

Alkermes plc.  
Form 10-K  
February 24, 2015

Use these links to rapidly review the document

[TABLE OF CONTENTS](#)

[Table of Contents](#)

**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 December 31, 2014

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: 001-35299

**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**  
**Title of each class**

**NASDAQ Global Select Stock Market**  
**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

## Edgar Filing: Alkermes plc. - Form 10-K

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

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 \$7,277,633,295.

As of February 12, 2015, 148,072,506 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 December 31, 2014 are incorporated by reference into Part III of this report.

---

Table of Contents

**ALKERMES PLC AND SUBSIDIARIES  
ANNUAL REPORT ON FORM 10-K  
FOR THE YEAR ENDED DECEMBER 31, 2014  
INDEX**

<u>PART I</u>		
<u>Item 1.</u>	<u>Business</u>	<u>5</u>
<u>Item 1A.</u>	<u>Risk Factors</u>	<u>33</u>
<u>Item 1B.</u>	<u>Unresolved Staff Comments</u>	<u>53</u>
<u>Item 2.</u>	<u>Properties</u>	<u>54</u>
<u>Item 3.</u>	<u>Legal Proceedings</u>	<u>54</u>
<u>Item 4.</u>	<u>Mine Safety Disclosures</u>	<u>54</u>
<u>PART II</u>		
<u>Item 5.</u>	<u>Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities</u>	<u>55</u>
<u>Item 6.</u>	<u>Selected Financial Data</u>	<u>58</u>
<u>Item 7.</u>	<u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	<u>60</u>
<u>Item 7A.</u>	<u>Quantitative and Qualitative Disclosures about Market Risk</u>	<u>87</u>
<u>Item 8.</u>	<u>Financial Statements and Supplementary Data</u>	<u>88</u>
<u>Item 9.</u>	<u>Changes in and Disagreements With Accountants on Accounting and Financial Disclosures</u>	<u>89</u>
<u>Item 9A.</u>	<u>Controls and Procedures</u>	<u>89</u>
<u>Item 9B.</u>	<u>Other Information</u>	<u>90</u>
<u>PART III</u>		
<u>Item 10.</u>	<u>Directors, Executive Officers and Corporate Governance</u>	<u>91</u>
<u>Item 11.</u>	<u>Executive Compensation</u>	<u>91</u>
<u>Item 12.</u>	<u>Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters</u>	<u>91</u>
<u>Item 13.</u>	<u>Certain Relationships and Related Transactions, and Director Independence</u>	<u>91</u>
<u>Item 14.</u>	<u>Principal Accounting Fees and Services</u>	<u>91</u>
<u>PART IV</u>		
<u>Item 15.</u>	<u>Exhibits and Financial Statement Schedules</u>	<u>92</u>
<u>SIGNATURES</u>		<u>93</u>

Table of Contents

**CAUTIONARY NOTE CONCERNING 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, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. 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," "believe," "plan," "estimate," "intend," 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 ("Annual Report") 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 our products, including the development, regulatory (including expectations about regulatory filing, regulatory approval and regulatory timelines), therapeutic and commercial scope and 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 competitive landscape, and changes therein, related to our products, including our development programs, and our industry generally;

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

our expectations regarding future amortization of intangible assets;

our expectations regarding our collaborations and other significant agreements with third parties relating to our products, including our development programs;

our expectations regarding the impact of adoption of new accounting pronouncements;

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

other factors discussed elsewhere in this Annual Report.

Actual results might differ materially from those expressed or implied by these forward-looking statements because these forward-looking statements are subject to risks, assumptions and uncertainties. You are cautioned not to place undue reliance on forward-looking statements, which speak only as of the date of this Annual Report. All subsequent written and oral forward-looking statements concerning the matters addressed in this Annual Report and attributable to us or any person acting on our behalf are expressly qualified in their entirety by the cautionary statements contained or referred to in this section. Except as required by applicable law or regulation, we do not undertake any

## Edgar Filing: Alkermes plc. - Form 10-K

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, assumptions and uncertainties, 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" in this Annual Report.

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

Table of Contents

sources (including, without limitation, 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 marketed products and product candidates. 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.

**NOTE REGARDING COMPANY AND PRODUCT REFERENCES**

Use of the terms such as "us," "we," "our," "Alkermes" or the "Company" in this Annual Report is meant to refer to Alkermes plc and its consolidated subsidiaries, except where 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. and its consolidated subsidiaries. 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 (the "NASDAQ") under the symbol "ALKS." Except as otherwise suggested by the context, references to "products" in this Annual Report include our marketed products and product candidates.

**NOTE REGARDING TRADEMARKS**

CODAS®, IPDAS®, LinkeRx®, MXDAS®, NanoCrystal®, SODAS®, VERELAN® and VIVITROL® are registered trademarks of Alkermes.

The following are trademarks of the respective companies listed: ABILIFY® and ABILIFY MAINTENA® Otsuka Pharmaceutical Co., Ltd.; AMPYRA®, FAMPYRA® Acorda Therapeutics, Inc.; ANTABUSE® Teva Women's Health, Inc.; AUBAGIO® and LEMTRADA® Sanofi Societe Anonyme France; AVONEX®, PLEGRIDY®, TECFIDERA®, and TYSABRI® Biogen Idec MA Inc.; BETASERON® Bayer Pharma AG; BUNAVAI<sup>TM</sup> BioDelivery Sciences; BYDUREON® and BYETTA® Amylin Pharmaceuticals, LLC; CAMPRAL® Merck Sante; COPAXONE® Teva Pharmaceutical Industries Ltd.; FOCALIN XR®, EXTAVIA®, GILENYA® and RITALIN LA® Novartis AG; INVEGA® SUSTENNA®, RISPERDAL® CONSTA® and XEPLION® Johnson & Johnson Corp. (or its affiliates); MEGACE® E.R. Squibb & Sons, LLC; RAPAMUNE® Wyeth LLC; NOVANTRONE® and REBIF® Ares Trading S.A.; SUBOXONE® and SUBUTEX® Reckitt Benckiser Healthcare (UK) Ltd.; TRICOR® Fournier Industrie et Sante Corporation; VICTOZA® Novo Nordisk A/S LLC; ZOHYDRO Zogenix, Inc.; ZUBSOLV® Orexo US, Inc.; and ZYPREXA® and ZYPREXA® RELPREVV® Eli Lilly and Company. Other trademarks, trade names and service marks appearing in this Annual Report are the property of their respective owners.

**NOTE REGARDING FISCAL YEAR**

On May 21, 2013, our Audit and Risk Committee, with such authority delegated to it by our Board of Directors, approved a change to our fiscal year-end from March 31 to December 31. This Annual Report reflects our financial results for the twelve month period from January 1, 2014 through December 31, 2014. The period ended December 31, 2013 reflects our financial results for the nine-month period from April 1, 2013 through December 31, 2013 (the "Transition Period"). The period ended March 31, 2013 reflects our financial results for the twelve-month period from April 1, 2012 to March 31, 2013.

Table of Contents

**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 "Cautionary Note Concerning Forward-Looking Statements" on pages 3 and 4 of this Annual Report. 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.*

**Overview**

Alkermes plc is a fully integrated, global biopharmaceutical company that applies its scientific expertise and proprietary technologies to research, develop and commercialize, both with partners and on our own, pharmaceutical products that are designed to address unmet medical needs of patients in major therapeutic areas. We have a diversified portfolio of more than 20 marketed products and a clinical pipeline of product candidates that address central nervous system ("CNS") disorders such as addiction, schizophrenia and depression.

**Products**

Marketed Products

Our key marketed products are expected to generate significant revenues for us. They possess long patent lives and, we believe, are singular or competitively advantaged products in their class. Refer to the "Patents and Proprietary Rights" section of this Annual Report for information with respect to the

## Edgar Filing: Alkermes plc. - Form 10-K

### Table of Contents

intellectual property protection for our marketed products. Summary information about our key marketed products is set forth in the table below.

<b>Product</b>	<b>Indication(s)</b>	<b>Collaboration Partner</b>	<b>Territory</b>
<i>RISPERDAL CONSTA</i>	Schizophrenia Bipolar I disorder	Janssen Pharmaceutica Inc. ("Janssen, Inc.") and Janssen Pharmaceutica International, a division of Cilag International AG ("Janssen International")	Worldwide
<i>INVEGA SUSTENNA/XEPLION</i>	Schizophrenia Schizoaffective disorder	Janssen Pharmaceutica N.V. (together with Janssen, Inc. Janssen International, and their affiliates "Janssen")	United States ("U.S.") Rest of World ("ROW")
<i>AMPYRA/FAMPYRA</i>	Treatment to improve walking in patients with multiple sclerosis ("MS"), as demonstrated by an increase in walking speed	Acorda Therapeutics, Inc. ("Acorda")  Biogen Idec International GmbH ("Biogen Idec"), under sublicense from Acorda	U.S.  ROW
<i>BYDUREON</i>	Type 2 diabetes	AstraZeneca plc ("AstraZeneca")	Worldwide
<i>VIVITROL</i>	Alcohol dependence Opioid dependence	Alkermes  Cilag GmbH International ("Cilag")	U.S.  Russia and Commonwealth of Independent States ("CIS")

### ***RISPERDAL CONSTA and INVEGA SUSTENNA/XEPLION***

RISPERDAL CONSTA (risperidone long-acting injection) and INVEGA SUSTENNA/XEPLION (paliperidone palmitate extended-release injectable suspension) are long-acting atypical antipsychotics that incorporate our proprietary technologies and are marketed and sold by of Janssen.

RISPERDAL CONSTA is approved in the U.S. for the treatment of schizophrenia and as both monotherapy and adjunctive therapy to lithium or valproate in the maintenance treatment of bipolar I disorder. RISPERDAL CONSTA is approved in numerous countries outside of the U.S. for the treatment of schizophrenia and the maintenance treatment of bipolar I disorder. RISPERDAL CONSTA 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 marketed and sold by Janssen worldwide.



Table of Contents

INVEGA SUSTENNA is approved in the U.S. for the acute and maintenance treatment of schizophrenia and, as of November 2014, for the treatment of schizoaffective disorder as either a monotherapy or adjunctive therapy. Paliperidone palmitate extended-release injectable suspension is approved in the European Union ("EU") and other countries worldwide for the treatment of schizophrenia and is marketed and sold under the trade name XEPLION. INVEGA SUSTENNA 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/XEPLION is manufactured and commercialized worldwide by Janssen.

Revenues from Janssen accounted for approximately 41%, 44% and 35% of our consolidated revenues for the fiscal year ended December 31, 2014, the nine months ended December 31, 2013 and the fiscal year ended March 31, 2013, respectively. See "*Collaborative Arrangements*" later in Part I of this Annual Report for information about our relationship with 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 over the age of 18 have schizophrenia in a given year, 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.

*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.

*What is schizoaffective disorder?*

Schizoaffective disorder is a condition in which a person experiences a combination of schizophrenia symptoms, such as delusions, hallucinations or other symptoms characteristic of schizophrenia, and mood disorder symptoms, such as mania or depression. Schizoaffective disorder is a serious mental illness that affects about one in 100 people.

**AMPYRA/FAMPYRA**

AMPYRA/FAMPYRA is the first treatment approved in the U.S. and in over 50 countries across Europe, Asia and the Americas to improve walking in adults with MS who have walking disability, as demonstrated by an increase in walking speed. Extended-release dalfampridine tablets are marketed and sold by Acorda in the U.S. under the trade name AMPYRA and by Biogen Idec outside the U.S. under the trade name FAMPYRA. In July 2011, the European Medicines Agency ("EMA") conditionally approved FAMPYRA in the EU for the improvement of walking in adults with MS. This authorization was renewed as of May 2014. AMPYRA and FAMPYRA incorporate our oral controlled-release technology. AMPYRA and FAMPYRA are manufactured by us.

Table of Contents

*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**

BYDUREON (exenatide extended-release for injectable suspension) is approved in the U.S. and the EU for the treatment of type 2 diabetes. From August 2012 until February 2014, Bristol-Myers Squibb Company ("Bristol-Myers") and AstraZeneca co-developed and marketed BYDUREON through their diabetes collaboration. In February 2014, AstraZeneca assumed sole responsibility for the development and commercialization of BYDUREON. BYDUREON, a once-weekly formulation of exenatide, the active ingredient in BYETTA, uses our polymer-based microsphere injectable extended-release technology. See "*Collaborative Arrangements*" later in Part I of this Annual Report for information about our relationship with AstraZeneca.

In September 2014, AstraZeneca announced that the once-weekly BYDUREON Pen 2 mg, which is a pre-filled, single-use pen injector that contains the same formulation and dose as the original BYDUREON single-dose tray, was available by prescription in pharmacies in the U.S. AstraZeneca stated that it received a positive opinion from the Committee for Medicinal Products for Human Use ("CHMP") on the BYDUREON dual-chamber pen and that it filed for approval of the dual-chamber pen in Japan in April 2014.

*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 382 million adults worldwide. Approximately 90-95% of those affected have type 2 diabetes. An estimated 80% of people with type 2 diabetes are overweight or obese. Data indicate that weight loss (even a modest amount) supports patients in their efforts to achieve and sustain glycemic control.

**VIVITROL**

VIVITROL is a once-monthly injectable medication approved in the U.S. and Russia for the treatment of alcohol dependence and for the prevention of relapse to opioid dependence, following opioid detoxification. VIVITROL 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., and Cilag sells VIVITROL in Russia and the CIS.

*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 2013

Table of Contents

U.S. National Survey on Drug Use and Health, an estimated 1.8 million people aged 18 or older were dependent on pain relievers or heroin in the U.S.

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. Nearly 18 million people aged 18 or older in the U.S. are dependent on or abuse alcohol. Adherence to medication is particularly challenging with this patient population.

*Other Marketed Products*

In addition to our key marketed products discussed above, we earn manufacturing and/or royalty revenues on the net sales of a diversified portfolio of products marketed by our partners. We expect these revenues, taken together, to decrease in the future due to existing and expected competition from generic manufacturers and the termination of manufacturing services at our Athlone, Ireland manufacturing facility for certain products that are expected to no longer be economically practicable to produce. Please see "Management's Discussion and Analysis of Financial Condition and Results of Operations" elsewhere in this Annual Report for a more detailed discussion of current and expected future revenue contributions from such products and our Athlone restructuring plan.

Key Development Programs

Our research and development is focused on leveraging our formulation expertise and proprietary product platforms to develop novel, competitively advantaged medications designed to enhance patient outcomes in major CNS disorders, such as schizophrenia and depression.

As part of our ongoing research and development efforts, we have devoted, and will continue to devote, significant resources to conducting clinical studies to advance the development of new pharmaceutical products. The discussion below primarily highlights our current research and development programs. Drug development involves a high degree of risk and investment, and the status, timing and scope of our development programs are subject to change. Important factors that could adversely affect our drug development efforts are discussed in "Item 1A Risk Factors." Refer to the "Patents and Proprietary Rights" section of this Annual Report for information with respect to the intellectual property protection for our product candidates.

<b>Product Candidate</b>	<b>Target Indication(s)</b>	<b>Status</b>
<i>Aripiprazole Lauroxil</i>	Schizophrenia	New Drug Application ("NDA") submitted and under FDA Review
<i>ALKS 5461</i>	Major Depressive Disorder	Phase 3
<i>ALKS 3831</i>	Schizophrenia	Phase 2
<i>ALKS 8700</i>	MS	Phase 1
<i>RDB 1419</i>	Cancer Immunotherapy	Pre-clinical

***Aripiprazole Lauroxil***

Aripiprazole lauroxil is an injectable atypical antipsychotic with one-month and extended-duration formulations in development for the treatment of schizophrenia. Once in the body, aripiprazole lauroxil converts into aripiprazole, which is commercially available under the name ABILIFY. As a long-acting investigational medication based on our proprietary LinkeRx technology, aripiprazole lauroxil is designed to have multiple dosing options and to be administered in a ready-to-use, pre-filled product format. Aripiprazole lauroxil is our first product candidate to leverage our proprietary LinkeRx technology.

In April 2014, we announced positive topline results from a randomized, double-blind, placebo-controlled phase 3 clinical trial of aripiprazole lauroxil in patients with schizophrenia. The primary

Table of Contents

endpoint of the study, the change from baseline at week 12 in Positive and Negative Syndrome Scale ("PANSS") total scores as compared to placebo, was met for both the 441 mg and 882 mg monthly doses. Results showed that aripiprazole lauroxil also met the key secondary endpoint of improvement on the Clinical Global Impression Improvement scale at week 12. In August 2014, we submitted an NDA to the U.S. Food and Drug Administration ("FDA") for aripiprazole lauroxil for the treatment of schizophrenia. The FDA accepted our application for filing in October 2014, and granted us a Prescription Drug User Fee Act ("PDUFA") date of August 22, 2015.

In December 2014, we announced the initiation of a phase 1 clinical study of extended dosing intervals of aripiprazole lauroxil in patients with schizophrenia. The phase 1 study is designed to evaluate the pharmacokinetics, safety and tolerability of aripiprazole lauroxil administered over two new extended durations: once every six weeks and once every two months. Results from this phase 1 study are expected mid-2016.

***ALKS 5461***

ALKS 5461 is a proprietary, oral investigational medicine in development for the treatment of major depressive disorder ("MDD") in patients who have an inadequate response to standard antidepressant therapies. ALKS 5461 is composed of samidorphan in combination with buprenorphine. Samidorphan, formerly referred to as ALKS 33, is a proprietary oral opioid modulator characterized by limited hepatic metabolism and durable pharmacologic activity in modulating brain opioid receptors. ALKS 5461 acts as a balanced neuromodulator in the brain and represents a new approach with a novel mechanism of action for treating MDD. In October 2013, the FDA granted fast track status for ALKS 5461 for the adjunctive treatment of MDD in patients with inadequate response to standard antidepressant therapies. See "*Regulatory*" later in Part I of this Annual Report for information about fast track status.

MDD is a condition in which patients exhibit depressive symptoms, such as a depressed mood or a loss of interest or pleasure in daily activities consistently for at least a two-week period, and demonstrate impaired social, occupational, educational or other important functioning. An estimated 16.1 million people in the U.S. suffer from MDD in a given year.

In March 2014, we announced the initiation of the pivotal clinical development program for ALKS 5461. The comprehensive pivotal program, named Focused On Results With A Rethinking of Depression ("FORWARD"), includes a total of twelve studies, including three core phase 3 efficacy studies and nine supportive studies. We announced initiation of two core efficacy studies in June 2014, and announced initiation of the third core efficacy study in July 2014. The core efficacy studies are designed to evaluate the safety and efficacy of ALKS 5461 as adjunctive treatment in patients with MDD. The FORWARD pivotal program will also include studies to evaluate the long-term safety, dosing, pharmacokinetic profile and human abuse liability of ALKS 5461. The three core efficacy studies will utilize state-of-the-art design methodologies intended to reduce the impact of clinically meaningful placebo response. Data from these three core efficacy studies are expected in 2016.

In January 2015, we announced topline results from FORWARD-1, one of a series of supportive clinical studies in the FORWARD phase 3 pivotal program designed to evaluate the safety and tolerability of two titration schedules of ALKS 5461. Data from FORWARD-1 confirmed the safety and tolerability of ALKS 5461 in both titration schedules evaluated one-week and two-week dose escalation schedules. These findings were consistent with the safety and tolerability profile seen in the phase 2 study of ALKS 5461 completed in 2013 in which ALKS 5461 met its primary endpoint, met key secondary endpoints and demonstrated significant reduction in depressive symptoms versus placebo. In addition, the exploratory efficacy analyses showed that ALKS 5461 reduced depressive symptoms from baseline in patients who received either of the two titration schedules. These data support the

Table of Contents

one-week titration schedule being utilized in the core phase 3 efficacy studies in the FORWARD program.

***ALKS 3831***

ALKS 3831 is a novel, proprietary investigational medicine designed as a broad-spectrum antipsychotic for the treatment of schizophrenia. ALKS 3831 is composed of samidorphan in combination with the established antipsychotic drug olanzapine, which is generally available under the name ZYPREXA. ALKS 3831 is designed to attenuate olanzapine-induced metabolic side effects, including weight gain, and to have utility in the treatment of schizophrenia in patients with alcohol use.

In January 2015, we announced data from the phase 2 study of ALKS 3831 designed to assess the efficacy, safety and tolerability of ALKS 3831 in the treatment of schizophrenia and its attenuation of weight gain, compared to olanzapine. ALKS 3831 met the primary endpoint of the study, demonstrating equivalence to olanzapine in reduction from baseline in PANSS total scores at week 12. Results showed that ALKS 3831 also met the secondary endpoint of demonstrating a lower mean weight gain compared to olanzapine at week 12 in the full study population, and a lower mean weight gain compared to olanzapine at week 12 in a pre-specified subset of patients who gained weight in the one-week olanzapine lead-in. Based on the positive results from this phase 2 study, we plan to request an end-of-phase 2 meeting with the FDA and advance ALKS 3831 into a pivotal development program in 2015.

In June 2014, we announced initiation of a randomized, double-blind, active-controlled phase 2 study to assess ALKS 3831's efficacy, safety and tolerability in treating schizophrenia in patients with alcohol use, compared to olanzapine. We expect topline results from this study in mid-2017.

***ALKS 8700***

ALKS 8700 is an oral, novel and proprietary monomethyl fumarate ("MMF") molecule in development for the treatment of MS. ALKS 8700 is designed to rapidly and efficiently convert to MMF in the body and to offer differentiated features as compared to the currently marketed dimethyl fumarate, TECFIDERA. In February 2015, we announced positive topline results from a phase 1, randomized, double-blind clinical study of ALKS 8700, designed to evaluate the safety, tolerability and single-dose pharmacokinetics of several oral formulations of ALKS 8700 compared to both placebo and active control groups.

***ALKS 7106***

ALKS 7106 is our novel, oral opioid analgesic drug candidate designed for the treatment of pain with intrinsically low potential for abuse and overdose death, two liabilities associated with opioid analgesics. In August 2014, we announced that we initiated a randomized, double-blind, placebo-controlled phase 1 study designed to evaluate the safety, tolerability and pharmacokinetics of ALKS 7106. We expect topline results from this study in the first half of 2015. In February 2015, we announced that data from the phase 1 study did not meet our pre-specified criteria for advancing into phase 2 clinical trials. Based on this evaluation, we will not pursue further development of ALKS 7106.

***RDB 1419***

RDB 1419 is a proprietary, investigational biologic cancer immunotherapy product based on interleukin-2 and its receptors. RDB 1419 was engineered using our proprietary fusion protein technology platform to modulate the natural mechanism of action of a biologic product. We expect to initiate clinical development of RDB 1419 in 2015.

