms of one to twenty years, expiring through the year 2020. Certain of the leases contain provisions for extensions of up to ten years. These lease commitments are primarily related to the Company's corporate headquarters in Ireland and its corporate offices and manufacturing facility in Massachusetts. As of March 31, 2012, the total future annual minimum lease payments under the Company's non-cancelable operating leases are as follows:

(In thousands)	Payment Amount
Fiscal Years:	
2013	\$ 6,190
2014	3,773
2015	4,068
2016	3,970
2017	3,472
Thereafter	12,000
	33,473
Less: estimated sublease income	(4,582)
Total future minimum lease payments	\$ 28,891

Rent expense related to operating leases charged to operations was \$4.2 million, \$5.4 million and \$11.2 million for the years ended March 31, 2012, 2011 and 2010, respectively. These amounts are net of sublease income of \$9.2 million, \$7.3 million and \$3.5 million earned in the years ended March 31, 2012, 2011 and 2010, respectively. In addition to its lease commitments, the Company has open purchase orders totaling \$114.8 million at March 31, 2012.

Litigation

From time to time, the Company may be subject to other legal proceedings and claims in the ordinary course of business. For example, the Company is currently involved in various sets of Paragraph IV litigations in the U.S. and similar suits in Canada and France in respect of certain of its products. The Company is not aware of any such proceedings or claims that it believes will have, individually or in the aggregate, a material adverse effect on its business, results of operations, cash flows and financial condition.

QuickLinks

ALKERMES PLC AND SUBSIDIARIES ANNUAL REPORT ON FORM 10-K FOR THE FISCAL YEAR ENDED MARCH 31, 2012
INDEX

FORWARD-LOOKING STATEMENTS

PART I

Item 1. Business

Item 1A. Risk Factors

Item 1B. Unresolved Staff Comments

Item 2. Properties

Item 3. Legal Proceedings

Item 4. Mine Safety Disclosures

PART II

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

Comparison of Cumulative Total Returns

Comparison of Cumulative Total Returns

Item 6. Selected Financial Data

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

Item 7A. Quantitative and Qualitative Disclosures about Market Risk

Item 8. Financial Statements and Supplementary Data

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

Item 9A. Controls and Procedures

Item 9B. Other Information

PART III

Item 10. Directors, Executive Officers and Corporate Governance

Item 11. Executive Compensation

Item 12. Security Ownership of Certain Beneficial Owners and Management

Item 13. Certain Relationships and Related Transactions and Director Independence

Item 14. Principal Accounting Fees and Services

PART IV

Item 15. Exhibits and Financial Statement Schedules

SIGNATURES

POWER OF ATTORNEY

EXHIBIT INDEX

Report of Independent Registered Public Accounting Firm

ALKERMES PLC AND SUBSIDIARIES CONSOLIDATED BALANCE SHEETS March 31, 2012 AND 2011

ALKERMES PLC AND SUBSIDIARIES CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS Years
Ended March 31, 2012, 2011 AND 2010

ALKERMES PLC AND SUBSIDIARIES CONSOLIDATED STATEMENTS OF CASH FLOWS Years Ended March 31, 2012, 2011 AND
2010