Table of Contents

Partnered Product Candidates Development Programs

*Acorda*

In December 2014, Acorda announced the initiation of a phase 3 clinical trial of dalfampridine extended release tablets for the treatment of post-stroke walking deficits. It expects this multicenter, double-blind, randomized trial to enroll approximately 540 participants who have experienced an ischemic stroke at least six months prior to enrollment.

*Janssen*

In July 2014, Janssen announced the submission of a supplemental New Drug Application to the FDA seeking a label change that, if approved, is expected to include new data showing delayed time to relapse in patients prescribed INVEGA SUSTENNA, as compared to selected oral antipsychotic therapies, in the treatment of schizophrenia.

In November 2014, Janssen announced the submission of an NDA to the FDA for three-month atypical antipsychotic paliperidone palmitate for the treatment of schizophrenia in adults. If approved, it will be the first and only long-acting atypical antipsychotic that has a four times a year dosing schedule.

*AstraZeneca*

AstraZeneca is developing line extensions for BYDUREON for the treatment of type 2 diabetes, including weekly and monthly suspension formulations using our proprietary technology for extended-release microspheres. In the third quarter of 2014, AstraZeneca announced the completion of two phase 3 trials of exenatide once weekly suspension for autoinjection, DURATION-NEO-1 and DURATION-NEO-2. The DURATION-NEO-1 phase 3 study evaluated exenatide once weekly suspension for autoinjection compared to twice-daily exenatide in adult patients with type 2 diabetes that had inadequate glycemic control. The trial met its primary endpoint of non-inferiority. The DURATION-NEO-2 study was a randomized, long-term, open-label, multicenter study comparing the glycemic effects, safety and tolerability of exenatide once weekly suspension to sitagliptin and placebo in subjects with type 2 diabetes. AstraZeneca expects to file marketing applications for this product candidate in the U.S. and EU in 2015.

**Our Research and Development Expenditures**

Please see "Management's Discussion and Analysis of Financial Condition and Results of Operations" for our R&D expenditures for our fiscal year ended December 31, 2014, our Transition Period ended December 31, 2013 and our fiscal year ended March 31, 2013.

**Collaborative Arrangements**

We have entered into several collaborative arrangements to develop and commercialize products and, in so doing, to access technological, financial, marketing, manufacturing and other resources.

*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.

Table of Contents

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. Either party may terminate the license agreements by written notice following a breach which continues for 90 days after the delivery of written notice thereof or upon the other party's insolvency. 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) 15 years after the date of the first commercial sale of the product in such country, provided that in no event will the license granted to Janssen expire later than the twentieth anniversary of the first commercial sale of the product in such country, with the exception of certain countries where the fifteen-year limitation shall pertain regardless. After expiration, Janssen retains a non-exclusive, royalty-free license to manufacture, use and sell RISPERDAL CONSTA.

We exclusively manufacture RISPERDAL CONSTA for commercial sale. Under our manufacturing and supply agreement with Janssen, we record manufacturing revenues when product is shipped to Janssen, based on 7.5% of Janssen's net unit sales price for RISPERDAL CONSTA for the calendar year. The manufacturing and supply agreement terminates on expiration of the license agreements. In addition, either party may terminate the manufacturing and supply agreement upon a material breach by the other party, which is not resolved within 60 days after receipt of a written notice specifying the material breach or upon written notice in the event of the other party's insolvency or bankruptcy. Janssen may terminate the agreement upon six months' written notice to us. In the event that Janssen terminates the manufacturing and supply agreement without terminating the license agreements, the royalty rate payable to us on Janssen's net sales of RISPERDAL CONSTA would increase from 2.5% to 5.0%.

INVEGA SUSTENNA/XEPLION

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

Under our license agreement, we received milestone payments upon the achievement of certain development goals from Janssen; there are no further milestones to be earned under this agreement. We receive 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. The tiered royalty payments consist of a patent royalty and a know-how royalty, both of which are determined on a county-by-country basis. The patent royalty, which equals 1.5% of net sales, is payable until the expiration of the last of the patents claiming the product in such country. The know-how royalty is a tiered royalty of 3.5%, 5.5% and 7.5% on aggregate worldwide net sales of below \$250 million, between \$250 million and \$500 million, and greater than \$500 million, respectively. The know-how royalty is payable for the later of 15 years from first commercial sale of a product in each individual country or March 31, 2019, subject in each case to the expiry of the license agreement. These royalty payments may be reduced in any country based on patent litigation or on competing products achieving certain minimum sales thresholds. The license agreement expires upon the later of (i) March 31, 2019 or (ii) the expiration of the last of the patents subject to the agreement. After expiration, Janssen retains a non-exclusive, royalty-free license to develop, manufacture and commercialize the products.

Table of Contents

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. We receive certain commercial and development milestone payments, license revenues and a royalty of approximately 10% based on net 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 we manufacture the product.

In June 2009, we entered into an amendment of the amended and restated license agreement and the supply agreement with Acorda and, pursuant to such amendment, consented to the sublicense by Acorda to Biogen Idec of Acorda's rights to use and sell FAMPYRA in certain territories outside of the U.S. (to the extent that such rights were to be sublicensed to Biogen Idec pursuant to its separate collaboration and license agreement with Acorda). Under this amendment, we agreed to modify certain terms and conditions of the amended and restated license agreement and the supply agreement with Acorda to reflect the sublicense by Acorda to Biogen Idec.

Acorda has the right to terminate the amended and restated license agreement upon 90 days' written notice. We have the right to terminate the amended and restated 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 of, and receipt of positive data from, all preclinical and clinical studies required for filing a marketing authorization application. Either party has the right to terminate the amended and restated license agreement by written notice following a material breach of the other party, which is not cured within a certain time period, or upon the other party's entry into bankruptcy or dissolution proceedings. 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 amended and restated license agreement, licenses granted under the license agreement terminate on a country-by-country basis on the later of (i) September 26, 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-licensee). Under the terms of the agreement, Acorda may obtain up to 25% of its total annual requirements of product from a second-source manufacturer. We receive manufacturing 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 commercial manufacturing supply agreement upon 12 months' prior written notice to Acorda, and either party may terminate the commercial manufacturing supply agreement following a material and uncured breach of the commercial manufacturing supply or amended and restated license agreement or the entry into bankruptcy or dissolution proceedings by the other party. In addition, subject to early termination of the commercial manufacturing supply agreement noted above, the commercial manufacturing supply agreement terminates upon the expiry or termination of the amended and restated license agreement.



Table of Contents

We are entitled to receive the following milestone payments under our amended and restated license agreement with Acorda for each of the third and fourth new indications of the product developed thereunder:

initiation of a phase 3 clinical trial: \$1.0 million;

acceptance of an NDA by the FDA: \$1.0 million;

approval of the NDA by the FDA: \$1.5 million; and

the first commercial sale: \$1.5 million.

In January 2011, we entered into a development and supplemental agreement to our amended and restated license agreement and commercial manufacturing supply 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. We are entitled to development fees we incur in developing formulations under the development and supplemental agreement and, if Acorda selects and commercializes any such formulation, to milestone payments (for new indications if not previously paid), license revenues and royalties in accordance with our amended and restated license agreement for the product, 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, under the development and supplemental agreement, 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 development and supplemental agreement expires upon the expiry or termination of the amended and restated license agreement and 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 of the agreement.

***AstraZeneca***

In May 2000, we entered into a development and license agreement with Amylin Pharmaceuticals, LLC ("Amylin") for the development of exendin products falling within the scope of our patents, including the once-weekly formulation of exenatide marketed as BYDUREON. In August 2012, Bristol-Myers acquired Amylin. From August 2012 through January 2014, Bristol-Myers and AstraZeneca jointly developed and commercialized Amylin's exendin products, including BYDUREON, through their diabetes collaboration. In April 2013, Bristol-Myers completed its assumption of all global commercialization responsibility related to the marketing of BYDUREON from Amylin's former collaborative partner, Eli Lilly & Company ("Lilly"). In February 2014, AstraZeneca acquired sole ownership of the intellectual property and global rights related to BYDUREON and Amylin's other exendin products, including Amylin's rights and obligations under our development and license agreement.

Pursuant to the development and license agreement, AstraZeneca 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 will also receive royalty payments based on future product sales. Upon the achievement of certain development and commercialization goals, we received milestone payments consisting of cash and warrants for Amylin common stock; there are no further milestones to

Table of Contents

be earned under the agreement. In October 2005 and in July 2006, we amended the development and license agreement. Under the amended agreement (i) 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, and (ii) we transferred certain of our technology related to the manufacture of BYDUREON to Amylin and agreed to the manufacture of BYDUREON by Amylin. Under our amended agreement, AstraZeneca is responsible for conducting clinical trials, securing regulatory approvals and commercializing exenatide products, including BYDUREON, on a worldwide basis.

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 calendar year and 5.5% of net sales from units sold beyond the first 40 million units for that calendar 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 were entitled to, and received, milestone payments related to the first commercial sale of BYDUREON in the EU and the first commercial sale of BYDUREON in the U.S.

The development and license agreement expires on the later of (i) ten 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 expiration, all licenses become non-exclusive and royalty-free. AstraZeneca 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. Alkermes may terminate the development and license agreement upon AstraZeneca's insolvency or bankruptcy.

**Other Arrangements**

*Civitas Therapeutics, Inc.*

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. We also participated in certain subsequent rounds of financing. In connection with this transaction, Civitas also entered into an agreement to sublease our pulmonary manufacturing facility located in Chelsea, Massachusetts. Civitas has the option to extend the term of such sublease, subject to certain pre-specified conditions.

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. Either party may also terminate the asset purchase and license agreement upon written notice in the event of the other party's insolvency or bankruptcy.

In October 2014, Civitas was acquired by Acorda for approximately \$525.0 million. As a result of this transaction and in exchange for our approximate 6% interest in Civitas (i) we received \$27.2 million, and (ii) we have the right to receive up to approximately \$2.4 million in future payments, subject to release of all amounts held in escrow. Also, in connection with Acorda's purchase of Civitas, we sold certain of our pulmonary manufacturing equipment to Acorda in exchange for \$30.0 million.

Table of Contents

**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 derived from known agents.

***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***

Our oral controlled release ("OCR") technologies are used to formulate, develop and manufacture oral dosage forms of pharmaceutical products that control the release characteristics of standard dosage forms. Our OCR platform includes technologies for tailored pharmacokinetic profiles including SODAS technology, CODAS technology, IPDAS 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) technology 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.

Table of Contents

MXDAS Technology: MXDAS (Matrix Drug Absorption System) technology 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 products for clinical trials and commercial use is subject to Current Good Manufacturing Practice ("cGMP") regulations 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 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 in finding 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 marketed 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 marketed products and product candidates, see "Item 1A Risk Factors" and specifically those sections entitled " We rely heavily on our collaborative partners in the commercialization and continued development of our products; 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" and " 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."

***Marketed 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. Our Wilmington, Ohio facility has been inspected by U.S., European including the Medicines and Healthcare Products Regulatory Agency, Chinese, Japanese, Brazilian and Saudi Arabian regulatory authorities for compliance with required cGMP standards for continued commercial manufacturing.

We manufacture AMPYRA/FAMPYRA, RAPAMUNE and other products in our Athlone, Ireland facility. This facility has been inspected by U.S., Irish, Brazilian, Turkish, Saudi Arabian, Korean and

Table of Contents

Belarusian regulatory authorities for compliance with required cGMP standards for continued commercial manufacturing.

We manufacture FOCALIN XR, RITALIN LA, VERAPAMIL, ZOXYDRO and other products in our Gainesville, Georgia facility. This facility has been inspected by U.S., Danish, Turkish and Brazilian regulatory authorities for compliance with required cGMP standards for continued commercial manufacturing.

For more information about our manufacturing facilities, see "Item 2 Properties."

***Product Candidates***

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 R&D programs. We focus our R&D efforts on finding novel therapeutics in areas of high unmet medical need. Our R&D 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" for our R&D expenditures for our fiscal year ended December 31, 2014, our Transition Period ended December 31, 2013 and our fiscal year ended March 31, 2013.

**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 of the U.S. Department of Justice ("DEA"), Controlled Substance Registration in respect of our Gainesville facility. We also hold a Manufacturers Authorization (No. M1067), an Investigational Medicinal Products Manufacturers Authorization (No. IMP074) and Certificates of Good Manufacturing Practice Compliance of a Manufacturer (Ref. 2014/7828/IMP074 and 2014/7828/M1067) from the Health Products Regulatory Authority (HPRA) in respect of our Athlone facility, and a number of Controlled Substance Licenses granted by the HPRA. 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 usually holds 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, 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.

Table of Contents

**Marketing, Sales and Distribution**

We are responsible for the marketing of VIVITROL in the U.S. 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, or contract with third-party vendors to 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 year ended December 31, 2014 to CVS Caremark Corporation and McKesson Corporation represented approximately 17% and 15%, respectively, of total VIVITROL sales.

Cardinal Health Specialty Pharmaceutical Services, a division of Cardinal, provides warehousing, shipping and administrative services for VIVITROL.

Under our collaboration agreements with Janssen, AstraZeneca, 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 marketed 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 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 marketed 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 marketed 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. In the treatment

Table of Contents

of schizophrenia, RISPERDAL CONSTA and INVEGA SUSTENNA compete with a number of other injectable products including ZYPREXA RELPREVV ((olanzapine) For Extended Release Injectable Suspension), which is marketed and sold by Lilly; ABILIFY MAINTENA, (aripiprazole for extended release injectable suspension), a once-monthly injectable formulation of ABILIFY (aripiprazole) developed by Otsuka Pharmaceutical Co., Ltd. ("Otsuka"); oral compounds currently on the market; and generic versions of branded oral and injectable products. In the treatment of bipolar disorder, RISPERDAL CONSTA competes with antipsychotics such as ABILIFY, LATUDA, risperidone, olanzapine, ziprasidone and clozapine.

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

In the treatment of opioid dependence, VIVITROL competes with methadone, oral naltrexone, 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., and BUNAVAIL buccal film (buprenorphine and naloxone) marketed by BioDelivery Sciences, and ZUBZOLV (buprenorphine and naloxone) marketed by Orexo US, Inc. It also competes with generic versions of SUBUTEX and SUBOXONE sublingual tablets. Other pharmaceutical companies are developing product candidates that have shown promise in treating opioid dependence that, if approved by the FDA, would compete with VIVITROL.

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

While AMPYRA/FAMPYRA is the first product approved as a treatment to improve walking in patients with MS, 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, TYSABRI, TECFIDERA, and PLEGRIDY from Biogen Idec; BETASERON from Bayer HealthCare Pharmaceuticals; COPAXONE from Teva Pharmaceutical Industries Ltd.; REBIF and NOVANTRONE from EMD Serono, Inc.; GILENYA and EXTAVIA from Novartis AG; AUBAGIO and LEMTRADA from Sanofi-Aventis and generic products.

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.

Table of Contents

**Patents and Proprietary Rights**

Our success will be dependent, in part, on our ability to obtain and maintain patent protection for our products, including those marketed and sold by 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. In addition, our collaborative partners may own issued patents that cover certain of our products. 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 patent 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, and we intend to defend our patent positions aggressively.

Our OCR technology is protected by a patent estate including patents and patent applications filed worldwide. Some OCR patent families are product-specific (including some which are owned by our collaborative partners), whereas others cover generic delivery platforms (e.g. different release profiles, taste masking, etc.). The latest of the patents covering AMPYRA/FAMPYRA 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 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 2022 in the EU. Additional pending applications may provide a longer period of patent coverage, if granted, and in certain countries, such as Australia and South Korea, patent coverage extends until 2023.

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

We also have patent protection for our Key Development Programs. U.S. Patent No. 8,431,576 and U.S. Patent No. 8,796,276, which issued in April 2013 and August 2014, respectively, cover a class of compounds that includes aripiprazole lauroxil and expire no earlier than 2030. U.S. Patent No. 7,262,298, which covers a class of compounds that includes the opioid modulators in each of the ALKS 5461 and ALKS 3831 combination products, expires in 2025. U.S. Patent No. 8,822,488, which issued in September 2014, covers ALKS 5461 and will expire no earlier than 2032. U.S. Patent No. 8,680,112, which issued in March 2014, contains method of treatment claims that will cover ALKS 5461, ALKS 3831 and ALKS 7106 and will expire in 2029. U.S. Patent No. 8,778,960, which issued in July 2014, covers ALKS 3831 and will expire no earlier than 2032. U.S. Patent No. 8,802,655, which issued in August 2014, covers ALKS 7106 and will expire no earlier than 2025. U.S. Patent No. 8,669,281, which issued in March 2014, contains composition of matter claims that will cover ALKS 8700 and will expire in 2033.

We have exclusive rights through licensing agreements with third parties to issued U.S. patents, pending patent applications and corresponding patents or patent applications in countries outside the U.S. 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 product candidates. The manufacture, use, offer for sale, sale or import of some of our product candidates might be found



Table of Contents

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, sell or import 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, selling or importing 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 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 currently involved in various Paragraph IV litigations in the U.S. and other proceedings outside of the U.S. involving our patents in respect of TRICOR, MEGACE ES, AMPYRA and ZOHYDRO ER.

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 "Item 1A Risk Factors."

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 registered trademarks of Johnson & Johnson Corp., BYDUREON, which is a trademark of Amylin, and AMPYRA and FAMPYRA, which are registered 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.

Table of Contents**Revenues and Assets by Region**

For the fiscal year ended December 31, 2014, the nine months ended December 31, 2013 and the fiscal year ended March 31, 2013, our revenue and assets are presented below by geographic area:

(In thousands)	Year Ended December 31, 2014	Nine Months Ended December 31, 2013	Year Ended March 31, 2013
<b>Revenue by region:</b>			
U.S.	\$ 398,189	\$ 269,005	\$ 380,565
Ireland	7,691	5,722	14,455
Rest of world	212,909	158,184	180,528
<b>Assets by region:</b>			
<b>Current assets:</b>			
U.S.	\$ 385,715	\$ 382,571	\$ 248,441
Ireland	490,577	187,023	159,544
Rest of world	501	544	603
<b>Long-term assets:</b>			
<b>U.S.:</b>			
Intangible assets	\$	\$	\$
Goodwill	3,677	3,677	3,677
Other	228,693	225,559	229,691
<b>Ireland:</b>			
Intangible assets	\$ 479,412	\$ 537,565	\$ 575,993
Goodwill	90,535	89,063	89,063
Other	242,162	151,586	163,279

**Regulatory*****Regulation of Pharmaceutical Products****United States*

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., pre-clinical studies and clinical trials of the products must be conducted and the results submitted to the FDA for approval. Clinical trial programs must determine an appropriate dose and regimen, establish substantial evidence of effectiveness and define the conditions for safe use. This is a high-risk process that requires stepwise clinical studies in which the product candidate must successfully meet pre-specified endpoints.

*Pre-Clinical Testing:* Before beginning testing of any compounds with potential therapeutic value in human subjects in the U.S., stringent government requirements for pre-clinical data must be satisfied. Pre-clinical testing includes both *in vitro*, or in an artificial environment outside of a living organism, and *in vivo*, or within a living organism, laboratory evaluation and characterization of the safety and efficacy of a drug and its formulation.

*Investigational New Drug ("IND") Exemption:* Pre-clinical testing results obtained from *in vivo* studies in several animal species, as well as from *in vitro* studies, are submitted to the FDA, as part of an IND, and are reviewed by the FDA prior to the commencement of human clinical trials. The pre-clinical data must provide an adequate basis for evaluating both the safety and the scientific rationale for the initial clinical studies in human volunteers.

*Clinical Trials:* Clinical trials involve the administration of the drug to healthy human volunteers or to patients under the supervision of a qualified investigator pursuant to an FDA-reviewed protocol. Human clinical trials are typically conducted in three sequential phases, although the phases may overlap with one another and, depending upon the nature of the clinical program, a specific phase may be skipped altogether. Clinical trials must be conducted under protocols that detail the objectives of the

Table of Contents

study, the parameters to be used to monitor safety, and the efficacy criteria, if any, to be evaluated. Each protocol must be submitted to the FDA as part of the IND.

Phase 1 clinical trials test for safety, dose tolerability, absorption, bio-distribution, metabolism, excretion and clinical pharmacology and, if possible, to gain early evidence regarding efficacy.

Phase 2 clinical trials involve a relatively small sample of the actual intended patient population and seek to assess the efficacy of the drug for specific targeted indications, to determine dose-response and the optimal dose range and to gather additional information relating to safety and potential adverse effects.

Phase 3 clinical trials consist of expanded, large-scale studies of patients with the target disease or disorder to obtain definitive statistical evidence of the efficacy and safety of the proposed product and dosing regimen.

In the U.S., the results of the pre-clinical and clinical testing of a product candidate are then submitted to the FDA in the form of a Biologics License Application ("BLA"), or an NDA. The NDA or BLA also includes information pertaining to the preparation of the new drug, analytical methods, details of the manufacture of finished products and proposed product packaging and labeling. The submission of an application is not a guarantee that the FDA will find the application complete and accept it for filing. The FDA may refuse to file the application if it is not considered sufficiently complete to permit a review and will inform the applicant of the reason for the refusal. The applicant may then resubmit the application and include the supplemental information.

Once an NDA or BLA, as the case may be, is accepted for filing, the FDA has 10 months, under its standard review process, within which to review the application (for some applications, the review process is longer than 10 months). For drugs that, if approved, would represent a significant improvement in the safety or effectiveness of the treatment, diagnosis, or prevention of serious conditions when compared to standard applications, the FDA may assign "priority review" designation and review the application within 6 months. The FDA has additional review pathways to expedite development and review of new drugs that are intended to treat serious or life-threatening conditions and demonstrate the potential to address unmet medical needs, including: "fast track," "breakthrough therapy," and "accelerated approval."

In October 2013, the FDA granted fast track status for ALKS 5461 for the adjunctive treatment of MDD in patients with inadequate response to standard antidepressant therapies. 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 a NDA or BLA for FDA review before the entire filing is completed. Fast track status does not ensure that a product will be developed more quickly or receive FDA approval.

As part of its review, the FDA may refer the application to an advisory committee for independent advice on questions related to the development of the drug and a recommendation as to whether the application should be approved. The FDA is not bound by the recommendation of an advisory committee; however, historically, it has typically followed such recommendations. The FDA may determine that a Risk Evaluation and Mitigation Strategy ("REMS") is necessary to ensure that the benefits of a new product outweigh its risks. If required, a REMS may include various elements, such as publication of a medication guide, patient package insert, a communication plan to educate health care providers of the drug's risks, limitations on who may prescribe or dispense the drug, or other measures that the FDA deems necessary to assure the safe use of the drug.

In reviewing a BLA or NDA, the FDA may grant marketing approval or issue a complete response letter to communicate to the applicant the reasons the application cannot be approved in the current

Table of Contents

form and provide input on the changes that must be made before an application can be approved. Even if such additional information and data are submitted, the FDA may ultimately decide that the BLA or NDA does not satisfy the criteria for approval. 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 pre-clinical or clinical tests, and the risks and benefits demonstrated in clinical trials. It is impossible to predict with any certainty whether and when the FDA will grant marketing approval. Even if a product is approved, the approval may be subject to limitations based on the FDA's interpretation of the data. For example, 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, any of which could negatively impact the commercial success of a drug. In addition, the FDA may require a sponsor to conduct additional post-marketing studies as a condition of approval to provide data on safety and effectiveness. In addition, prior to commercialization, controlled substances are generally subject to review and potential scheduling by the DEA.

The FDA tracks 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 identified during clinical trials can delay, impede or prevent marketing approval. Based on new safety information that emerges after approval, the FDA can mandate product labeling changes, impose a new REMS or the addition of elements to an existing REMS, require new post-marketing studies (including additional clinical trials), or suspend or withdraw approval of the product. 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.

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, the FDA will need to review and approve such changes in advance. In the case of a new indication, we are required to demonstrate with additional clinical data that the product is safe and effective for the new intended use. 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 promotional activities for products under its jurisdiction. 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 certain medical specialties and often reflect a physician's belief that the off-label use is the best treatment for a particular patient. 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 and the U.S. Department of Justice, corrective advertising and the full range of civil and criminal penalties available to the FDA and the U.S. Department of Justice.

**Controlled Substances Act:** The DEA regulates pharmaceutical products that are controlled substances. Controlled substances are those drugs that appear on one of the five schedules promulgated and administered by the DEA under the Controlled Substances Act (the "CSA"). The CSA governs, among other things, the inventory, distribution, recordkeeping, handling, security and disposal of controlled substances. Pharmaceutical products that act on the CNS are often evaluated for abuse potential; a product that is then classified as controlled substance must undergo scheduling by the DEA, which is a separate process that may delay the commercial launch of a pharmaceutical product even after FDA approval of the NDA. Companies with a scheduled pharmaceutical product are subject

Table of Contents

to periodic and ongoing inspections by the DEA and similar state drug enforcement authorities to assess ongoing compliance with the DEA's regulations. Any failure to comply with these regulations could lead to a variety of sanctions, including the revocation or a denial of renewal of any DEA registration, injunctions, or civil or criminal penalties.

*Outside the United States*

Our products are marketed in numerous jurisdictions outside the U.S. Most of these jurisdictions have product approval and post-approval regulatory processes that are similar in principle to those in the U.S. In Europe, there are several tracks for marketing approval, depending on the type of product for which approval is sought. Under the centralized procedure, a company submits a single application to the EMA. The marketing application is similar to the NDA in the U.S. and is evaluated by the CHMP, the expert scientific committee of the EMA. If the CHMP determines that the marketing application fulfills the requirements for quality, safety, and efficacy, it will submit a favorable opinion to the European Commission ("EC"). The CHMP opinion is not binding, but is typically adopted by the EC. A marketing application approved by the EC is valid in all member states.

In addition to the centralized procedure, Europe also has: (i) a nationalized procedure, which requires a separate application to, and approval determination by, each country; (ii) a decentralized procedure, whereby applicants submit identical applications to several countries and receive simultaneous approval; and (iii) a mutual recognition procedure, where applicants submit an application to one country for review and other countries may accept or reject the initial decision. Regardless of the approval process employed, various parties share responsibilities for the monitoring, detection and evaluation of adverse events post-approval, including national authorities, the EMA, the EC and the marketing authorization holder.

*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 parties to comply with GCP can likewise result in rejection of our clinical trial data or other sanctions.

Table of Contents

***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 an NDA for a product that contains an active ingredient, known as the active drug moiety, 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 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 (e.g., under 505(b)(1)), 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 FDA's Approved Drugs Product List, commonly referred to as 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 20 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.

***Sales and Marketing***

We 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

Table of Contents

referral of business, including the purchase or prescription of a particular drug. Due to the broad scope of the U.S. statutory provisions, the general absence of guidance in the form of regulations, and 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 payers (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. 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, federal and state authorities are paying increased attention to enforcement of these laws within the pharmaceutical industry and private individuals have been active in alleging violations of the laws and bringing suits on behalf of the government under the federal civil False Claims Act. If we were subject to allegations concerning, or were convicted of violating, these laws, our business could be harmed. See "Item 1A 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 payers, and a reduction in payment rate or reimbursement or an increase in our financial obligation to governmental payers could result in decreased sales of our products and decreased revenues" and "Litigation, including product liability litigation, and arbitration may result in financial losses, harm our reputation and may divert management resources."

Laws and regulations have been enacted by the federal government and various states to regulate the sales and marketing practices of pharmaceutical manufacturers. The laws and regulations generally limit financial interactions between manufacturers and healthcare providers or require disclosure to the government and public of such interactions. The laws include federal "sunshine" provisions enacted in 2010 as part of the comprehensive federal healthcare reform legislation; Centers for Medicare and Medicaid Services ("CMS") issued a final rule with respect to such provisions in February 2013 and manufacturer reporting commenced in March 2014. The sunshine provisions apply to pharmaceutical manufacturers with products reimbursed under certain government programs and require those manufacturers to disclose annually to the federal government (for re-disclosure to the public) certain payments made to, or at the request of or on behalf of, physicians or to teaching hospitals. Certain state laws also require disclosure of pharmaceutical pricing information and marketing expenditures. Given the ambiguity found in many of these laws and their implementation, our reporting actions could be subject to the penalty provisions of the pertinent federal and state laws and regulations.

***Pricing and Reimbursement***

*United States*

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 payers such as state and federal governments, including Medicare and Medicaid, managed care providers and private insurance plans. Third-party payers are increasingly challenging the prices charged for medical products and services and examining the medical necessity and cost-effectiveness of medical products and services, in addition to their safety and efficacy.

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 average manufacturer price ("AMP") or the difference between

Table of Contents

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 this difference being the amount by which the rebate is adjusted upwards. 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 the 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.

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 CMS on a quarterly basis. This information is used to compute Medicare payment rates, with rates for Medicare Part B drugs outside the hospital outpatient setting and in the hospital outpatient setting consisting of ASP plus a specified percentage. These rates are adjusted periodically. 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.

Medicare Part D provides coverage to enrolled Medicare patients for self-administered drugs (i.e. drugs that do not need to be injected or otherwise administered by a physician). Medicare Part D also covers the prescription drug benefit for dual eligible beneficiaries. Medicare Part D is administered by private prescription drug plans approved by the U.S. government and each drug plan establishes its own Medicare Part D formulary for prescription drug coverage and pricing, which the drug plan may modify from time-to-time. The prescription drug plans negotiate pricing with manufacturers and may condition formulary placement on the availability of manufacturer discounts. Except for dual eligible Medicare Part D beneficiaries who qualify for low income subsidies, manufacturers, including us, are required to provide a 50% discount on brand name prescription drugs utilized by Medicare Part D beneficiaries when those beneficiaries reach the coverage gap in their drug benefits.

The availability of federal funds to pay for our products under the Medicaid Drug Rebate Program and Medicare Part B requires that we extend discounts to certain purchasers under the Public Health Services ("PHS") pharmaceutical pricing program. Purchasers eligible for discounts include a variety of community health clinics, other entities that receive health services grants from PHS, and hospitals that serve a disproportionate share of financially needy patients.

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 by such federal agencies and certain federal grantees. Coverage under Medicaid, the Medicare Part B program and the PHS pharmaceutical pricing program is also conditioned upon FSS participation. FSS pricing is negotiated periodically with the Department of Veterans Affairs. FSS pricing is intended not to exceed the price that we charge our most-favored non-federal customer for a product. In addition, prices for drugs purchased by the Department of Veterans Affairs, Department of Defense (including drugs purchased by military personnel and dependents through the TriCare retail pharmacy program), Coast Guard and PHS are subject to a cap on pricing equal to 76% of the non-federal average



Table of Contents

manufacturer price ("non-FAMP"). An additional discount applies if non-FAMP increases more than inflation (measured by the Consumer Price Index - Urban). 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.

The U.S. government and governments outside the U.S. regularly consider reforming healthcare coverage and lessening healthcare costs. Such reforms may include changes to the coverage and reimbursement of our products, which may have a significant impact on our business. In addition, emphasis on managed care in the U.S. has increased and we expect will continue to increase the pressure on drug pricing. Private insurers regularly seek to manage drug cost and utilization by implementing coverage and reimbursement limitations through means including, but not limited to, formularies, increased out-of-pocket obligations and various prior authorization requirements. Even if favorable coverage and reimbursement status is attained for one or more products for which we have received regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

*Outside the United States*

Within the EU, products are paid for by a variety of payers, with governments being the primary source of payment. Governments may determine or influence reimbursement of products. Governments may also set prices or otherwise regulate pricing. Negotiating prices with governmental authorities can delay commercialization of products. Governments may use a variety of cost-containment measures to control the cost of products, including price cuts, mandatory rebates, value-based pricing and reference pricing (i.e. referencing prices in other countries and using those reference prices to set a price). Recent budgetary pressures in many EU countries are causing governments to consider or implement various cost-containment measures, such as price freezes, increased price cuts and rebates, and expanded generic substitution and patient cost-sharing. If budget pressures continue, governments may implement additional cost-containment measures.

*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 healthcare professionals with whom we regularly interact 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.

**UK Bribery Act:** We are also subject to the UK Bribery Act, 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 UK Bribery Act. Penalties under the UK 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

Table of Contents

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, these 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 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 February 12, 2015, we had approximately 1,300 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 16, 2011, the business of Alkermes, Inc. and the drug technologies business ("EDT") of Elan Corporation, plc ("Elan") were combined under Alkermes plc (this combination is referred to as the "Business Combination," the "acquisition of EDT" or the "EDT acquisition"). Our ordinary shares are listed on the NASDAQ Global Select Market, where our trading symbol is "ALKS." Headquartered in Dublin, Ireland, we have an R&D center in Waltham, Massachusetts; R&D and manufacturing facilities in Athlone, Ireland; and manufacturing facilities in Gainesville, Georgia and Wilmington, Ohio.

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](http://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 Annual Report. 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

Table of Contents

(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](http://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 Annual Report, including the matters addressed under the caption "Cautionary Note Concerning Forward-Looking Statements" above. If any events described by the following risks actually occur, they could materially adversely affect our business, financial condition, cash flows 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.*

***We rely heavily on our collaborative partners in the commercialization and continued development of our products; and if they are not effective, our revenues could be materially adversely affected.***

Our arrangements with collaborative partners are critical to bringing our products to the market and successfully commercializing them. We rely on these parties in various respects, including providing funding for development programs and conducting pre-clinical testing and clinical trials with respect to new formulations or other development activities for our marketed products; managing the regulatory approval process; and commercializing our products.

The revenues that we receive from manufacturing fees and royalties depend primarily upon the success of our collaborative partners, and particularly Janssen, Acorda, Biogen Idec, and AstraZeneca, in commercializing our partnered products. Janssen is responsible for the commercialization of RISPERDAL CONSTA, INVEGA SUSTENNA/XEPLION, and VIVITROL in Russia and the CIS. Acorda and Biogen Idec are responsible for commercializing AMPYRA/FAMPYRA. AstraZeneca is responsible for commercializing BYDUREON. We have no involvement in the commercialization efforts for such products. Our revenues 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. Such revenues will depend on numerous factors, many of which are outside our control.

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, 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.

In addition, 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, or failure of, 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.

Table of Contents

***We receive substantial revenues from certain of our products and collaborative partners.***

We depend substantially upon continued sales of RISPERDAL CONSTA and INVEGA SUSTENNA/XEPLION by our partner, Janssen, and upon continued sales of AMPYRA/FAMPYRA by our partner Acorda and its sublicensee, Biogen Idec. Any significant negative developments relating to these products, or to our collaborative relationships, could have a material adverse effect on our business, results of operations, cash flows and financial condition.

***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 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 payers;

unfavorable publicity concerning our products, similar classes of drugs or the industry generally;

the introduction, availability and acceptance of competing treatments, including treatments marketed and sold by our collaborators;

the reaction of companies that market competitive products;

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

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

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

## Edgar Filing: Alkermes plc. - Form 10-K

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, including from our collaborators;

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.

Table of Contents

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 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 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, financial condition, cash flows and results of operations.

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

The manufacture of pharmaceutical products is a highly complex process in which a variety of difficulties may arise from time to time including, but not limited to, product loss due to material failure, equipment 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.

Table of Contents

***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, requires 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 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 and register 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 (for example, in the cases of INVEGA SUSTENNA/XEPLION and BYDUREON) 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 regulations and other applicable government and corresponding and foreign standards. In the U.S., the DEA and other state-level agencies heavily regulate the manufacturing, holding, processing, security, recordkeeping and distribution of controlled substances. Our marketed products and product candidates that are scheduled by the DEA as controlled substances make us subject to the DEA's regulations. We are subject to unannounced inspections by the FDA, the DEA or comparable state and foreign 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 or other regulatory agencies, and ultimate amendment acceptance by such agencies, prior to release of product to the applicable marketplace. Our inability or the inability of our third-party service providers to demonstrate ongoing cGMP or other regulatory compliance could require us to withdraw or recall products and interrupt commercial supply of our products. Any delay, interruption or other issues that may 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

Table of Contents

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 and other 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 and, if the foregoing activities involve controlled substances, the DEA. Failure to gain or maintain regulatory compliance with the FDA or regulatory agencies 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 payers, and a reduction in payment rate or reimbursement or an increase in our financial obligation to governmental payers could result in decreased sales of our products and decreased revenues.***

In both U.S. and non-U.S. markets, sales of our products depend, in part, on the availability of reimbursement from third-party payers 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. In addition, when a new product is approved, the availability of government and private reimbursement for that product is uncertain, as is the amount for which that product will be reimbursed. We cannot predict the availability or amount of reimbursement for our product candidates.

In the U.S., federal and state legislatures, health agencies and third-party payers continue to focus on containing the cost of healthcare, including by comparing the effectiveness, benefits and costs of similar treatments. For example, the 2010 Patient Protection and Affordable Care Act encourages comparative effectiveness research. Any adverse findings for our products from such research may reduce the extent of reimbursement for our products. Economic pressure on state budgets may result in states increasingly seeking to achieve budget savings through mechanisms that limit coverage or payment for drugs. State Medicaid programs are increasingly requesting manufacturers to pay supplemental rebates and requiring prior authorization by the state program for use of any drug for which supplemental rebates are not being paid. Managed care organizations continue to seek price discounts and, in some cases, to impose restrictions on the coverage of particular drugs. Government efforts to reduce Medicaid expenses may lead to increased use of managed care organizations by Medicaid programs. This may result in managed care organizations influencing prescription decisions for a larger segment of the population and a corresponding constraint on prices and reimbursement for our products.

The government-sponsored healthcare systems in Europe and many other countries are the primary payers for healthcare expenditures, including payment for drugs and biologics. We expect that countries may take actions to reduce expenditure on drugs and biologics, including mandatory price reductions, patient access restrictions, suspensions of price increases, increased mandatory discounts or rebates, preference for generic products, reduction in the amount of reimbursement and greater importation of drugs from lower-cost countries. These cost-control measures likely would reduce our revenues. In addition, certain countries set prices by reference to the prices in other countries where our products are marketed. Thus, the inability to secure adequate prices in a particular country may



Table of Contents

not only limit the marketing of products within that country, but may also adversely affect the ability to obtain acceptable prices in other markets.

***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 marketed 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 patents issued in the U.S. to third parties that may relate to our product candidates. We also know of patent applications filed by other parties in the U.S. and various countries outside the U.S. that may relate to some of our product candidates if such patents are issued in their present form. If patents are issued that cover our product candidates, we may not be able to manufacture, use, offer for sale, import or sell such product candidates without first getting a license from the patent holder. The patent holder may not grant us a license on reasonable terms, or it may refuse to grant us a license at all. This could delay or prevent us from developing, manufacturing or selling those of our product candidates that would require the license. A patent holder might also file an infringement action against us claiming that the manufacture, use, offer for sale, import or sale of our product candidates infringed one or more of its patents. Even if we believe that such claims are without merit, our cost of defending such an action is likely to be high and we might not receive a favorable ruling, and the action could be time-consuming and distract management's attention and resources. Claims of intellectual property infringement also might require us to redesign affected products, enter into costly settlement or license agreements or pay costly damage awards, or face a temporary or permanent injunction prohibiting us from marketing or selling certain of our products. Even if we have an agreement to indemnify us against such costs, the indemnifying party may be unable to uphold its contractual obligations. If we cannot or do not license the infringed technology at all, license the technology on reasonable terms or substitute similar technology from another source, our revenue and earnings could be adversely impacted.

Table of Contents

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 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, financial condition, cash flows and results of operations.

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

There is considerable uncertainty within the pharmaceutical industry about the validity, scope and enforceability of many issued patents in the U.S. and elsewhere in the world. 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 or 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 pharmaceutical 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, certify that their products either do not infringe the innovator's patents or that the innovator's patents are invalid. This often results in litigation between the innovator and the ANDA applicant. This type of litigation is commonly known as "Paragraph IV" litigation in the U.S. We and our collaborative partners are currently involved in various Paragraph IV litigations in the U.S. and other proceedings in Europe involving our patents in respect of TRICOR, MEGACE ES, AMPYRA and ZOHYDRO ER. 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

Table of Contents

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.***

Pursuant to an amended and restated credit agreement, dated as of September 25, 2012, as amended (the "Term Loan Facility"), we have approximately \$375.0 million in original principal term loans, consisting of a \$300.0 million, seven-year term loan with an interest rate at LIBOR plus 2.75% with a LIBOR floor of 0.75% ("Term Loan B-1"), and a \$75.0 million, four-year term loan with an interest rate at LIBOR plus 2.75% with no LIBOR floor ("Term Loan B-2").

Our existing indebtedness is secured by a first priority lien on substantially all of the combined company assets and properties of Alkermes plc and most of its subsidiaries, which serve as guarantors. The agreements governing the Term Loan Facility include a number of restrictive covenants that, among other things, subject to certain exceptions and baskets, impose operating and financial restrictions on us. 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 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 the products that we market and sell. 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 or if wholesaler buying decisions or other factors outside of our control change, such events could materially adversely affect our business, financial condition, cash flows and results of operations.

Table of Contents

***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.***

Our long-term viability and growth will depend upon the successful development of new products from our research and development activities. Product development is very expensive and involves a high degree of risk. Only a small number of research and development programs result in the commercialization of a product. Success in pre-clinical work or early-stage clinical trials does not ensure that later-stage or larger-scale clinical trials will be successful. Conducting clinical trials is a complex, time-consuming and expensive process. Our ability to complete our clinical trials in a timely fashion depends in large part on a number of key factors including protocol design, regulatory and institutional review board approval, the rate of patient enrollment in clinical trials and compliance with extensive current Good Clinical Practices. Refer to the risk factor herein entitled " Clinical trials for our product candidates are expensive, and their outcome is uncertain."

In addition, since 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, obtain a final DEA scheduling designation (to the extent our products are controlled substances) or market any approved products on a worldwide basis. We expect the development of products for our own account to consume substantial resources. If we are able to develop commercial products on our own, the risks associated with these programs may be greater than those associated with our programs with collaborative partners.

If 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, such events could materially adversely affect our business, financial condition, cash flows and results of operations. For factors that may affect the market acceptance of our products approved for sale, see " We face competition in the biotechnology and pharmaceutical industries."

***The FDA or other regulatory agencies may not approve our product candidates or may impose limitations upon any product approval.***

We must obtain government approvals before marketing or selling our product candidates in the U.S. and in jurisdictions outside the U.S. The FDA, DEA, to the extent a product candidate is a controlled substance, and comparable regulatory agencies in other countries, impose substantial and rigorous requirements for the development, production and commercial introduction of drug products. These include pre-clinical, laboratory and clinical testing procedures, sampling activities, clinical trials and other costly and time-consuming procedures. In addition, regulation is not static, and regulatory 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 product 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."

## Edgar Filing: Alkermes plc. - Form 10-K

### Table of Contents

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 pre-clinical 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 CROs 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 GCP, or EU legislation governing GCP, 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. In summary, we cannot be sure that regulatory approval will be granted for product candidates that we submit for regulatory review. Our ability to generate revenues from the commercialization and sale of additional products will be limited by any failure to obtain these approvals. In addition, share prices have declined significantly in certain instances where companies have failed to obtain FDA approval of a product 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 share 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 the temporary or permanent withdrawal by the FDA or other regulatory agencies of our products from commercial marketing, which could seriously harm our business and cause our share price to decline. Further, even if the FDA provides regulatory approval, controlled substances will not become commercially available until after the DEA provides its final schedule designation, which may take longer and may be more restrictive than we expect or change after its initial designation. We currently expect ALKS 5461 and ALKS 3831 to require such DEA final schedule designation prior to commercialization.



Table of Contents

***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 pre-clinical testing and clinical trials.

Our pre-clinical 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 a 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 issues, including those by the FDA, DEA and other regulatory agencies.

In addition, we are currently conducting and enrolling patients in clinical studies in a number of countries where our experience is more limited. For example, the phase 3 extension study of ALKS 5461 is being conducted in many countries around the world, including in Eastern Europe and Asia. We depend on independent clinical investigators, CROs and other third-party service providers and our collaborators in the conduct of clinical trials for our product candidates and in the accurate reporting of results from such clinical trials. 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 pre-clinical testing and early clinical trials often have not predicted results of later clinical trials. A number of product candidates 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, and such events could 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, which could adversely affect our business and share price.***

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





Table of Contents

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, financial condition, cash flows and results of operations. In addition, the reporting of adverse safety events involving our products and public rumors about such events could cause our product sales or share 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 also 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 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, including 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 other regulatory agencies inside and outside of the U.S., including new or different approval requirements, timelines and processes, may also delay or prevent the approval of product candidates, 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 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 business, financial condition, cash flows and results of operations.

Table of Contents

*We face competition in the biotechnology and pharmaceutical industries.*

We face intense competition in the development, manufacture, marketing and commercialization of our marketed 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, 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 marketed 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 marketed 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. In the treatment of schizophrenia, RISPERDAL CONSTA and INVEGA SUSTENNA compete with a number of other injectable products including ZYPREXA RELPREVV ((olanzapine) For Extended Release Injectable Suspension), which is marketed and sold by Lilly; ABILIFY MAINTENA, (aripiprazole for extended release injectable suspension), a once-monthly injectable formulation of ABILIFY (aripiprazole) developed by Otsuka Pharmaceutical Co., Ltd. ("Otsuka"); oral compounds currently on the market; and generic versions of branded oral and injectable products. In the treatment of bipolar disorder, RISPERDAL CONSTA competes with antipsychotics such as ABILIFY, LATUDA, risperidone, olanzapine, ziprasidone and clozapine.

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, including generic drugs, also formulated from naltrexone. Other pharmaceutical companies are developing product candidates that have shown some promise in treating alcohol dependence that, if approved by the FDA, would compete with VIVITROL.

In the treatment of opioid dependence, VIVITROL competes with methadone, oral naltrexone, 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., and BUNAVAIL buccal film (buprenorphine and naloxone) marketed by BioDelivery Sciences, and ZUBZOLV (buprenorphine and naloxone) marketed by Orexo US, Inc. It also competes with generic versions of SUBUTEX and

Table of Contents

SUBOXONE sublingual tablets. Other pharmaceutical companies are developing product candidates that have shown promise in treating opioid dependence that, if approved by the FDA, would compete with VIVITROL.

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

While AMPYRA/FAMPYRA is the first product approved as a treatment to improve walking in patients with MS, 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, TYSABRI, TECFIDERA, and PLEGRIDY from Biogen Idec; BETASERON from Bayer HealthCare Pharmaceuticals; COPAXONE from Teva Pharmaceutical Industries Ltd.; REBIF and NOVANTRONE from EMD Serono, Inc.; GILENYA and EXTAVIA from Novartis AG; AUBAGIO and LEMTRADA from Sanofi-Aventis, and generic products.

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

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

***We may not become profitable on a sustained basis.***

At December 31, 2014, our accumulated deficit was \$512.3 million, which was primarily the result of net losses incurred from 1987, the year Alkermes, Inc., was founded, through March 31, 2012, partially offset by net income over certain of our recent fiscal periods. 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 and our partners' ability to manufacture economically, our marketed products. In April 2013, we announced the two-year restructuring plan of our Athlone, Ireland manufacturing facility, pursuant to which we terminated manufacturing services for certain products that were no longer expected to be economically practicable to produce.

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

obtain and maintain regulatory approval for our product candidates and marketed products, respectively, both in the U.S. and in other countries;

efficiently manufacture our products;

support the commercialization of our products by our collaborative partners;

## Edgar Filing: Alkermes plc. - Form 10-K

### Table of Contents

successfully market and sell VIVITROL and, if approved by the FDA, aripiprazole lauroxil 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 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 payers;

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, including clinical trials;

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

the time that will be required for the DEA to provide its final scheduling designation for our product candidates that are controlled substances;

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;

## Edgar Filing: Alkermes plc. - Form 10-K

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 execute on our business strategy, 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 in the future to execute on our business strategy, and we may seek funds through various sources, including debt and equity offerings, corporate collaborations, bank

Table of Contents

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 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. In addition, as a condition to providing additional funds to us, future investors or lenders may demand, and may be granted, rights superior to those of existing shareholders. If we issue additional debt securities in the future, our existing debt service obligations will increase further. If we are unable to generate sufficient cash to meet these obligations and need to use existing cash or liquidate investments in order to fund our debt service obligations or to repay our debt, we may be forced to delay or terminate clinical trials or curtail operations. We cannot be certain, however, that additional financing will be available from any of these sources when needed or, if available, will be on acceptable terms, if at all, particularly if the credit and financial markets are constrained at the time we require funding. If we fail to obtain additional capital when we need it, we may not be able to execute our business strategy successfully and may have to give up rights to our product platforms, product candidates or marketed products or grant licenses on terms that may not be favorable to us.

***Litigation, including product liability litigation, and arbitration may result in financial losses, 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 and fraud and abuse laws and derivative actions. The administration of drugs in humans, whether in clinical studies or commercially, carries the inherent risk of product liability claims whether or not the drugs are actually the cause of an injury. Our marketed products or product candidates may cause, or may appear to have caused, 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. We are subject from time to time to lawsuits based on product liability and related claims. 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 litigation or arbitration and, as a result, our business could be materially harmed. This may result in large judgments or settlements against us, any of which could have a negative effect on our financial condition and business. 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.

***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

Table of Contents

connection with any contamination for which we may be responsible could materially 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 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, financial condition, cash flows and results of operations would be adversely affected.

***Currency exchange rates may affect revenues and expenses.***

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. We also incur substantial operating costs in Ireland and 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 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. Refer to "Item 7A. Quantitative and Qualitative Disclosure about Market Risk" for additional information relating to our foreign currency exchange rate risk.

***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.

Table of Contents

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, such events could materially adversely affect our business, financial condition, cash flows and results of operations. Merger and acquisition transactions involve various inherent risks, including:

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

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

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

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

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

difficulties that could be encountered in managing international operations; and

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

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

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

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

At December 31, 2014, we have \$479.4 million of amortizable intangible assets and \$94.2 million of goodwill. 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 December 31, 2014, a majority 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,





Table of Contents

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 biopharmaceutical 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, but not limited to, the distribution of our profits or losses between the jurisdictions where we operate and differences in interpretation of tax laws. 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 us. 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, cash flows, results of operations and growth prospects.

***The Business Combination of Alkermes, Inc. 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, Alkermes, Inc. transferred certain intellectual property to one of our Irish subsidiaries, and Alkermes, Inc. 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, Alkermes, Inc. 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.

Table of Contents

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.

***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 our board of directors with a specific agenda, it may adversely affect our ability to effectively implement our strategic plan in a timely manner and create additional value for our shareholders.

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

***If any of our partners undergoes a change in control or in management, this may adversely affect our collaborative relationships or revenues from our products.***

RISPERDAL CONSTA is commercialized by Janssen. AMPYRA/FAMPYRA is commercialized by Acorda in the U.S. and by Biogen Idec outside the U.S. BYDUREON and INVEGA SUSTENNA are developed, manufactured and commercialized by AstraZeneca and Janssen, respectively. We have established relationships with members of the management teams of Janssen, Acorda and AstraZeneca in relevant functional areas in respect of our partnered products.

If any of our partners undergoes a change of control or a change of management, we will need to re-establish many of these relationships, and we may need to gain alignment on certain issues related to our products. Given the inherent uncertainty and disruption that arises in a change of control, we cannot be sure that we would be able to successfully execute these courses of action. Finally, any change of control or in management may result in a reprioritization of our product within such partner's portfolio, or such partner may fail to maintain the financial or other resources necessary to continue supporting its role in the collaborative arrangement.

If any of our partners undergoes a change of control and the acquirer either is unable to perform such partner's obligations under its agreements with us or has a product that competes with ours that such acquirer does not divest, it could materially adversely affect our business, financial condition, cash flows and results of operations.

Table of Contents

***Security breaches and other disruptions could compromise our information and expose us to liability, which would cause our business and reputation to suffer.***

In the ordinary course of our business, we collect and store sensitive data, including intellectual property, our proprietary business information and that of our suppliers and partners, as well as personally identifiable information of patients, clinical trial participants and employees. Similarly, our partners and third-party providers possess certain of our sensitive data. The secure maintenance of this information is critical to our operations and business strategy. Despite our security measures, our information technology and infrastructure may be vulnerable to attacks by hackers or breached due to employee error, malfeasance or other disruptions. Certain types of information technology or infrastructure attacks or breaches may go undetected for a prolonged period of time. Any such breach could compromise our networks and the information stored there could be accessed, publicly disclosed, lost or stolen. Any such access, disclosure or other loss of information, including our data being breached at our partners or third-party providers, could result in legal claims or proceedings and liability under laws that protect the privacy of personal information, disrupt our operations, and damage our reputation which could adversely affect our business.

***If we identify a material weakness in our internal control over financial reporting, our ability to meet our reporting obligations and the trading price of our ordinary shares could be negatively affected.***

A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of our financial statements will not be prevented or detected on a timely basis. Accordingly, a material weakness increases the risk that the financial information we report contains material errors.

We regularly review and update our internal controls, disclosure controls and procedures, and corporate governance policies. In addition, we are required under the Sarbanes-Oxley Act of 2002 to report annually on our internal control over financial reporting. Any system of internal controls, however well designed and operated, is based in part on certain assumptions and can provide only reasonable, not absolute, assurances that the objectives of the system are met. If we, or our independent registered public accounting firm, determine that our internal controls over financial reporting are not effective, or we discover areas that need improvement in the future, these shortcomings could have an adverse effect on our business and financial results, and the price of our ordinary shares could be negatively affected.

If we cannot conclude that we have effective internal control over our financial reporting, or if our independent registered public accounting firm is unable to provide an unqualified opinion regarding the effectiveness of our internal control over financial reporting, investors could lose confidence in the reliability of our financial statements, which could lead to a decline in the trading price of our ordinary shares. Failure to comply with reporting requirements could also subject us to sanctions and/or investigations by the SEC, the NASDAQ Stock Market or other regulatory authorities.

***Because we do not anticipate paying any cash dividends on our ordinary shares in the foreseeable future, capital appreciation, if any, will be the source of gain for our shareholders.***

We have never declared or paid cash dividends on our ordinary shares. We currently intend to retain all of our current and future earnings to finance the growth and development of our business. As a result, capital appreciation, if any, of our ordinary shares will be the sole source of gain for our shareholders for the foreseeable future.

**Item 1B. Unresolved Staff Comments**

None.

Table of Contents

**Item 2. *Properties***

We lease approximately 14,600 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 160,000 square feet of space in Waltham, Massachusetts, which houses corporate offices, administrative areas and laboratories. This lease expires in 2021 and includes a tenant option to extend the term for up to two five-year periods. We lease approximately 3,800 square feet of office space in Washington, DC. This lease expires in 2020.

We own manufacturing, office and laboratory sites in Wilmington, Ohio (approximately 195,000 square feet); Athlone, Ireland (approximately 410,000 square feet); and Gainesville, Georgia (approximately 90,000 square feet).

We have a lease agreement in place for a commercial manufacturing facility in Chelsea, Massachusetts designed for clinical and commercial manufacturing of inhaled products that we are currently subleasing. The lease term is for 15 years, expiring in 2015, with a tenant option to extend the term for up to two five-year periods. 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, there are currently Paragraph IV litigations in the U.S. and other proceedings in Europe involving our patents in respect of TRICOR, MEGACE ES, AMPYRA and ZOHYRDO ER. For information about risks relating to Paragraph IV litigations and other proceedings see "Item 1A Risk Factors" in this Annual Report and specifically the section entitled "Uncertainty over intellectual property in the pharmaceutical industry has been the source of litigation, which is inherently costly and unpredictable." 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, financial condition, cash flows and results of operations.

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

Not Applicable.

Table of Contents**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.

	Year Ended		Nine Months	
	December 31, 2014		Ended	
	High	Low	High	Low
1st Quarter	\$ 53.82	\$ 40.07	\$ 33.72	\$ 22.35
2nd Quarter	50.94	41.10	35.35	28.66
3rd Quarter	51.75	41.54	41.12	30.17
4th Quarter	58.88	40.23		

There were 239 shareholders of record for our ordinary shares on February 12, 2015. In addition, the last reported sale price of our ordinary shares as reported on the NASDAQ Global Select Stock Market on February 12, 2015 was \$73.29.

**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 2014 Annual Meeting of Shareholders (the "2014 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 year ended December 31, 2014. As of December 31, 2014, 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 January 31, 2015, and on discussions and correspondence with the Irish Revenue Commissioners. Legislative, administrative or judicial changes may modify the tax consequences described below.

Table of Contents

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 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 (outside of DTC) will not be subject to DWT provided that the shareholder has completed the appropriate Irish DWT form and this form remains valid. Such shareholders must provide the appropriate Irish DWT form to our transfer agent at least seven business days before the record date for the first dividend payment to which they are entitled.

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.

*Income tax on dividends*

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.

*Irish tax on capital gains.*

A shareholder who is neither resident nor ordinarily resident in Ireland and does not hold our ordinary shares in connection with a trade or business carried on by such shareholder in Ireland through a branch or agency should not be within the charge to Irish tax on capital gains on a disposal of our ordinary shares.

*Capital acquisitions tax*

Irish capital acquisitions tax ("CAT") is comprised principally of gift tax and inheritance tax. CAT could apply to a gift or inheritance of our ordinary shares irrespective of the place of residence, ordinary residence or domicile of the parties. This is because our ordinary shares are regarded as property situated in Ireland as our share register must be held in Ireland. The person who receives the gift or inheritance has primary liability for CAT.

CAT is levied at a rate of 33% 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

Table of Contents

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 of 1933, as amended or the Securities Exchange Act of 1934, as amended (the "Exchange Act"), except to the extent that we specifically incorporate it by reference into such filing.

The following graph compares the cumulative total shareholder return on our ordinary shares since March 31, 2010 through December 31, 2014 with the NASDAQ Composite Total Return Index and the NASDAQ Biotechnology Index. As a result of a change in the total return data made available to us through our vendor provider, our performance graphs going forward will use the NASDAQ Composite Total Return Index in lieu of the NASDAQ US & Foreign Index. Please note that information for the NASDAQ US & Foreign Index is provided only from March 31, 2010 through December 31, 2013, the last day this data was made available by our third-party index provider. The NASDAQ Biotechnology Index was not affected by this change. 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 Alkermes, Inc., 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, 2010 in our common stock and in each of the foregoing indices and



Table of Contents

further assumes reinvestment of any dividends. We did not declare or pay any dividends on our common stock or ordinary shares during the comparison period.

	Year Ended March 31,				Nine Months Ended December 31, 2013	Year Ended December 31, 2014
	2010	2011	2012	2013		
Alkermes	100	100	143	183	313	452
NASDAQ Composite Total Return	100	117	131	141	182	209
NASDAQ Biotechnology Index	100	111	136	178	252	338
NASDAQ Stock Market (U.S. and Foreign) Index	100	117	132	141	186	

**Item 6. Selected Financial Data**

The selected historical financial data set forth below at December 31, 2014 and 2013 and for the year ended December 31, 2014, the nine months ended December 31, 2013 and the year ended March 31, 2013 are derived from our audited consolidated financial statements, which are included elsewhere in this Annual Report. The selected historical financial data set forth below at March 31, 2013, 2012 and 2011 and for the years ended March 31, 2012 and 2011 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 Alkermes, Inc., while the selected historical financial data for the period after September 16, 2011 is that of Alkermes plc. The Company has elected not to recast prior period amounts to conform to the change in its fiscal year.

## Edgar Filing: Alkermes plc. - Form 10-K

### Table of Contents

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 December 31, 2014	Nine Months Ended December 31, 2013	Year Ended March 31,		
			2013	2012(1)	2011
(In thousands, except per share data)					
<b>Consolidated Statements of Operations Data:</b>					
<b>REVENUES:</b>					
Manufacturing and royalty revenues	\$ 516,876	\$ 371,039	\$ 510,900	\$ 326,444	\$ 156,840
Product sales, net	94,160	57,215	58,107	41,184	28,920
Research and development revenue	7,753	4,657	6,541	22,349	880
<b>Total revenues</b>	<b>618,789</b>	<b>432,911</b>	<b>575,548</b>	<b>389,977</b>	<b>186,640</b>
<b>EXPENSES:</b>					
Cost of goods manufactured and sold	175,832	134,306	170,466	127,578	52,185
Research and development	272,043	128,125	140,013	141,893	97,239
Selling, general and administrative(2)	199,905	116,558	125,758	137,632	82,847
Amortization of acquired intangible assets	58,153	38,428	41,852	25,355	
Restructuring(3)			12,300		
Impairment of long-lived assets(4)			3,346	45,800	
<b>Total expenses</b>	<b>705,933</b>	<b>417,417</b>	<b>493,735</b>	<b>478,258</b>	<b>232,271</b>
<b>OPERATING (LOSS) INCOME</b>	<b>(87,144)</b>	<b>15,494</b>	<b>81,813</b>	<b>(88,281)</b>	<b>(45,631)</b>
<b>OTHER INCOME (EXPENSE), NET</b>	<b>73,115</b>	<b>(10,097)</b>	<b>(46,372)</b>	<b>(26,111)</b>	<b>(860)</b>
<b>(LOSS) INCOME BEFORE INCOME TAXES</b>	<b>(14,029)</b>	<b>5,397</b>	<b>35,441</b>	<b>(114,392)</b>	<b>(46,491)</b>
<b>PROVISION (BENEFIT) FOR INCOME TAXES</b>	<b>16,032</b>	<b>(12,252)</b>	<b>10,458</b>	<b>(714)</b>	<b>(951)</b>
<b>NET (LOSS) INCOME</b>	<b>\$ (30,061)</b>	<b>\$ 17,649</b>	<b>\$ 24,983</b>	<b>\$ (113,678)</b>	<b>\$ (45,540)</b>
<b>(LOSS) EARNINGS PER COMMON SHARE:</b>					
<b>BASIC</b>	<b>\$ (0.21)</b>	<b>\$ 0.13</b>	<b>\$ 0.19</b>	<b>\$ (0.99)</b>	<b>\$ (0.48)</b>
<b>DILUTED</b>	<b>\$ (0.21)</b>	<b>\$ 0.12</b>	<b>\$ 0.18</b>	<b>\$ (0.99)</b>	<b>\$ (0.48)</b>
<b>WEIGHTED AVERAGE NUMBER OF COMMON SHARES OUTSTANDING:</b>					
<b>BASIC</b>	145,274	135,960	131,713	114,702	95,610
<b>DILUTED</b>	145,274	144,961	137,100	114,702	95,610

**Consolidated Balance Sheet Data:**

Cash, cash equivalents and investments	\$	801,646	\$	449,995	\$	304,179	\$	246,138	\$	294,730
Total assets		1,921,272		1,577,588		1,470,291		1,435,217		452,448
Long-term debt		357,970		364,293		369,008		444,460		
Shareholders' equity		1,396,837		1,065,186		952,374		853,852		392,018

---

(1)

On September 16, 2011, the businesses of Alkermes, Inc., and EDT were combined under Alkermes plc. We paid Elan \$500.0 million in cash and issued Elan 31.9 million ordinary shares of Alkermes plc, which had a fair value of approximately \$525.1 million on the closing date, for the

Table of Contents

EDT business. Alkermes, Inc.'s results are included for all periods being presented, whereas the results of the acquiree, EDT, are included only after the date of acquisition, September 16, 2011, through the end of the period.

- (2) 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.
- (3) Represents a one-time charge in connection with the restructuring plan related to our Athlone, Ireland manufacturing facility recorded in the year ended March 31, 2013. The charge consists of severance payments and other employee-related expenses.
- (4) Includes an impairment charge of \$3.3 million related to the impairment of certain of our equipment located at our Wilmington, Ohio manufacturing facility in the year ended March 31, 2013, and an impairment charge of \$45.8 million related to the impairment of certain of our in-process R&D ("IPR&D") in 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 "Item 1A Risk Factors" and elsewhere in this Annual Report.

On September 16, 2011, the businesses of Alkermes, Inc. and EDT were combined under the Business Combination in a transaction accounted for as a reverse acquisition with Alkermes, Inc. treated as the accounting acquirer. As a result, the operating results of the acquiree, EDT, are included only after the date of acquisition, September 16, 2011. Prior to September 16, 2011, the operating results are that of Alkermes, Inc.

On May 21, 2013, our Audit and Risk Committee, with such authority delegated to it by our Board of Directors, approved a change to our fiscal year-end from March 31 to December 31 of each year. This Annual Report reflects our financial results for the twelve month period from January 1, 2014 through December 31, 2014. The period ended December 31, 2013 reflects our financial results for the nine month period from April 1, 2013 through December 31, 2013. The period ended March 31, 2013 reflects our financial results for the twelve month period from April 1, 2012 to March 31, 2013.

**Overview**

We develop medicines that address the unmet needs and challenges of people living with chronic diseases. 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.

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 key marketed products are expected to generate significant revenues for us in the near- and medium-term, as they possess long remaining patent lives and we believe are singular or competitively advantaged products in their classes and are generally in the launch phases of their commercial lives. These key marketed products consist

Table of Contents

of our antipsychotic franchise, RISPERDAL CONSTA and INVEGA SUSTENNA/XEPLION; AMPYRA/FAMPYRA; BYDUREON; and VIVITROL. Revenues from these products accounted for 74% of our total revenues during the year ended December 31, 2014, as compared to 68% and 59% during the years ended December 31, 2013 and 2012, respectively.

During the year ended December 31, 2014, we incurred an operating loss of \$87.1 million. Although revenues increased by \$22.5 million from the year ended December 31, 2013, we made significant investments in R&D and SG&A during the year. R&D expense increased by \$108.1 million from the year ended December 31, 2013, driven by our rapidly advancing development pipeline. In 2014, we initiated pivotal clinical development programs for ALKS 5461 and informative studies for ALKS 3831, ALKS 8700 and ALKS 7106. SG&A expense increased by \$48.7 million, driven primarily by pre-launch activities for aripiprazole lauroxil, as the FDA accepted the NDA for aripiprazole lauroxil in October 2014 and assigned a PDUFA date of August 22, 2015.

During the year ended December 31, 2014, we recorded income of \$86.8 million from certain non-recurring, non-operating transactions. In October 2014, Acorda acquired Civitas for approximately \$525.0 million. In connection with the acquisition of Civitas by Acorda, we received \$30.0 million for the sale of certain commercial-scale pulmonary manufacturing equipment used by Civitas. We also received \$27.2 million and have the right to receive up to an additional \$2.4 million, subject to the release of all amounts held in escrow, for our approximate 6% equity interest in Civitas. In the second quarter of 2014, we sold our investment in Acceleron, which consisted of equity securities, resulting in a realized gain of \$15.3 million and sold certain of our land, buildings and equipment at our Athlone, Ireland facility resulting in a gain of \$12.3 million at the time of the sale.

**Results of Operations****Year Ended December 31, 2014 and 2013*****Manufacturing and Royalty Revenues***

Manufacturing revenues are earned from the sale of products under arrangements with our collaborators when product is shipped to them at an agreed upon price. Royalties are generally earned on our collaborators' sales of products that incorporate our technologies and are recognized in the period the products are sold by our collaborators. The following table compares manufacturing and royalty revenues earned in the year ended December 31, 2014 and 2013:

(In millions)	Year Ended December 31,		Change Favorable/ (Unfavorable)
	2014	2013 (unaudited)	
Manufacturing and royalty revenues:			
INVEGA SUSTENNA/XEPLION	\$ 127.8	\$ 97.7	\$ 30.1
RISPERDAL CONSTA	120.6	137.9	(17.3)
AMPYRA/FAMPYRA	80.9	75.7	5.2
RITALIN LA/FOCALIN XR	40.7	41.6	(0.9)
BYDUREON	36.6	24.8	11.8
Other	110.3	140.3	(30.0)
Manufacturing and royalty revenues	\$ 516.9	\$ 518.0	\$ (1.1)

Our long-acting, antipsychotic franchise consists of RISPERDAL CONSTA and INVEGA SUSTENNA/XEPLION. Under our INVEGA SUSTENNA/XEPLION agreement with Janssen, we earn royalties on end-market sales of INVEGA SUSTENNA/XEPLION of 5% up to the first \$250 million in calendar-year sales, 7% on calendar-year sales of between \$250 million and \$500 million, and 9% on calendar-year sales exceeding \$500 million. The royalty rate resets at the

Table of Contents

beginning of each calendar-year to 5%. Under our RISPERDAL CONSTA supply and license agreements with Janssen, we earn manufacturing revenues at 7.5% of Janssen's unit net sales price of RISPERDAL CONSTA and royalty revenues at 2.5% of end-market sales.

The increase in INVEGA SUSTENNA/XEPLION royalty revenues was due to an increase in Janssen's end-market sales of INVEGA SUSTENNA/XEPLION. Janssen's end-market sales of INVEGA SUSTENNA/XEPLION were \$1,588.0 million and \$1,248.0 million, during the years ended December 31, 2014 and 2013, respectively.

The decrease in RISPERDAL CONSTA revenue was due to a 13% decrease in manufacturing revenues and a 10% decrease in royalty revenues. The decrease in manufacturing revenues was primarily due to a 39% decrease in units shipped to Janssen for resale in the U.S., partially offset by an 8% increase in price and a 5% increase in units shipped to Janssen for resale in countries other than the U.S., partially offset by a 4% decrease in price. Janssen's end-market sales of RISPERDAL CONSTA were \$1,190.0 million and \$1,318.0 million, during the years ended December 31, 2014 and 2013, respectively.

We expect revenues from 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 2022 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.

Under our AMPYRA supply and license agreements with Acorda, we earn manufacturing and royalty revenues when AMPYRA is shipped to Acorda, either by us or a third-party manufacturer. Under our FAMPYRA supply and license agreements with Biogen, we earn manufacturing revenue when FAMPYRA is shipped to Biogen, and we earn royalties upon end-market sales of FAMPYRA by Biogen.

The increase in AMPYRA/FAMPYRA revenue was due to an 11% increase in royalty revenue and a 6% increase in manufacturing revenue. The increase in royalty revenue was primarily due to a 77% increase in the amount of royalty earned on third-party shipments of AMPYRA to Acorda. The increase in manufacturing revenue was primarily due to an 18% increase in the selling price of AMPYRA/FAMPYRA, partially offset by a 13% decrease in the amount of AMPYRA/FAMPYRA shipped to Acorda and Biogen.

We expect AMPYRA/FAMPYRA sales to continue to grow as Acorda continues to penetrate the U.S. market with AMPYRA and Biogen 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.

The increase in BYDUREON revenues was due to an increase in end-market sales of BYDUREON. During the year ended December 31, 2014, AstraZeneca's end-market sales of BYDUREON was \$457.3 million, as compared to \$311.5 million sold under the Bristol-Myers and AstraZeneca diabetes collaboration in the year ended December 31, 2013. BYDUREON is covered by a patent until 2025 in the U.S. and until 2024 in the EU, and as such, we do not anticipate any generic versions of this product in the near-term.

Table of Contents

Included in other manufacturing and royalty revenues during the year ended December 31, 2013 was \$30.0 million of IP license revenue unrelated to key development programs.

We expect sales from RITALIN LA/FOCALIN XR and our other mature products to decline over the next few fiscal years due to competition from generic products.

Certain of our manufacturing and royalty revenues are earned in countries outside of the U.S. and are denominated in currencies in which the product is sold. See "Item 7A. Quantitative and Qualitative Disclosures about Market Risk" for information on currency exchange rate risk related to our revenues.

**Product Sales, Net**

Our product sales, net 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 December 31, 2014 and 2013:

(In millions)	Year Ended December 31, 2014		Year Ended December 31, 2013 (unaudited)	
	Amount	% of Sales	Amount	% of Sales
Product sales, gross	\$ 137.1	100.0 %	\$ 99.4	100.0 %
Adjustments to product sales, gross:				
Medicaid rebates	(11.1)	(8.1)%	(7.0)	(7.1)%
Chargebacks	(9.3)	(6.8)%	(6.5)	(6.5)%
Product discounts	(7.2)	(5.3)%	(4.5)	(4.5)%
Co-pay assistance	(6.1)	(4.4)%	(4.6)	(4.7)%
Product returns	(3.0)	(2.2)%	(1.1)	(1.1)%
Other	(6.2)	(4.5)%	(3.9)	(3.9)%
Total adjustments	(42.9)	(31.3)%	(27.6)	(27.8)%
Product sales, net	\$ 94.2	68.7 %	\$ 71.8	(72.2)%

The increase in product sales, gross was due to a 32% increase in the number of units sold and a 5% increase in price. The increase in Medicaid rebates, chargebacks, product discounts and co-pay assistance were all primarily due to the increase in gross sales. The increase in product returns as a percentage of gross sales was due to the increase in the price of VIVITROL. Included in other adjustments is a \$1.4 million charge in the first quarter of 2014 related to a limited recall for a needle clog issue.

We expect VIVITROL sales, net to continue to grow as we continue to penetrate the opioid dependence indication market in the U.S. A number of companies, including us, are working to develop products to treat addiction, including alcohol and opioid dependence that may compete with and 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.

Table of Contents**Costs and Expenses*****Cost of Goods Manufactured and Sold***

(In millions)	Year Ended December 31,		
	2014	2013 (unaudited)	Change Favorable/ (Unfavorable)
Cost of goods manufactured and sold	\$ 175.8	\$ 182.3	\$ 6.5

The decrease in cost of goods manufactured and sold was primarily due to an \$8.5 million decrease in cost of goods manufactured for RISPERDAL CONSTA, which primarily due to a 5% decrease in the number of units shipped to Janssen. This decrease was partially offset by a \$3.2 million increase in the cost of goods manufactured and sold for VIVITROL, which was primarily due to a 17% increase in the number of units sold in the U.S. and Russia and the CIS.

***Research and Development Expenses***

For each of our R&D programs, we incur both external and internal expenses. External R&D expenses include costs related to clinical and non-clinical activities performed by CROs, consulting fees, laboratory services, purchases of drug product materials and third-party manufacturing development costs. Internal R&D expenses include employee-related expenses, occupancy costs, depreciation and general overhead. We track external R&D expenses for each of our development programs, however, internal R&D expenses are not tracked by individual program as they benefit multiple programs or our technologies in general.

The following table sets forth our external R&D expenses relating to our individual Key Development Programs and all other development programs, and our internal R&D expenses by the nature of such expenses:

(In millions)	Year Ended December 31,		
	2014	2013 (unaudited)	Change Favorable/ (Unfavorable)
External R&D Expenses:			
Key development programs:			
ALKS 5461	\$ 77.1	\$ 8.4	\$ (68.7)
Aripiprazole lauroxil	30.9	45.1	14.2
ALKS 3831	28.8	7.6	(21.2)
ALKS 8700	10.1	2.6	(7.5)
ALKS 7106	6.6	2.5	(4.1)
Other development programs	18.4	15.8	(2.6)
<b>Total external expenses</b>	<b>171.9</b>	<b>82.0</b>	<b>(89.9)</b>
Internal R&D expenses:			
Employee-related	75.7	57.9	(17.8)
Occupancy	6.9	11.1	4.2
Depreciation	8.2	7.6	(0.6)
Other	9.3	5.3	(4.0)
<b>Total internal R&amp;D expenses</b>	<b>100.1</b>	<b>81.9</b>	<b>(18.2)</b>
Research and development expenses	\$ 272.0	\$ 163.9	\$ (108.1)





Table of Contents

The decrease in R&D expenses related to the aripiprazole lauroxil program was primarily due to the completion of our phase 3 study in April 2014 and the submission of our NDA in August 2014. This decrease was partially offset by the continuation of an extension study which began in September 2013 to assess the long-term safety and durability effect of aripiprazole lauroxil in patients with stable schizophrenia. The increase in expenses related to the ALKS 5461 program was due to the timing of three core phase 3 efficacy studies, long-term safety studies and other supporting studies related to the program. The increase in expenses related to the ALKS 3831 program was due to the timing of studies related to the program. We completed a phase 2 study of ALKS 3831 to assess the safety, tolerability and impact of ALKS 3831 on weight gain and other metabolic factors in patients with schizophrenia and announced positive topline results in January 2015. ALKS 8700 and ALKS 7106 were added to our key development program portfolio in 2013 and we initiated phase 1 studies for these programs in July 2014 and August 2014, respectively. The increase in employee-related expenses is primarily due to an increase in headcount and share-based compensation expense. Expense incurred under the RDB 1419 program was not material in the years ended December 31, 2014 and 2013.

These amounts are not necessarily predictive of future R&D expenses. In an effort to allocate our spending most effectively, we continually evaluate the products under development, based on the performance of such products in pre-clinical and/or clinical trials, our expectations regarding the likelihood of their regulatory approval and our view of their commercial viability, among other factors.

***Selling, General and Administrative Expenses***

(In millions)	Year Ended December 31,		Change Favorable/ (Unfavorable)
	2014	2013 (unaudited)	
Selling, general and administrative	\$ 199.9	\$ 151.2	\$ (48.7)

The increase in SG&A expenses was primarily due to a \$22.4 million increase in employee-related expenses, a \$15.9 million increase in professional services and a \$5.0 million increase in marketing expense. The increase in employee-related expense was primarily due to an increase in share-based compensation expense resulting from our increased stock price and an increase in headcount. The increase in professional services was primarily due to activities surrounding the anticipated launch of aripiprazole lauroxil in 2015. The increase in marketing expense was primarily due to activity around a label update for VIVITROL and aripiprazole lauroxil pre-launch activity.

***Amortization of Acquired Intangible Assets***

(In millions)	Year Ended December 31,		Change Favorable/ (Unfavorable)
	2014	2013 (unaudited)	
Amortization of acquired intangible assets	\$ 58.2	\$ 48.8	\$ (9.4)

Our amortizable intangible assets consist of technology and collaborative arrangements acquired as part of the acquisition of EDT in September 2011 which are being 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. Based on our most recent analysis, amortization of intangible assets included within our consolidated balance sheet at December 31, 2014 is expected to be approximately \$65.0 million, \$70.0 million, \$70.0 million, \$70.0 million and \$60.0 million in the years ended December 31, 2015 through 2019, respectively.

Table of Contents**Other Income (Expense), Net**

(In millions)	Year Ended December 31,		Change Favorable/ (Unfavorable)
	2014	2013 (unaudited)	
Interest income	\$ 2.0	\$ 0.9	\$ 1.1
Interest expense	(13.4)	(21.9)	8.5
Gain on sale of property, plant and equipment	41.9		41.9
Gain on sale of investment in Civitas Therapeutics, Inc.	29.6		29.6
Gain on sale of investment in Acceleron Pharma Inc.	15.3		15.3
Other (expense), net	(2.3)	(0.2)	(2.1)
<b>Total other income (expense), net</b>	<b>\$ 73.1</b>	<b>\$ (21.2)</b>	<b>\$ 94.3</b>

The decrease in interest expense in the year ended December 31, 2014, as compared to the year ended December 31, 2013, was primarily due to an amendment of our long-term debt in February 2013, which resulted in a \$7.5 million charge to interest expense during the year ended December 31, 2013.

The increase in the gain on the sale of property, plant and equipment was primarily due to two transactions. In April 2014, we sold certain of our land, buildings and equipment at our Athlone, Ireland facility that had a carrying value of \$2.2 million, in exchange for \$17.5 million and recorded a gain of \$12.3 million, as \$3.0 million of the sale proceeds were placed in escrow pending the completion of certain additional services we are obligated to perform. In October 2014, we sold certain of our commercial-scale pulmonary manufacturing equipment to Acorda in exchange for \$30.0 million.

In October 2014, in connection with the acquisition of Civitas by Acorda, we received \$27.2 million and have the right to receive up to an additional \$2.4 million, subject to the release of amounts held in escrow, for our approximate 6% equity interest in Civitas. During the second quarter of 2014, we sold our investment in Acceleron, which consisted of equity securities, for a gain of \$15.3 million.

**Provision (Benefit) for Income Taxes**

(In millions)	Year Ended December 31,		Change Favorable/ (Unfavorable)
	2014	2013 (unaudited)	
Provision (benefit) for income taxes	\$ 16.0	\$ (7.4)	\$ (23.4)

The income tax provision for the year ended December 31, 2014 was primarily due to U.S. federal and state taxes on income earned in the U.S. The income tax benefit in the year ended December 31, 2013 was primarily due to the release of the valuation allowance held against U.S. deferred tax assets, partially offset by federal and state taxes on income earned in the U.S.

At December 31, 2014, we maintained a valuation allowance of \$1.7 million against certain U.S. federal and state deferred tax assets and \$70.1 million against certain Irish deferred tax assets as we determined that it is more-likely-than-not that these net deferred tax assets will not be realized. If we demonstrate consistent profitability in the future, the evaluation of the recoverability of these deferred tax assets may change and the remaining valuation allowance may be released in part or in whole.

Table of Contents

As of December 31, 2014, we had \$574.4 million of Irish Net Operating Loss ("NOL") carryforwards, \$23.9 million of U.S. federal NOL carryforwards and \$8.3 million of U.S. state NOL carryforwards, \$33.8 million of federal R&D credits, \$8.6 million of alternative minimum tax credits and \$4.3 million of U.S. state tax credits which either expire on various dates through 2034 or can be carried forward indefinitely. These loss carryforwards and credits are available to reduce certain future Irish and U.S. taxable income and tax, respectively, 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 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.

**Nine Months Ended December 31, 2013 and 2012*****Manufacturing and Royalty Revenues***

The following table compares manufacturing and royalty revenues earned in the nine months ended December 31, 2013 and 2012:

(In millions)	Nine Months Ended December 31,		Change Favorable/ (Unfavorable)
	2013	2012 (unaudited)	
Manufacturing and royalty revenues:			
RISPERDAL CONSTA	\$ 107.2	\$ 102.9	\$ 4.3
INVEGA SUSTENNA/XEPLION	82.9	48.6	34.3
AMPYRA/FAMPYRA	51.1	40.5	10.6
RITALIN LA & FOCALIN XR	31.1	29.7	1.4
BYDUREON	20.0	11.6	8.4
TRICOR 145	10.6	31.3	(20.7)
IP License revenue		20.0	(20.0)
Other	68.1	79.4	(11.3)
Manufacturing and royalty revenues	\$ 371.0	\$ 364.0	\$ 7.0

The increase in RISPERDAL CONSTA manufacturing and royalty revenues was primarily due to a 9% increase in the number of units shipped to Janssen, partially offset by a 7% decrease in royalties. The decrease in royalties was due to a decrease in Janssen's end-market sales of RISPERDAL CONSTA from \$1,064.0 million during the nine months ended December 31, 2012 to \$981.0 million during the nine months ended December 31, 2013. The increase in royalty revenues from INVEGA SUSTENNA/XEPLION was due to an increase in Janssen's end-market sales of INVEGA SUSTENNA/XEPLION from \$636.0 million in the nine months ended December 31, 2012 to \$966.0 million in the nine months ended December 31, 2013.

The increase in revenue from AMPYRA/FAMPYRA was primarily due to a 69% increase in the amount of AMPYRA shipped to Acorda and a 22% increase in our estimate of Biogen's end-market sales of FAMPYRA, partially offset by a 26% decrease in royalties earned from a decrease in third-party manufacturing of AMPYRA.

The increase in BYDUREON royalty revenues was due to an increase in end-market sales of BYDUREON from \$145.7 million during the nine months ended December 31, 2012 to \$242.1 million during the nine months ended December 31, 2013. BYDUREON is covered by a patent until 2025 in

Table of Contents

the U.S. and until 2024 in the EU, and as such, we do not anticipate any generic versions of this product in the near-term.

The decrease in revenue from TRICOR 145 was due to generic competition. Other manufacturing and royalty revenue in the nine months ended December 31, 2012 included \$20.0 million for the sale of a license to certain of our intellectual property that were not used in our key clinical development programs or commercial products.

**Product Sales, Net**

The following table presents the adjustments to arrive at VIVITROL product sales, net for sales of VIVITROL in the U.S. during the nine months ended December 31, 2013 and 2012:

(In millions)	Nine Months Ended December 31, 2013		Nine Months Ended December 31, 2012 (unaudited)	
	Amount	% of Sales	Amount	% of Sales
Product sales, gross	\$ 79.1	100.0%	\$ 58.2	100.0%
Adjustments to product sales, gross:				
Medicaid rebates	(5.5)	(7.0)%	(4.3)	(7.4)%
Chargebacks	(5.2)	(6.6)%	(4.1)	(7.0)%
Product discounts	(3.7)	(4.7)%	(2.0)	(3.4)%
Co-pay assistance	(3.7)	(4.7)%	(2.3)	(4.0)%
Product returns <sup>(1)</sup>	(0.9)	(1.1)%	0.4	0.7%
Other	(2.9)	(3.6)%	(2.4)	(4.2)%
<b>Total adjustments</b>	<b>(21.9)</b>	<b>(27.7)%</b>	<b>(14.7)</b>	<b>(25.3)%</b>
Product sales, net	\$ 57.2	72.3%	\$ 43.5	74.7%

(1) Prior to August 1, 2012, product returns was a reserve for inventory in the channel; an estimate to defer the recognition of revenue on shipments of VIVITROL to our customers until the product left the distribution channel as we did not have the history to reasonably estimate returns related to these shipments. Beginning on August 1, 2012, we changed the method of revenue recognition to recognize revenue upon delivery to our customers and provide for a reserve for future returns. This change in the method of revenue recognition resulted in a one-time \$1.7 million increase to product sales, net, which was recognized during the three months ended September 30, 2012.

The increase in product sales, gross was due to a 37% increase in the number of units sold.

**Costs and Expenses**

**Cost of Goods Manufactured and Sold**

(In millions)	Nine Months Ended December 31,		Change Favorable/ (Unfavorable)
	2013	2012 (unaudited)	
Cost of goods manufactured and sold	\$ 134.3	\$ 122.5	\$ (11.8)

## Edgar Filing: Alkermes plc. - Form 10-K

The increase in cost of goods manufactured and sold was primarily due to a \$6.2 million increase in cost of goods manufactured for RISPERDAL CONSTA and a \$4.5 million increase in depreciation at our Athlone, Ireland manufacturing facility. The increase in RISPERDAL CONSTA cost of goods manufactured was primarily due to the 9% increase in the number of units shipped to Janssen. The increase in depreciation expense at our Athlone, Ireland manufacturing facility was due to \$5.4 million

Table of Contents

of accelerated depreciation on certain of our manufacturing assets that will have no future use at the completion of our restructuring plan in the year ending December 31, 2015.

**Research and Development Expenses**

The following table sets forth our external R&D expenses related to our individual Key Development Programs and all other development programs, and our internal R&D expenses by the nature of such expenses:

(In millions)	Nine Months Ended December 31,		Change Favorable/ (Unfavorable)
	2013	2012 (unaudited)	
<b>External R&amp;D Expenses:</b>			
<b>Key development programs:</b>			
Aripiprazole lauroxil	\$ 34.9	\$ 30.1	\$ (4.8)
ALKS 3831	7.6		(7.6)
ALKS 5461	6.1	6.1	
ALKS 8700	2.6		(2.6)
ALKS 7106	2.5		(2.5)
ALKS 37		3.5	3.5
Other development programs	11.3	10.8	(0.5)
<b>Total external expenses</b>	<b>65.0</b>	<b>50.5</b>	<b>(14.5)</b>
<b>Internal R&amp;D expenses:</b>			
Employee-related	44.1	38.6	(5.5)
Occupancy	6.8	3.7	(3.1)
Depreciation	6.1	4.3	(1.8)
Other	6.1	7.1	1.0
<b>Total internal R&amp;D expenses</b>	<b>63.1</b>	<b>53.7</b>	<b>(9.4)</b>
<b>Research and development expenses</b>	<b>\$ 128.1</b>	<b>\$ 104.2</b>	<b>\$ (23.9)</b>

The increase in R&D expenses related to the aripiprazole lauroxil program was primarily due to the timing of patient enrollments in our phase 3 study, which began in December 2011, and the start of an extension study in September 2013 to assess the long-term safety and durability of effect of aripiprazole lauroxil in patients with stable schizophrenia. The increase in expenses related to the ALKS 3831 program was due to the timing of studies related to the program. We announced positive topline results from a phase 1 study in January 2013, and in July 2013, we announced the initiation of a phase 2 study of ALKS 3831 to assess the safety, tolerability and impact of ALKS 3831 on weight gain and other metabolic factors in patients with schizophrenia. The decrease in R&D expenses related to the ALKS 37 program was due to the decision in May 2012 not to advance ALKS 37 after the results from the phase 2b multicenter, randomized, double-blind, placebo-controlled, repeat-dose study did not satisfy our pre-specified criteria for advancing into phase 3 clinical trials. ALKS 8700 and ALKS 7106 were added to our key development program portfolio during the period and we plan to file an IND and initiate phase 1 studies for both programs in 2014. The increase in employee-related expenses is primarily due to an increase in headcount and share-based compensation expense. Expense incurred under the RDB 1419 program was not material in the nine months ended December 31, 2013 and 2012.

Table of Contents*Selling, General and Administrative Expenses*

(In millions)	Nine Months Ended December 31,		Change Favorable/ (Unfavorable)
	2013	2012 (unaudited)	
Selling, general and administrative	\$ 116.6	\$ 91.1	\$ (25.5)

The increase in SG&A expenses was primarily due to an \$11.7 million increase in employee-related expenses, a \$5.9 million increase in professional services and a \$5.3 million increase in marketing expense. The increase in employee-related expense was primarily due to an increase in share-based compensation expense as a result of our increased stock price and an increase in headcount. The increase in professional services was primarily due to activities surrounding the anticipated launch of aripiprazole lauroxil in 2015. The increase in marketing expense was primarily due to activity around a label update for VIVITROL and aripiprazole lauroxil launch activity.

*Amortization of Acquired Intangible Assets*

(In millions)	Nine Months Ended December 31,		Change Favorable/ (Unfavorable)
	2013	2012 (unaudited)	
Amortization of acquired intangible assets	\$ 38.4	\$ 31.5	\$ (6.9)

Our amortizable intangible assets consist of technology and collaborative arrangements acquired as part of the acquisition of EDT in 2011 which are being 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.

*Other Expense, Net*

(In millions)	Nine Months Ended December 31,		Change Favorable/ (Unfavorable)
	2013	2012 (unaudited)	
Interest income	\$ 0.7	\$ 0.6	\$ 0.1
Interest expense	(10.4)	(37.5)	27.1
Other (expense) income, net	(0.4)	1.6	(2.0)
Total other expense, net	\$ (10.1)	\$ (35.3)	\$ 25.2

The decrease in interest expense was due to a decrease in the principal amount and interest rates associated with our long-term debt. As a result of two refinancing transactions we completed during the year ended March 31, 2013, we reduced our outstanding principal balance from \$450.0 million to \$375.0 million, and reduced our blended interest rate from 7.6% to 3.4%. Included in interest expense in the nine months ended December 31, 2012 was a charge of \$12.2 million due to the accounting for the restructuring of our long-term debt.



Table of Contents***(Benefit) Provision for Income Taxes***

(In millions)	Nine Months Ended December 31,		Change Favorable/ (Unfavorable)
	2013	2012 (unaudited)	
(Benefit) provision for income taxes	\$ (12.3)	\$ 5.6	\$ 17.9

The income tax benefit in the nine months ended December 31, 2013 was due to the release of a valuation allowance against substantially all of our U.S. federal and state deferred tax assets, partially offset by current tax expense on income earned in the U.S. During the last quarter of 2013, we performed an analysis and determined that it was more-likely-than-not that we would utilize these deferred tax assets in future periods. Income tax expense in the nine months ended December 31, 2012 primarily related to U.S. federal and state taxes on income earned in the U.S.

**Year Ended March 31, 2013 and 2012*****Manufacturing and Royalty Revenues***

The following table compares manufacturing and royalty revenues earned in the years ended March 31, 2013 and 2012:

(In millions)	Year Ended March 31,		Change Favorable/ (Unfavorable)
	2013	2012	
Manufacturing and royalty revenues:			
RISPERDAL CONSTA	\$ 133.6	\$ 168.3	\$ (34.7)
INVEGA SUSTENNA/XEPLION	63.5	18.0	45.5
AMPYRA/FAMPYRA	65.0	24.6	40.4
RITALIN LA & FOCALIN XR	40.3	23.1	17.2
TRICOR 145	37.5	27.8	9.7
VERELAN	23.8	14.2	9.6
BYDUREON	16.4	1.5	14.9
IP License revenue	50.0		50.0
Other	80.8	48.9	31.9
Manufacturing and royalty revenues	\$ 510.9	\$ 326.4	\$ 184.5

The decrease in RISPERDAL CONSTA manufacturing and royalty revenues was primarily due to a 24% decrease in the number of units shipped to Janssen and a 9% decrease in royalties. The decrease in royalties was due to a decrease in Janssen's end-market sales of RISPERDAL CONSTA from \$1,540.3 million during the year ended March 31, 2012 to \$1,399.1 million during the year ended March 31, 2013. The increase in royalties from INVEGA SUSTENNA/XEPLION was due to having a full twelve months of INVEGA SUSTENNA/ROYALTIES in the year ended March 31, 2013 and an increase in end-market sales of the product. Janssen's end-market sales of INVEGA SUSTENNA/XEPLION increased from \$473.6 million in the year ended March 31, 2012 to \$920.0 million in the year ended March 31, 2013.

The increase in royalty revenues from AMPYRA/FAMPYRA was due to having a full twelve months of AMPYRA/FAMPYRA royalties in the year ended March 31, 2013, an increase in demand for AMPYRA in the U.S. and an increase in the number of countries in which FAMPYRA was sold. Acorda's end-market sales of AMPYRA/FAMPYRA in the years ended March 31, 2013 and 2012 were \$329.4 million and \$249.7 million, respectively.

## Edgar Filing: Alkermes plc. - Form 10-K

### Table of Contents

The increase in royalty revenues from RITALIN LA & FOCALIN XR, TRICOR 145 and VERELAN and the other manufacturing and royalty revenues was primarily due to the addition of the portfolio of commercialized products from the former EDT business. During the year ended March 31, 2013, we sold a license to certain of our intellectual property that was not used in our key clinical development programs or commercial products for \$50.0 million.

### *Product Sales, Net*

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, 2013 and 2012:

(In millions)	Year Ended March 31, 2013		Year Ended March 31, 2012	
	Amount	% of Sales	Amount	% of Sales
Product sales, gross	\$ 78.5	100.0%	\$ 57.6	100.0%
Adjustments to product sales, gross:				
Medicaid rebates	(5.9)	(7.5)%	(4.6)	(8.0)%
Chargebacks	(5.4)	(6.9)%	(4.1)	(7.1)%
Product returns(1)	0.2	0.3%	(1.3)	(2.3)%
Co-pay assistance	(3.2)	(4.1)%	(1.6)	(2.8)%
Other	(6.1)	(7.8)%	(4.8)	(8.3)%
Total adjustments	(20.4)	(26.0)%	(16.4)	(28.5)%
Product sales, net	\$ 58.1	74.0%	\$ 41.2	71.5%

(1)

Prior to August 1, 2012, product returns was a reserve for inventory in the channel; an estimate to defer the recognition of revenue on shipments of VIVITROL to our customers until the product left the distribution channel as we did not have the history to reasonably estimate returns related to these shipments. Beginning on August 1, 2012, we changed the method of revenue recognition to recognize revenue upon delivery to our customers and provide for a reserve for future returns. This change in the method of revenue recognition resulted in a one-time \$1.7 million increase to product sales, net, which was recognized during the three months ended September 30, 2012.

The increase in product sales, gross was due to a 36% increase in the number of units sold. The increase in Medicaid rebates and chargebacks was primarily due to the increase in VIVITROL sales during the period.

### *Research and Development Revenue*

(In millions)	Year Ended March 31,		Change Favorable/ (Unfavorable)
	2013	2012	
Research and development revenue	\$ 6.5	\$ 22.3	\$ (15.8)

The decrease in R&D revenue was primarily due to \$14.0 million in BYDUREON milestone payments we received during the year ended March 31, 2012. Under our agreement with Amylin, we received a \$7.0 million milestone payment related to the first commercial sale of BYDUREON in the EU in July 2011 and a \$7.0 million milestone payment related to the first commercial sale of BYDUREON in the U.S. in February 2012. 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.



Table of Contents**Costs and Expenses*****Cost of Goods Manufactured and Sold***

(In millions)	Year Ended March 31,		Change Favorable/ (Unfavorable)
	2013	2012	
Cost of goods manufactured and sold	\$ 170.5	\$ 127.6	\$ (42.9)

The increase in cost of goods manufactured and sold was primarily due to an increase of \$48.5 million in cost of goods manufactured from the EDT portfolio of commercialized products and a \$4.2 million increase in VIVITROL cost of goods manufactured and sold, partially offset by a \$10.4 million decrease in RISPERDAL CONSTA cost of goods manufactured. The increase in cost of goods manufactured from the EDT portfolio of commercialized products was primarily due to having a full twelve months of cost of goods manufactured in the year ended March 31, 2013. The increase in VIVITROL cost of goods manufactured and sold was due to a 25% increase in the amount of VIVITROL sold in the U.S. and shipped to Russia for resale by Cilag. The decrease in RISPERDAL CONSTA cost of goods manufactured was due to a 24% decrease in the amount of RISPERDAL CONSTA shipped to Janssen.

***Research and Development Expenses***

The following table sets forth our external R&D expenses relating to our individual Key Development Programs and all other development programs, and our internal R&D expenses by the nature of such expenses:

(In millions)	Year Ended March 31,		Change Favorable/ (Unfavorable)
	2013	2012	
<b>External R&amp;D Expenses:</b>			
Key development programs:			
Aripiprazole lauroxil	\$ 40.2	\$ 21.8	\$ (18.4)
ALKS 5461	8.3		(8.3)
ALKS 37	3.4	23.5	20.1
ALKS 3831	2.9		(2.9)
Other development programs	12.7	26.6	13.9
Total external expenses	67.5	71.9	4.4
<b>Internal R&amp;D expenses:</b>			
Employee-related	52.9	48.3	(4.6)
Occupancy	5.0	5.1	0.1
Depreciation	5.8	4.7	(1.1)
Other	8.8	11.9	3.1
Total internal R&D expenses	72.5	70.0	(2.5)
Research and development expenses	\$ 140.0	\$ 141.9	\$ 1.9

The increase in R&D expenses related to the aripiprazole lauroxil program was primarily due to the continuation of the phase 3 study, initiated in December 2011, to assess the efficacy, safety and tolerability of aripiprazole lauroxil in patients experiencing acute exacerbation of schizophrenia. The increase in R&D expenses related to the ALKS 5461 program was primarily due to the phase 2 study of ALKS 5461, initiated in January 2012, to evaluate the efficacy and safety of ALKS 5461 in patients with MDD. The decrease in R&D expenses related to the ALKS 37 program was due to the decision



Table of Contents

in May 2012 not to advance ALKS 37 after the results from the phase 2b multicenter, randomized, double-blind, placebo-controlled, repeat-dose study did not satisfy our pre-specified criteria for advancing into phase 3 clinical trials. The increase in total internal R&D expenses is primarily due to the addition of the former EDT business in September 2011.

***Selling, General and Administrative Expenses***

(In millions)	Year Ended March 31,		Change Favorable/ (Unfavorable)
	2013	2012	
Selling, general and administrative	\$ 125.8	\$ 137.6	\$ 11.8

The decrease in SG&A expenses was primarily due to a \$26.0 million decrease in professional service expense, partially offset by an \$11.4 million increase in employee-related expenses. The decrease in professional service expense was primarily due to \$29.1 million of costs incurred in connection with the Business Combination during the year ended March 31, 2012. The increase in employee-related expenses was primarily due to having a full twelve months of employee-related expenses from the former EDT business as well as an increase in share-based compensation expense due in part to the increase in the number of eligible participants in our equity plans as a result of the Business Combination, and the fact that equity grants in the year ended March 31, 2013 were awarded with higher grant-date fair values than older grants due to the increase in our stock price.

***Amortization of Acquired Intangible Assets***

(In millions)	Year Ended March 31,		Change Favorable/ (Unfavorable)
	2013	2012	
Amortization of acquired intangible assets	\$ 41.9	\$ 25.4	\$ (16.5)

The increase in amortization of acquired intangible assets was primarily due to having a full twelve months of amortization expense in the year ended March 31, 2013.

***Restructuring***

(In millions)	Year Ended March 31,		Change Favorable/ (Unfavorable)
	2013	2012	
Restructuring	\$ 12.3	\$	\$ (12.3)

On April 4, 2013, we approved a restructuring plan at our Athlone, Ireland manufacturing facility consistent with the evolution of our product portfolio and designed to improve operational performance in the future. The restructuring plan, which is expected to be implemented over a two-year period, calls for us to terminate manufacturing services for certain older products that were expected to no longer be economically practicable to produce due to decreasing demand from our customers resulting from generic competition. We expect to continue to generate revenues for certain of these products into 2015.

As a result of the termination of these services, we expect a corresponding reduction in headcount of up to 130 employees. During the twelve months ended March 31, 2013, we recorded a one-time restructuring charge, expected to be settled in cash payments, consisting solely of severance and other employee-related expenses of \$12.3 million. We expect the restructuring plan will result in annual cost savings of between \$15.0 million and \$20.0 million by 2016 and beyond. As part of the restructuring



Table of Contents

plan, we expect to incur non-cash charges resulting from the acceleration of depreciation of certain of our manufacturing assets of \$7.8 million in 2014.

***Impairment of Long-Lived Assets***

(In millions)	Year Ended March 31,		Change Favorable/ (Unfavorable)
	2013	2012	
Impairment of long-lived assets	\$ 3.3	\$ 45.8	\$ 42.5

During the three months ended March 31, 2013, we performed an impairment analysis on certain of our manufacturing equipment dedicated to the production of VIVITROL. This equipment was originally purchased by Cephalon in connection with our VIVITROL collaboration and later acquired by us upon the termination of the VIVITROL collaboration with Cephalon. We determined that these assets will not be used in the future production of VIVITROL and recorded an impairment charge of \$3.3 million to write the assets down to their fair value. Fair value was determined using level 3 inputs including internally established estimates and the selling prices of similar assets. The manufacturing space previously assigned to VIVITROL is being used for the scale-up of the aripiprazole lauroxil manufacturing line.

During the year ended March 31, 2012, and after finalization of the purchase accounting for the Business Combination, we identified events and changes in circumstances, 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 and consequently recorded an impairment charge of \$45.8 million.

***Other Expense, Net***

(In millions)	Year Ended March 31,		Change Favorable/ (Unfavorable)
	2013	2012	
Interest income	\$ 0.8	\$ 1.5	\$ (0.7)
Interest expense	(49.0)	(28.1)	(20.9)
Other income (expense), net	1.8	0.5	1.3
Total other expense, net	\$ (46.4)	\$ (26.1)	\$ (20.3)



Table of Contents

The increase in interest expense was primarily due to an amendment and restatement, and partial repayment, of existing long-term debt (the "2011 Term Loans") during the year ended March 31, 2013, referred to as the "Refinancing" and "Repricing" transactions. The Refinancing and Repricing transactions were considered a restructuring of our 2011 Term Loans and involved multiple lenders who were considered a part of a loan syndicate. For accounting purposes, certain of the debt restructuring was treated either as an extinguishment or modification of term loan agreements entered into during the year ended March 31, 2012. The treatment of the debt restructuring and the \$19.7 million charge to interest expense in connection with the Refinancing and Repricing is as follows:

(In millions)	September 2012 Refinancing	February 2013 Repricing	Total
Extinguished debt:			
Unamortized deferred financing costs	\$ 4.6	\$ 1.6	\$ 6.2
Unamortized original issue discount	2.7	1.4	4.1
Modified debt:			
Debt financing costs	2.0	0.8	2.8
Original issue discount	0.1		0.1
Prepayment penalty	2.8	3.7	6.5
<b>Total</b>	<b>\$ 12.2</b>	<b>\$ 7.5</b>	<b>\$ 19.7</b>

***Provision (Benefit) for Income Taxes***

(In millions)	Year Ended March 31,		Change Favorable/ (Unfavorable)
	2013	2012	
Income tax expense (benefit)	\$ 10.5	\$ (0.7)	\$ (11.2)

Our income tax expense for the twelve months ended March 31, 2013 consisted of a current income tax provision of \$12.5 million and a deferred income tax benefit of \$2.0 million. The current income tax provision was primarily due to U.S. federal and state taxes of \$8.2 million and \$2.6 million, respectively, on income earned in the U.S., and foreign withholding taxes of \$1.7 million. The deferred income tax benefit was primarily due to a benefit of \$2.0 million in Ireland as a result of the reversals of deferred tax liabilities for intangible assets for which the book basis exceeded the tax basis. The intangible assets are being amortized for book purposes over the life of the assets.

Our income tax benefit for the twelve months ended March 31, 2012 consisted 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 was 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 was 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 acquisition of EDT 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 acquisition of EDT.

Table of Contents**Liquidity and Capital Resources**

Our financial condition is summarized as follows:

(In millions)	December 31, 2014	December 31, 2013
Cash and cash equivalents	\$ 224.0	\$ 167.6
Investments short-term	407.1	194.6
Investments long-term	170.5	87.8
 Total cash and investments	 \$ 801.6	 \$ 450.0

Outstanding borrowings current and long-term	\$ 358.0	\$ 364.3
--	----------	----------

At December 31, 2014, our investments consisted of the following:

(In millions)	Amortized Cost	Gross Unrealized		Estimated Fair Value
		Gains	Losses	
Investments short-term	\$ 407.1	\$ 0.1	\$ (0.1)	\$ 407.1
Investments long-term available-for-sale	169.2		(0.3)	168.9
Investments long-term held-to-maturity	1.6			1.6
 Total	 \$ 577.9	 \$ 0.1	 \$ (0.4)	 \$ 577.6

*Sources and Uses of Cash*

We have generated cash from operations of \$11.1 million, \$92.2 million and \$126.6 million during the year ended December 31, 2014, the nine months ended December 31, 2013 and the year ended March 31, 2013, respectively. We expect that our existing cash and investments plus the amounts generated by our operating activities will be sufficient to finance our anticipated working capital and other cash requirements, such as capital expenditures and principal and interest payments on our long-term debt for the foreseeable future. In the event business conditions were to deteriorate, we could rely on borrowings under our long-term debt agreement, which has an incremental facility capacity in the amount of \$140.0 million, plus additional amounts as long as we meet certain conditions, including a specified leverage ratio.

Our investment objectives are, first, to preserve liquidity and conserve capital and, second, to generate investment income. We mitigate credit risk in our cash reserves by maintaining a well-diversified portfolio that limits the amount of investment exposure as to institution, maturity and investment type. Our available-for-sale investments consist primarily of short- and long-term U.S. government and agency debt securities and corporate debt securities. We classify available-for-sale investments in an unrealized loss position, which do not mature within 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 December 31, 2014, we performed an analysis of our investments with unrealized losses for impairment and determined that they were temporarily impaired.

Information about our cash flows, by category, is presented in the accompanying consolidated statements of cash flows. The following table summarizes our cash flows for the year ended

Table of Contents

December 31, 2014, the nine months ended December 31, 2013 and the year ended December 31, 2013:

(In millions)	Year Ended		Year Ended	
	December 31, 2014	December 31, 2013	December 31, 2013	March 31, 2013
Cash and cash equivalents, beginning of period	\$ 167.6	\$ 97.0	\$ 97.0	\$ 83.6
Cash provided by operating activities	11.1	92.2	92.2	126.5
Cash used in investing activities	(263.4)	(65.4)	(65.4)	(68.1)
Cash provided by (used in) financing activities	308.8	43.8	43.8	(45.0)
Cash and cash equivalents, end of period	\$ 224.1	\$ 167.6	\$ 167.6	\$ 97.0

*Operating Activities*

During the year ended December 31, 2014, we generated \$11.1 million in cash from operating activities, of which \$10.7 million came from working capital and \$0.5 million from net (loss) income. Cash from net (loss) income is equal to net (loss) income plus adjustments to reconcile net (loss) income to cash flows from operating activities. During the nine months ended December 31, 2013, we generated \$92.2 million in cash from operating activities, of which \$2.9 million came from working capital and \$89.3 million from net (loss) income. During the year ended March 31, 2013, we generated \$126.5 million in cash from operating activities, of which \$142.0 million came from net (loss) income, partially offset by \$15.4 million used for working capital. The decrease in cash provided by operating activities over the three periods was primarily due to the increase in spending on our R&D pipeline and sales and marketing activities as previously discussed, partially offset by an increase in revenues over each of these periods.

*Investing Activities*

During the year ended December 31, 2014, we used \$263.4 million in cash for investing activities, \$301.3 million of which was for purchases of available-for-sale securities, net of sales of available-for-sale securities. In October 2014, we received \$57.2 million from Civitas, \$30.0 million from the sale of certain commercial-scale pulmonary manufacturing equipment and \$27.2 million for our approximate 6% equity interest in Civitas when they were acquired by Acorda. We have the right to receive up to an additional \$2.4 million, subject to the release of all amounts held in escrow. We also sold certain of our land, buildings and equipment located at our Athlone, Ireland facility for \$17.5 million in April 2014. \$3.0 million of these sales proceeds were recorded as a deferred gain and will remain in escrow pending the completion of certain additional services we are obligated to perform.

During the year ended December 31, 2014, we spent \$33.7 million in additions to our property, plant and equipment. We expect to spend approximately \$53.0 million during the year ended December 31, 2015 for capital expenditures. The increase in capital spending from the year ended December 31, 2014 is primarily for the construction of facilities and equipment at our Wilmington, Ohio and Athlone, Ireland locations for the manufacture of products currently in development and existing proprietary products. Amounts included as construction in progress at December 31, 2014 primarily include capital expenditures at our manufacturing facility in Ohio. We continue to evaluate our manufacturing capacity based on expectations of demand for our products and will continue to record such amounts within construction in progress until such time as the underlying assets are placed into service, or we determine we have sufficient existing capacity and the assets are no longer required, at which time we would recognize an impairment charge. We continue to periodically evaluate whether facts and circumstances indicate that the carrying value of these long-lived assets to be held and used may not be recoverable.

Table of Contents

During the nine months ended December 31, 2013 and the year ended March 31, 2013, we had purchases of available-for-sale investments, net of sales of available for sale investments of \$45.2 million and \$45.0 million, respectively and additions to property, plant and equipment of \$19.1 million and \$22.2 million, respectively.

*Financing Activities*

Cash provided by financing activities in the year ended December 31, 2014 was primarily due to the sale of 5.9 million ordinary shares, through a registered direct offering to the Invesco Funds, for gross proceeds of \$250.0 million in January 2014. We also received \$47.6 million from our employees upon the exercise of stock options, net of \$12.8 million in employee taxes paid related to the net share settlement of equity awards.

Cash provided by financing activities the nine months ended December 31, 2013 was primarily due to \$49.1 million we received from our employees upon the exercise of stock options, net of \$11.7 million in employee taxes paid related to the net share settlement of equity awards.

Cash used in financing activities in the year ended March 31, 2013 was primarily due to \$74.2 million used to refinance our Term Loan facility in September 2012. This was partially offset by \$34.4 million we received from our employees upon the exercise of stock options, net of \$4.8 million in employee taxes paid related to the net share settlement of equity awards.

*Borrowings*

At December 31, 2014, our borrowings consisted of \$359.8 million outstanding under our Term Loan Facility. 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 December 31, 2014:

Contractual Obligations	Total	Less Than	One to	Three to	More than
		One Year (2015)	Three Years (2016 - 2017)	Five Years (2018 - 2019)	Five Years (After 2020)
(In thousands)					
Term Loan Facility Principal	\$ 359,813	\$ 6,750	\$ 68,813	\$ 284,250	\$
Term Loan Facility Interest	50,925	12,148	21,504	17,273	
Operating lease obligations	31,304	5,837	10,440	10,804	4,223
Purchase obligations	272,158	272,158			
<b>Total contractual cash obligations</b>	<b>\$ 714,200</b>	<b>\$ 296,893</b>	<b>\$ 100,757</b>	<b>\$ 312,327</b>	<b>\$ 4,223</b>

As interest on Term Loan B-1 is based on three-month LIBOR, we assumed LIBOR to be 0.75%, which is the LIBOR rate floor under the terms of Term Loan B-1. As there is no LIBOR rate floor under Term Loan B-2, we assumed one-month LIBOR to be 0.17%, which was the approximate one-month LIBOR rate at December 31, 2014. 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.

At December 31, 2014, we had \$2.6 million of net liabilities associated with uncertain tax positions. We do not anticipate that the amount of existing unrecognized tax benefits will significantly increase or decrease within the next 12 months.

Table of Contents

In September 2006, we entered into a license agreement with the Rensselaer Polytechnic Institute ("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 \$8.0 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 expenses.

Due to the contingent nature of the payments under the RPI arrangement, 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 obligations.

**Off-Balance Sheet Arrangements**

At December 31, 2014, 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, results of operations, liquidity, capital expenditures or capital resources.

**Critical Accounting Estimates**

Our consolidated financial statements are prepared in accordance with GAAP. In connection with the preparation of our financial statements, we are required to make assumptions and estimates about future events, and apply judgments on historical experience, current trends and other factors that management believes to be relevant at the time our consolidated financial statements are prepared. On a regular basis, we review the accounting policies, assumptions, estimates and judgments to ensure that our financial statements are presented fairly and in accordance with GAAP. However, because future events and their effects cannot be determined with certainty, actual results could differ from our assumptions and estimates, and such differences could be material.

Our significant accounting policies are discussed in Note 2, *Summary of Significant Accounting Policies*, of the Notes to Consolidated Financial Statements. We believe that the following accounting estimates are the most critical to aid in fully understanding and evaluating our reported financial results, and they require our most difficult, subjective or complex judgments, resulting from the need to make estimates about the effect of matters that are inherently uncertain. We have reviewed these critical accounting estimates and related disclosures with the Audit and Risk Committee of our Board of Directors.

***Manufacturing and Royalty Revenue***

Our manufacturing and royalty revenues are earned under the terms of collaboration agreements with pharmaceutical companies, the most significant of which include Janssen for RISPERDAL CONSTA and INVEGA SUSTENNA/XEPLION, Acorda for AMPYRA/FAMPYRA and AstraZeneca for BYDUREON. 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.

Table of Contents

The sales price for certain of our manufacturing revenues is based on the end-market sales price earned by our collaborative partners. As the end-market sale occurs after we have shipped our product and the risk of loss has passed to our collaborative partner, we estimate the sales price for our product based on information supplied to us by our collaborative partners, our historical transaction experience and other third-party data. Differences between the actual manufacturing revenues and estimated manufacturing revenues are reconciled and adjusted for in the period in which they become known, which is generally the following quarter. The difference between actual and estimated manufacturing revenues has not been material.

Royalty revenues are related to the sale of products by our collaborative partners that incorporate our technologies. Royalties, with the exception of AMPYRA, 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, which is generally the following quarter. The difference between actual and estimated royalty revenues has not been material. Royalties on AMPYRA are earned in the period product is shipped to Acorda. We also earn royalties on shipments of AMPYRA to Acorda manufactured by third-party manufacturers.

***Product Sales, Net***

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, 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 pharmaceutical and biotechnology companies selling products in the U.S. market are required to provide statutorily defined rebates and discounts to various U.S. government and state 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 Prices. 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

## Edgar Filing: Alkermes plc. - Form 10-K

### Table of Contents

participation in these programs. To date, actual wholesaler chargebacks have not differed materially from our estimates;

**Product Discounts** 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. To date, actual product discounts have not differed materially from our estimates;

**Co-pay Assistance** we have a program whereby a patient can receive up to \$500 per month toward their co-payment, co-insurance or deductible, provided the patient meets certain eligibility criteria. Reserves are recorded upon the sale of VIVITROL. To date, actual co-pay assistance payments have not differed materially from our estimates; and

**Product Returns** we record an estimate for product returns at the time our customer takes title to our product. We estimate the liability based on our historical return levels and specifically identified anticipated returns due to known business conditions and product expiry dates. Once VIVITROL is returned, it is destroyed. At December 31, 2014, our product return reserve was estimated to be approximately 2% of our product sales.

Prior to August 2012, we deferred the recognition of revenue on shipments of VIVITROL to our customers until the product left the distribution channel as we did not have sufficient history to reasonably estimate returns related to VIVITROL shipments. We estimated 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 sold related to products shipped to customers with the associated revenue, we deferred the recognition of the cost of goods sold to the period in which the associated revenue was recognized.

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

(In millions)	Medicaid Rebates	Chargebacks	Product Discounts	Co-Pay Assistance	Product Returns	Other	Total
<b>Balance, April 1, 2013</b>	\$ 1.9	\$	\$ 0.4	\$	\$ 3.1	\$ 0.6	\$ 6.0
Provision:							
Current period	5.6	5.2	3.8	4.0	1.5	2.6	22.7
Prior period	(0.2)				(0.6)		(0.8)
<b>Total</b>	5.4	5.2	3.8	4.0	0.9	2.6	21.9
Actual:							
Current period	(2.9)	(5.2)	(3.2)	(3.8)		(2.4)	(17.5)
Prior period	(1.7)		(0.2)		(0.2)	(0.8)	(2.9)
<b>Total</b>	(4.6)	(5.2)	(3.4)	(3.8)	(0.2)	(3.2)	(20.4)
<b>Balance, December 31, 2013</b>							
	\$ 2.7	\$	\$ 0.8	\$ 0.2	\$ 3.8	\$	\$ 7.5
Provision:							
Current period	11.0	9.3	7.4	5.8	3.0	4.7	41.2
Prior period	0.1		(0.2)	0.3		1.5	1.7
<b>Total</b>	11.1	9.3	7.2	6.1	3.0	6.2	42.9
Actual:							
Current period	(7.2)	(9.2)	(7.0)	(6.3)		(3.4)	(33.1)
Prior period	(2.9)		(0.1)		(1.3)	(0.9)	(5.2)
<b>Total</b>	(10.1)	(9.2)	(7.1)	(6.3)	(1.3)	(4.3)	(38.3)
<b>Balance, December 31, 2014</b>							
	\$ 3.7	\$ 0.1	\$ 0.9	\$	\$ 5.5	\$ 1.9	\$ 12.1





Table of Contents

***Investments***

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

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

For equity securities, when assessing whether a decline in fair value below our cost basis is other-than-temporary, we consider the fair market value of the security, the duration of the security's decline 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 investment at December 31, 2013 included warrants to purchase the common stock of a publicly traded company and was valued using a Black-Scholes option-pricing model. The Black-Scholes model required us to estimate certain subjective assumptions. These assumptions included the expected term, the expected volatility of the underlying common stock over the warrant's expected term, the risk-free interest rate over the warrant's expected term and an expected annual dividend yield. While we believe our 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***

We have a share-based compensation plan, which includes incentive stock options, non-qualified stock options and restricted stock units. See Note 2, *Summary of Significant Accounting Policies*, and Note 14, *Share-Based Compensation*, in our Notes to Consolidated Financial Statements for a complete discussion of our share-based compensation plans.

Table of Contents

The fair value of restricted stock units is equal to the closing price of our stock on the date of grant. The fair value of stock option awards is determined through the use of a Black-Scholes option-pricing model. The Black-Scholes model 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 December 31, 2014, the nine months ended December 31, 2013 and the year ended March 31, 2013, the ranges in weighted-average assumptions were as follows:

	<b>Year Ended December 31, 2014</b>	<b>Nine Months Ended December 31, 2013</b>	<b>Year Ended March 31, 2013</b>
Expected option term	5 - 7 years	5 - 7 years	5 - 7 years
Expected stock volatility	39% - 46%	45% - 48%	47% - 49%
Risk-free interest rate	1.46% - 2.24%	0.75% - 2.15%	0.61% - 1.18%

Expected annual dividend yield

In addition to the above, we apply judgment in developing estimates of award forfeitures. For the year ended December 31, 2014, we used an estimated forfeiture rate of zero for our non-employee directors, 1.75% 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.

***Amortization and Impairment of Long-Lived Assets***

Long-lived assets, other than goodwill which is separately tested for impairment, are evaluated for impairment whenever events or changes in circumstances indicate the carrying value of an asset may not be recoverable. When evaluating long-lived assets for potential impairment, we first compare the carrying value of the asset to the asset's estimated future cash flows (undiscounted and without interest charges). If the estimated future cash flows are less than the carrying value of the asset, we calculate an impairment loss. The impairment loss calculation compares the carrying value of the asset to the asset's estimated fair value, which may be based on estimated future cash flows (discounted and with interest charges). We recognize an impairment loss if the amount of the asset's carrying value exceeds the asset's estimated fair value. If we recognize an impairment loss, the adjusted carrying amount of the asset becomes its new cost basis. For a depreciable long-lived asset, the new cost basis will be depreciated over the remaining useful life of that asset.

When reviewing long-lived assets for impairment, we group long-lived assets with other assets and liabilities at the lowest level for which identifiable cash flows are largely independent of the cash flows of other assets and liabilities. Our impairment loss calculations contain uncertainties because they require management to make assumptions and to apply judgment to estimate future cash flows and asset fair values, including forecasting useful lives of the assets and selecting the discount rate that reflects the risk inherent in future cash flows.

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

Table of Contents

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.

In order to determine the pattern in which the economic benefits of our intangible assets are consumed, we estimated the future revenues to be earned under our collaboration agreements and our NanoCrystal and OCR technology-based intangible assets from the date of acquisition to the end of their respective useful lives. The factors used to estimate such future revenues included: (i) our and our collaborative partners' projected future sales of the existing commercial products based on these intangible assets; (ii) our projected future sales of new products based on these intangible assets which we anticipate will be launched commercially; (iii) the patent lives of the technologies underlying such existing and new products; and (iv) our expectations regarding the entry of generic and/or other competing products into the markets for such existing and new products. These factors involve known and unknown risks and uncertainties, many of which are beyond our control and could cause the actual economic benefits of these intangible assets to be materially different from our estimates.

Based on our most recent analysis, amortization of intangible assets included within our consolidated balance sheet at December 31, 2014, is expected to be approximately \$65.0 million, \$70.0 million, \$70.0 million, \$70.0 million and \$60.0 million in the years ending December 31, 2015 through 2019, respectively. Although we believe such available information and assumptions are reasonable, given the inherent risks and uncertainties underlying our expectations regarding such future revenues, there is the potential for our actual results to vary significantly from such expectations. If revenues are projected to change, the related amortization of the intangible asset will change in proportion to the change in revenue.

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 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.

***Goodwill***

We evaluate goodwill for impairment annually, as of October 31, and whenever events or changes in circumstances indicate its carrying value may not be recoverable. The goodwill for each reporting unit is tested using a two-step process. A reporting unit is an operating segment, as defined by the segment reporting accounting standards, or a component of an operating segment. A component of an operating segment is a reporting unit if the component constitutes a business for which discrete financial information is available and is reviewed by management. Two or more components of an operating segment may be aggregated and deemed a single reporting unit for goodwill impairment testing purposes if the components have similar economic characteristics. As of December 31, 2014, we have one operating segment and two reporting units. Our goodwill, which solely relates to the EDT acquisition in the year ended March 31, 2012, has been assigned to one reporting unit which consists of the former EDT business.

We have the option to first assess qualitative factors to determine whether it is necessary to perform the two-step impairment test. If we elect this option and determine, as a result of the qualitative assessment, that it is more-likely-than-not that the fair value of our reporting unit is less than its carrying amount, the quantitative two-step impairment test is required; otherwise, no further testing is required. Among other relevant events and circumstances that affect the fair value of reporting units, we consider individual factors, such as microeconomic conditions, changes in the industry and the markets in which we operate as well as historical and expected future financial

Table of Contents

performance. Alternatively, we may elect to not first assess qualitative factors and immediately perform the quantitative two-step impairment test.

The first step of the goodwill impairment test requires us to compare the fair value of the reporting unit to its respective carrying value, which includes goodwill. If the fair value of the reporting unit exceeds its carrying value, the goodwill is not considered impaired. If the carrying value is higher than the fair value, there is an indication that an impairment may exist and the second step is required. In step two, the implied fair value of goodwill is calculated as the excess of the fair value of a reporting unit over the fair values assigned to its assets and liabilities. If the implied fair value of goodwill is less than the carrying value of the reporting unit's goodwill, the difference is recognized as an impairment loss.

At October 31, 2014, we elected to first assess qualitative factors to determine whether it was necessary to perform the two-step impairment test. Based on the weight of all available evidence, we determined that the fair value of the reporting unit more-likely-than-not exceeds its carrying value.

***Valuation of Deferred Tax Assets***

We evaluate the need for deferred tax asset valuation allowances based on a more-likely-than-not standard. The ability to realize deferred tax assets depends on the ability to generate sufficient taxable income within the carryback or carryforward periods provided for in the tax law for each applicable tax jurisdiction. We consider the following possible sources of taxable income when assessing the realization of deferred tax assets:

future reversals of existing taxable temporary differences;

future taxable income exclusive of reversing temporary differences and carryforwards;

taxable income in prior carryback years; and

tax-planning strategies.

The assessment regarding whether a valuation allowance is required or should be adjusted also considers all available positive and negative evidence factors including, but not limited to:

nature, frequency and severity of recent losses;

duration of statutory carryforward periods;

historical experience with tax attributes expiring unused; and

near- and medium-term financial outlook.

It is difficult to conclude a valuation allowance is not required when there is significant objective and verifiable negative evidence, such as cumulative losses in recent years. We utilize a rolling three years of actual and current year anticipated results as the primary measure of cumulative losses in recent years.

The evaluation of deferred tax assets requires judgment in assessing the likely future tax consequences of events that have been recognized in our financial statements or tax returns and future profitability. Our accounting for deferred tax consequences represents our best estimate of those future events. Changes in our current estimates, due to unanticipated events or otherwise, could have a material effect on our financial condition and results of operations.



Table of Contents

**Recent Accounting Pronouncements**

Please refer to Note 2, *Summary of Significant Accounting Policies*, "New Accounting Pronouncements" in our Notes to 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 an immaterial amount over an annual period. 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 approximately 57% of our investments are in debt securities issued by the U.S. government or its agencies, our exposure to liquidity and credit risk is not believed to be significant.

At December 31, 2014, our borrowings consisted of \$359.6 million outstanding under our Term Loan Facility. Term Loan B-1 bears interest at three-month LIBOR plus 2.75% with a LIBOR floor of 0.75%. As the three-month LIBOR rate was 0.26% at December 31, 2014, and the LIBOR floor under Term Loan B-1 is 0.75%, we do not expect changes in the three-month LIBOR to have a material effect on our financial statements through December 31, 2015. Term Loan B-2 bears interest at one-month LIBOR plus 2.75% with no LIBOR floor. At December 31, 2014, the one-month LIBOR rate was 0.17%. A 10% increase in the one-month LIBOR rate would have increased our interest expense in the year ended December 31, 2014 by an immaterial amount.

**Currency Exchange Rate Risk**

Manufacturing and royalty revenues we receive on certain of our products and services are a percentage of the net sales made by our collaborative partners and a 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 are 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 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 revenues will increase given a constant amount of sales in such non-U.S. currency. For the year ended December 31, 2014, an average 10% strengthening of the USD relative to the currencies in which these products are sold would have resulted in revenues being reduced by approximately \$21.8 million.

We incur operating costs in Ireland and 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 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 year ended December 31, 2014, an average 10% weakening in the USD relative to the Euro would have resulted in an increase to our expenses denominated in Euro of approximately \$7.7 million.

Table of Contents**Item 8. Financial Statements and Supplementary Data****Selected Quarterly Financial Data (unaudited)**

(In thousands, except per share data)	First Quarter	Second Quarter	Third Quarter	Fourth Quarter	Total
<b>Year Ended December 31, 2014</b>					
<b>REVENUES:</b>					
Manufacturing and royalty revenues	\$ 111,280	\$ 130,366	\$ 132,028	\$ 143,202	\$ 516,876
Product sales, net	17,079	21,595	25,802	29,684	94,160
Research and development revenue	1,853	1,463	2,162	2,275	7,753
Total revenues	130,212	153,424	159,992	175,161	618,789
<b>EXPENSES:</b>					
Cost of goods manufactured and sold	38,839	43,290	47,335	46,368	175,832
Research and development	52,140	67,207	78,263	74,433	272,043
Selling, general and administrative	42,550	50,663	51,888	54,804	199,905
Amortization of acquired intangible assets	12,576	15,089	15,244	15,244	58,153
Total expenses	146,105	176,249	192,730	190,849	705,933
OPERATING (LOSS) INCOME	(15,893)	(22,825)	(32,738)	(15,688)	(87,144)
OTHER (EXPENSE) INCOME, NET	(4,695)	25,037	(3,695)	56,468	73,115
(LOSS) INCOME BEFORE INCOME TAXES	(20,588)	2,212	(36,433)	40,780	(14,029)
INCOME TAX PROVISION (BENEFIT)	3,766	(1,523)	3,523	10,266	16,032
NET (LOSS) INCOME	\$ (24,354)	\$ 3,735	\$ (39,956)	\$ 30,514	\$ (30,061)
(LOSS) EARNINGS PER SHARE BASIC	\$ (0.17)	\$ 0.03	\$ (0.27)	\$ 0.21	\$ (0.21)
(LOSS) EARNINGS PER SHARE DILUTED	\$ (0.17)	\$ 0.02	\$ (0.27)	\$ 0.20	\$ (0.21)

	First Quarter	Second Quarter	Third Quarter	Total
<b>Nine Months Ended December 31, 2013</b>				
<b>REVENUES:</b>				
Manufacturing and royalty revenues	\$ 119,788	\$ 118,571	\$ 132,680	\$ 371,039
Product sales, net	17,379	19,227	20,609	57,215
Research and development revenue	1,464	2,004	1,189	4,657
Total revenues	138,631	139,802	154,478	432,911
<b>EXPENSES:</b>				
Cost of goods manufactured and sold	45,991	45,423	42,892	134,306

Edgar Filing: Alkermes plc. - Form 10-K

Research and development	33,462	45,947	48,716	128,125
Selling, general and administrative	32,933	39,454	44,171	116,558
Amortization of acquired intangible assets	12,716	12,856	12,856	38,428
Total expenses	125,102	143,680	148,635	417,417
OPERATING INCOME (LOSS)	13,529	(3,878)	5,843	15,494
OTHER (EXPENSE), NET	(3,477)	(3,651)	(2,969)	(10,097)
INCOME (LOSS) BEFORE INCOME TAXES	10,052	(7,529)	2,874	5,397
INCOME TAX PROVISION (BENEFIT)	2,718	233	(15,203)	(12,252)
NET INCOME (LOSS)	\$ 7,334	\$ (7,762)	\$ 18,077	\$ 17,649
EARNINGS (LOSS) PER SHARE BASIC	\$ 0.05	\$ (0.06)	\$ 0.13	\$ 0.13
EARNINGS (LOSS) PER SHARE DILUTED	\$ 0.05	\$ (0.06)	\$ 0.12	\$ 0.12



Table of Contents

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 Exchange Act), as of December 31, 2014. 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 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 December 31, 2014 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 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

Table of Contents

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 December 31, 2014. In making this assessment, management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission ("COSO") in its 2013 Internal Control Integrated Framework.

Based on this assessment, our management has concluded that, as of December 31, 2014, our internal control over financial reporting was effective.

The effectiveness of our internal control over financial reporting as of December 31, 2014 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**

The Company's policy governing transactions in its securities by its directors, officers and employees permits its officers, directors and employees to enter into trading plans in accordance with Rule 10b5-1 under the Exchange Act. During the quarter ended December 31, 2014, Dr. Floyd E. Bloom, a director of the Company, and Mr. Shane M. Cooke, Dr. Elliot W. Ehrich, Mr. James M. Frates, Ms. Rebecca J. Peterson and Mr. Gordon G. Pugh, each an executive officer of the Company, entered into trading plans in accordance with Rule 10b5-1, and the Company's policy governing transactions in its securities by its directors, officers and employees. The Company undertakes no obligation to update or revise the information provided herein, including for revision or termination of an established trading plan.

Table of Contents

**PART III**

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

The information required by this item is incorporated herein by reference to the 2014 Proxy Statement.

**Item 11. *Executive Compensation***

The information required by this item is incorporated herein by reference to the 2014 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 2014 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 2014 Proxy Statement.

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

The information required by this item is incorporated herein by reference to the 2014 Proxy Statement.

Table of Contents

**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 Annual Report.
- (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.



Table of Contents**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 Annual Report, 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)	February 24, 2015
<u>/s/ JAMES M. FRATES</u> James M. Frates	Senior Vice President and Chief Financial Officer (Principal Financial and Accounting Officer)	February 24, 2015
<u>/s/ DAVID W. ANSTICE</u> David W. Anstice	Director	February 24, 2015
<u>/s/ FLOYD E. BLOOM</u> Floyd E. Bloom	Director	February 24, 2015
<u>/s/ ROBERT A. BREYER</u> Robert A. Breyer	Director	February 24, 2015
<u>/s/ WENDY L. DIXON</u> Wendy L. Dixon	Director	February 24, 2015
<u>/s/ GERALDINE HENWOOD</u> Geraldine Henwood	Director	February 24, 2015
<u>/s/ PAUL J. MITCHELL</u> Paul J. Mitchell	Director	February 24, 2015
<u>/s/ NANCY J. WYSENSKI</u> Nancy J. Wysenski	Director	February 24, 2015

## Edgar Filing: Alkermes plc. - Form 10-K

### Table of Contents

#### EXHIBIT INDEX

<b>Exhibit No.</b>	<b>Description of Exhibit</b>
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.)
10.1++	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 year ended March 31, 2009 (File No. 001-14131).)
10.2++	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).)
10.3++*	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) (with certain confidential information deleted). (Incorporated by reference to Exhibit 10.19 to the Alkermes, Inc. Annual Report on Form 10-K for the year ended March 31, 1996 (File No. 000-19267).)
10.4++*	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) (with certain confidential information deleted). (Incorporated by reference to Exhibit 10.20 to the Alkermes, Inc. Annual Report on Form 10-K for the year ended March 31, 1996 (File No. 000-19267).)
10.5++**	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) (with certain confidential information deleted). (Incorporated by reference to Exhibit 10.19 to the Alkermes, Inc. Annual Report on Form 10-K for the year ended March 31, 2002 (File No. 001-14131).)
10.6++***	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).)

## Edgar Filing: Alkermes plc. - Form 10-K

### Table of Contents

<b>Exhibit No.</b>	<b>Description of Exhibit</b>
10.7++**	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).)
10.8++**	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) (with certain confidential information deleted). (Incorporated by reference to Exhibit 10.19(b) to the Alkermes, Inc. Annual Report on Form 10-K for the year ended March 31, 2002 (File No. 001-14131).)
10.9++**	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) (with certain confidential information deleted). (Incorporated by reference to Exhibit 10.19(a) to the Alkermes, Inc. Annual Report on Form 10-K for the year ended March 31, 2002 (File No. 001-14131).)
10.10++***	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).)
10.11++***	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).)
10.12++***	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).)
10.13++***	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).)



## Edgar Filing: Alkermes plc. - Form 10-K

### Table of Contents

<b>Exhibit No.</b>	<b>Description of Exhibit</b>
10.14++****	Second Amendment, dated as of August 16, 2012, to the License Agreement, dated as of February 13, 1996, as amended, by and between Alkermes, Inc. ("Alkermes") and Janssen Pharmaceutica, Inc. ("Janssen US") and the License Agreement, dated as of February 21, 1996, as amended, by and between Alkermes and JPI Pharmaceutica International, a division of Cilag GmbH International ("JPI") (Janssen US and JPI together, "Janssen"), and the Fifth Amendment, dated as of August 16, 2012, to the Manufacturing and Supply Agreement, dated as of August 6, 1997, as amended, by and between Alkermes and Janssen (with certain confidential information deleted). (Incorporated by reference to Exhibit 10.3 of the Alkermes plc Quarterly Report on Form 10-Q for the quarter ended September 30, 2012 (File No. 001-35299).)
10.15++	Amended and Restated License Agreement, dated September 26, 2003, by and between Acorda Therapeutics, Inc. and Elan Corporation, plc. (Incorporated by reference to Exhibit 10.14 of the Acorda Therapeutics, Inc. Quarterly Report on Form 10-Q/A for the period ended March 31, 2011 (File No.000-50513; film No. 11821367).)
10.16++	Amendment No. 1 Agreement and Sublicense Consent Between Elan Corporation, plc and Acorda Therapeutics, Inc. dated June 30, 2009. (Incorporated by reference to Exhibit 10.56 to Acorda Therapeutics, Inc.'s Quarterly Report on Form 10-Q filed on August 10, 2009 (File No.000-50513; film No. 09999376).)
10.17++	Amendment No. 2, dated as of March 29, 2012, to the Amended and Restated License Agreement, dated September 26, 2003, as amended and the Supply Agreement, dated September 26, 2003, as amended. (Incorporated by reference to Exhibit 10.46 of the Acorda Therapeutics, Inc. Annual Report on Form 10-K filed on February 28, 2013 (File No.000-50513; film no. 13653677).)
10.18++	Amendment No. 3, dated as of February 14, 2013, to the Amended and Restated License Agreement, dated September 26, 2003, as amended and the Supply Agreement, dated September 26, 2003, as amended. (Incorporated by reference to Exhibit 10.1 of the Acorda Therapeutics, Inc. Quarterly Report on Form 10-Q filed on May 10, 2013 (File No. 000-50513; film No. 13831684).)
10.19++*****	Development and Supplemental Agreement between Elan Pharma International Limited and Acorda Therapeutics, Inc. dated January 14, 2011(with certain confidential information deleted). (Incorporated by reference to Exhibit 10.21 of the Alkermes plc Annual Report on Form 10-K for the year ended March 31, 2013 (File No. 001-35299).)
10.20++*****	Supply Agreement, dated September 26, 2003, by and between Acorda Therapeutics, Inc. and Elan Corporation, plc (with certain confidential information deleted). (Incorporated by reference to Exhibit 10.22 of the Alkermes plc Annual Report on Form 10-K for the year ended March 31, 2013 (File No. 001-35299).)

## Edgar Filing: Alkermes plc. - Form 10-K

### Table of Contents

<b>Exhibit No.</b>	<b>Description of Exhibit</b>
10.21++*****	License Agreement by and among Elan Pharmaceutical Research Corp., d/b/a Nanosystems and Elan Pharma International Limited and Janssen Pharmaceutica N.V. dated as of March 31, 1999 (with certain confidential information deleted). (Incorporated by reference to Exhibit 10.23 of the Alkermes plc Annual Report on Form 10-K for the year ended March 31, 2013 (File No. 001-35299).)
10.22++	First Amendment, dated as of July 31, 2003, to the License Agreement by and among Elan Drug Delivery, Inc. (formerly Elan Pharmaceutical Research Corp.) and Elan Pharma International Limited and Janssen Pharmaceutica NV dated March 31, 1999. (Incorporated by reference to Exhibit 10.24 of the Alkermes plc Annual Report on Form 10-K for the year ended March 31, 2013 (File No. 001-35299).)
10.23++*****	Agreement Amendment No. 2, dated as of July 31, 2009, to the License Agreement by and among Elan Pharmaceutical Research Corp., d/b/a Nanosystems and Elan Pharma International Limited and Janssen Pharmaceutica N.V. dated as of March 31, 1999, as amended by the First Amendment, dated as of July 31, 2003 (with certain confidential information deleted). (Incorporated by reference to Exhibit 10.25 of the Alkermes plc Annual Report on Form 10-K for the year ended March 31, 2013 (File No. 001-35299).)
10.24 ++	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).)
10.25 ++	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).)
10.26 ++	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).)
10.27 ++	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).)
10.28 ++	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).)

## Edgar Filing: Alkermes plc. - Form 10-K

### Table of Contents

<b>Exhibit No.</b>	<b>Description of Exhibit</b>
10.29 ++	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).)
10.30 ++	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).)
10.31 ++	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).)
10.32 ++	Stock Option Plan for Non-Employee Directors, as amended. (Incorporated by reference to Exhibit 99.2 to the Alkermes, Inc. Registration Statement on Form S-8 filed on October 1, 2003 (File No. 333-109376).)
10.33 ++	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).)
10.34 ++	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 year ended March 31, 2006 (File No. 001-14131).)
10.35 ++	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 year ended March 31, 2006 (File No. 001-14131).)
10.36 ++	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 quarter ended December 31, 2006 (File No. 001-14131).)
10.37 ++	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).)
10.38 ++	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 quarter ended September 30, 2006 (File No. 001-14131).)
10.39 ++	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).)

## Edgar Filing: Alkermes plc. - Form 10-K

### Table of Contents

<b>Exhibit No.</b>	<b>Description of Exhibit</b>
10.40 ++	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).)
10.41 ++	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 year ended March 31, 2010 (File No. 001-14131).)
10.42 ++	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 year ended March 31, 2010 (File No. 001-14131).)
10.43 ++	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).)
10.44 ++	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).)
10.45 ++	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).)
10.46++****	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) (with certain confidential information deleted). (Incorporated by reference to Exhibit 10.28 to the Alkermes, Inc. Annual Report on Form 10-K for the year ended March 31, 2010 (File No. 001-14131).)
10.47++	Amendment to First Lien Credit Agreement, dated September 25, 2012, among Alkermes, Inc., Alkermes plc, 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 of the Alkermes plc Current Report on Form 8-K filed on September 25, 2012.)
10.48++	Amendment No. 2, dated as of February 14, 2013, to Amended and Restated Credit Agreement, dated as of September 16, 2011, as amended and restated on September 25, 2012, among Alkermes, Inc., Alkermes plc, 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 of the Alkermes plc Current Report on Form 8-K filed on February 19, 2013.)

## Edgar Filing: Alkermes plc. - Form 10-K

### Table of Contents

<b>Exhibit No.</b>	<b>Description of Exhibit</b>
10.49++	Amendment No. 3 and Waiver to Amended and Restated Credit Agreement, dated as of May 22, 2013, among Alkermes, Inc., Alkermes plc, Alkermes Pharma Ireland Limited, Alkermes US Holdings, Inc., Morgan Stanley Senior Funding, Inc. as Administrative Agent and Collateral Agent and the lenders party thereto. (Incorporated by reference to Exhibit 10.52 of the Alkermes plc Annual Report on Form 10-K for the year ended March 31, 2013 (File No. 001-35299).)
10.50 ++	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.)
10.51 ++	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.)
10.52 ++	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.)
10.53 ++	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.)
10.54 ++	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.)
10.55 ++	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.)
10.56 ++	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.)
10.57 ++	Alkermes plc 2011 Stock Option and Incentive Plan, Stock Option Award Certificate (Incentive Stock Option U.S.), as amended. (Incorporated by reference to Exhibit 10.63 of the Alkermes plc Annual Report on Form 10-K for the year ended March 31, 2013 (File No. 001-35299).)
10.58 ++	Alkermes plc 2011 Stock Option and Incentive Plan, Stock Option Award Certificate (Non-Qualified Option U.S.), as amended. (Incorporated by reference to Exhibit 10.64 of the Alkermes plc Annual Report on Form 10-K for the year ended March 31, 2013 (File No. 001-35299).)
10.59 ++	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.)

## Edgar Filing: Alkermes plc. - Form 10-K

### Table of Contents

<b>Exhibit No.</b>	<b>Description of Exhibit</b>
10.60 ++	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.)
10.61 ++	Employment agreement, dated as of July 30, 2012, by and between Rebecca J. Peterson and Alkermes, Inc. (Incorporated by reference to Exhibit 10.1 of the Alkermes plc Quarterly Report on Form 10-Q for the quarter ended September 30, 2012.)
10.62++	Second Amendment to Lease Agreement between Alkermes, Inc. and PDM Unit 850, LLC, dated as of November 12, 2013. (Incorporated by reference to Exhibit 10.74 of the Alkermes plc Transition Report on Form 10-K for the nine-month transition period ended December 31, 2013.)
10.63 ++	Alkermes plc 2011 Stock Option and Incentive Plan, Restricted Stock Unit Award Certificate (Time Vesting Only U.S.), as amended. (Incorporated by reference to Exhibit 10.75 of the Alkermes plc Transition Report on Form 10-K for the nine-month transition period ended December 31, 2013.)
10.64 ++	Alkermes plc 2011 Stock Option and Incentive Plan, Restricted Stock Unit Award Certificate (Performance Vesting Only U.S.), as amended. (Incorporated by reference to Exhibit 10.76 of the Alkermes plc Transition Report on Form 10-K for the nine-month transition period ended December 31, 2013.)
10.65 ++	Alkermes plc 2011 Stock Option and Incentive Plan, Restricted Stock Unit Award Certificate (Time Vesting Only Irish), as amended. (Incorporated by reference to Exhibit 10.77 of the Alkermes plc Transition Report on Form 10-K for the nine-month transition period ended December 31, 2013.)
10.66 ++	Alkermes plc 2011 Stock Option and Incentive Plan, Restricted Stock Unit Award Certificate (Performance Vesting Only Irish), as amended. (Incorporated by reference to Exhibit 10.78 of the Alkermes plc Transition Report on Form 10-K for the nine-month transition period ended December 31, 2013.)
10.67 ++	Alkermes plc 2011 Stock Option and Incentive Plan, Stock Option Award Certificate (Non-Employee Director). (Incorporated by reference to Exhibit 10.79 of the Alkermes plc Transition Report on Form 10-K for the nine-month transition period ended December 31, 2013.)
10.68 ++	Alkermes plc 2011 Stock Option and Incentive Plan, Stock Option Award Certificate (Non-Qualified Option Irish). (Incorporated by reference to Exhibit 10.80 of the Alkermes plc Transition Report on Form 10-K for the nine-month transition period ended December 31, 2013.)
10.69 ++	Alkermes plc 2011 Stock Option and Incentive Plan, as amended. (Incorporated by reference to Exhibit 10.1 of the Alkermes plc Current Report on Form 8-K filed on May 28, 2014.)
10.70++	Third Amendment to Lease Agreement between Alkermes, Inc. and PDM 850 Unit, LLC, dated as of May 15, 2014. (Incorporated by reference to Exhibit 10.2 of the Alkermes plc Quarterly Report on Form 10-Q for the quarter ended June 30, 2014.)

## Edgar Filing: Alkermes plc. - Form 10-K

### Table of Contents

<b>Exhibit No.</b>	<b>Description of Exhibit</b>
10.71++	Amendment No. 3 and Waiver, dated as of May 22, 2013, to Amended and Restated Credit Agreement, dated as of September 16, 2011, as amended and restated on September 25, 2012, as further amended as of February 14, 2013 among Alkermes, Inc., Alkermes plc, 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 of the Alkermes plc Quarterly Report on Form 10-Q for the quarter ended September 30, 2014.)
10.72 ++	Alkermes plc Affiliated Company Fiscal Year 2015 Reporting Officer Performance Pay Plan (Incorporated by reference to Exhibit 10.1 of the Alkermes plc Current Report on Form 8-K filed on December 5, 2014.)
21.1#	List of subsidiaries
23.1#	Consent of PricewaterhouseCoopers LLP, an independent registered public accounting firm
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
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).

#  
Filed herewith.

Furnished herewith.

\*  
Confidential treatment 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 treatment 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.





Table of Contents

\*\*\*

Confidential treatment 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 treatment 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.

\*\*\*\*\*

Confidential treatment has been granted for certain portions thereof pursuant to a Commission Order granted December 10, 2012. Such provisions have been filed separately with the Commission.

\*\*\*\*\*

Confidential treatment has been granted for certain portions thereof pursuant to a Commission Order granted August 9, 2013. Such provisions have been filed separately with the Commission.

Table of Contents

**Report of Independent Registered Public Accounting Firm**

To Board of Directors and Shareholders of Alkermes plc

In our opinion, the accompanying consolidated balance sheets and the related consolidated statements of comprehensive (loss) income, of shareholders' equity and of cash flows present fairly, in all material respects, the financial position of Alkermes plc and its subsidiaries as at December 31, 2014 and December 31, 2013, and the results of their operations and their cash flows for the year ending December 31, 2014, nine month period ended December 31, 2013 and the year ended March 31, 2013 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 December 31, 2014, based on criteria established in *Internal Control Integrated Framework* 2013 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 Report on Internal Control over Financial Reporting. 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.

/s/ Pricewaterhouse Coopers LLP  
Boston, Massachusetts  
February 24, 2015

Table of Contents**ALKERMES PLC AND SUBSIDIARIES****CONSOLIDATED BALANCE SHEETS**

December 31, 2014 and 2013

	December 31, 2014	December 31, 2013
	(In thousands, except share and per share amounts)	
<b>ASSETS</b>		
<b>CURRENT ASSETS:</b>		
Cash and cash equivalents	\$ 224,064	\$ 167,562
Investments short-term	407,102	194,669
Receivables, net	151,551	134,154
Inventory	51,357	46,218
Prepaid expenses and other current assets	29,289	14,758
Deferred tax assets current	13,430	12,777
<b>Total current assets</b>	<b>876,793</b>	<b>570,138</b>
PROPERTY, PLANT AND EQUIPMENT, NET	265,740	274,490
INTANGIBLE ASSETS NET	479,412	537,565
GOODWILL	94,212	92,740
INVESTMENTS LONG-TERM	170,480	87,764
OTHER ASSETS	34,635	14,891
<b>TOTAL ASSETS</b>	<b>\$ 1,921,272</b>	<b>\$ 1,577,588</b>
<b>LIABILITIES AND SHAREHOLDERS' EQUITY</b>		
<b>CURRENT LIABILITIES:</b>		
Accounts payable and accrued expenses	\$ 121,258	\$ 91,173
Long-term debt short-term	6,750	6,750
Deferred revenue short-term	2,574	2,974
<b>Total current liabilities</b>	<b>130,582</b>	<b>100,897</b>
LONG-TERM DEBT	351,220	357,543
DEFERRED TAX LIABILITIES, NET LONG-TERM	18,918	29,169
DEFERRED REVENUE LONG-TERM	11,801	12,213
OTHER LONG-TERM LIABILITIES	11,914	12,580
<b>Total liabilities</b>	<b>524,435</b>	<b>512,402</b>
<b>COMMITMENTS AND CONTINGENCIES (Note 18)</b>		
<b>SHAREHOLDERS' EQUITY:</b>		
Preferred stock, par value, \$0.01 per share; 50,000,000 shares authorized; zero issued and outstanding at December 31, 2014 and 2013, respectively		
Ordinary shares, par value, \$0.01 per share; 450,000,000 shares authorized; 148,545,150 and 138,482,571 shares issued; 147,538,519 and 137,792,586 shares outstanding at December 31, 2014 and 2013, respectively	1,482	1,382
Treasury stock, at cost (1,006,631 and 689,945 shares at December 31, 2014 and 2013, respectively)	(32,052)	(17,833)
Additional paid-in capital	1,942,878	1,553,337

Edgar Filing: Alkermes plc. - Form 10-K

Accumulated other comprehensive (loss) income	(3,136)	10,574
Accumulated deficit	(512,335)	(482,274)
Total shareholders' equity	1,396,837	1,065,186
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	\$ 1,921,272	\$ 1,577,588

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

F-2

---

Table of Contents

## ALKERMES PLC AND SUBSIDIARIES

## CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE (LOSS) INCOME

Year Ended December 31, 2014, Nine Months Ended December 31, 2013 and Year Ended March 31, 2013

	Year Ended December 31, 2014	Nine Months Ended December 31, 2013	Year Ended March 31, 2013
(In thousands, except per share amounts)			
<b>REVENUES:</b>			
Manufacturing and royalty revenues	\$ 516,876	\$ 371,039	\$ 510,900
Product sales, net	94,160	57,215	58,107
Research and development revenue	7,753	4,657	6,541
<b>Total revenues</b>	<b>618,789</b>	<b>432,911</b>	<b>575,548</b>
<b>EXPENSES:</b>			
Cost of goods manufactured and sold (exclusive of amortization of acquired intangible assets shown below)	175,832	134,306	170,466
Research and development	272,043	128,125	140,013
Selling, general and administrative	199,905	116,558	125,758
Amortization of acquired intangible assets	58,153	38,428	41,852
Restructuring			12,300
Impairment of long-lived assets			3,346
<b>Total expenses</b>	<b>705,933</b>	<b>417,417</b>	<b>493,735</b>
<b>OPERATING (LOSS) INCOME</b>	<b>(87,144)</b>	<b>15,494</b>	<b>81,813</b>
<b>OTHER INCOME (EXPENSE), NET:</b>			
Interest income	1,972	711	841
Interest expense	(13,430)	(10,379)	(48,994)
Gain on sale of property, plant and equipment	41,933		
Gain on sale of investment in Civitas Therapeutics, Inc.	29,564		
Gain on sale of investment in Acceleron Pharma Inc.	15,296		
Other income (expense), net	(2,220)	(429)	1,781
<b>Total other income (expense), net</b>	<b>73,115</b>	<b>(10,097)</b>	<b>(46,372)</b>
<b>(LOSS) INCOME BEFORE INCOME TAXES</b>	<b>(14,029)</b>	<b>5,397</b>	<b>35,441</b>
<b>PROVISION (BENEFIT) FOR INCOME TAXES</b>	<b>16,032</b>	<b>(12,252)</b>	<b>10,458</b>
<b>NET (LOSS) INCOME</b>	<b>\$ (30,061)</b>	<b>\$ 17,649</b>	<b>\$ 24,983</b>
<b>(LOSS) EARNINGS PER COMMON SHARE:</b>			
Basic	\$ (0.21)	\$ 0.13	\$ 0.19
Diluted	\$ (0.21)	\$ 0.12	\$ 0.18
<b>WEIGHTED AVERAGE NUMBER OF COMMON SHARES OUTSTANDING:</b>			
Basic	145,274	135,960	131,713

Edgar Filing: Alkermes plc. - Form 10-K

Diluted		145,274		144,961		137,100
COMPREHENSIVE (LOSS) INCOME:						
Net (loss) income	\$	(30,061)	\$	17,649	\$	24,983
Unrealized (losses) gains on marketable securities, net of tax:						
Holding gains, net of tax of \$7,739, \$8,217 and none, respectively		1,586		13,092		703
Less: Reclassification adjustment for gains included in net (loss) income		(15,296)				(1,030)
Unrealized (losses) gains on marketable securities		(13,710)		13,092		(327)
Unrealized gains on derivative contracts:						
Unrealized losses on derivative contracts, net of tax of none, none and \$(194), respectively						(72)
Less: Reclassification adjustment for losses included in net (loss) income						594
Unrealized gains on derivative contracts						522
COMPREHENSIVE (LOSS) INCOME	\$	(43,771)	\$	30,741	\$	25,178

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

Table of Contents

**ALKERMES PLC AND SUBSIDIARIES**  
**CONSOLIDATED STATEMENTS OF SHAREHOLDERS' EQUITY**  
**Year Ended December 31, 2014, Nine Months Ended December 31, 2013 and Year Ended March 31, 2013**

	Ordinary Shares		Additional Paid-In Capital	Accumulated Other Comprehensive Income (Loss)		Accumulated Deficit	Treasury Stock		Total
	Shares	Amount		Shares	Amount		Shares	Amount	
(In thousands, except share data)									
BALANCE March 31, 2012	130,212,530	\$ 1,300	\$ 1,380,742	\$ (2,713)	\$ (524,906)	(35,078)	\$ (571)	\$	853,852
Issuance of ordinary shares under employee stock plans	3,852,577	38	34,322						34,360
Receipt of Alkermes' stock for the purchase of stock options or to satisfy minimum tax withholding obligations related to stock based awards						(278,419)	(4,809)		(4,809)
Share-based compensation expense			34,926						34,926
Excess tax benefit from share-based compensation			8,867						8,867
Unrealized gains on marketable securities				703					703
Unrealized loss on cash flow hedge				(72)					(72)
Reclassification of unrealized gains to realized gains				(1,030)					(1,030)
Reclassification of unrealized losses to realized losses				594					594
Net income					24,983				24,983
BALANCE March 31, 2013	134,065,107	\$ 1,338	\$ 1,458,857	\$ (2,518)	\$ (499,923)	(313,497)	\$ (5,380)	\$	952,374
Issuance of ordinary shares under employee stock plans	4,417,464	44	49,033						49,077
Receipt of Alkermes' stock for the purchase of stock options or to satisfy minimum tax withholding obligations related to stock based awards			788			(376,448)	(12,453)		(11,665)
Share-based compensation expense			33,265						33,265
Excess tax benefit from share-based compensation			11,394						11,394
Unrealized gains on marketable securities, net of tax of \$8,217				13,092					13,092
Net income					17,649				17,649
BALANCE December 31, 2013	138,482,571	\$ 1,382	\$ 1,553,337	\$ 10,574	\$ (482,274)	(689,945)	\$ (17,833)	\$	1,065,186
Issuance of ordinary shares, net	5,917,160	59	248,347						248,406
Issuance of ordinary shares under employee stock plans	4,145,419	41	47,536						47,577
Receipt of Alkermes' stock for the purchase of stock options or to satisfy minimum tax withholding obligations related to stock based awards			1,379			(316,686)	(14,219)		(12,840)
Share-based compensation expense			59,912						59,912
Excess tax benefit from share-based compensation			32,367						32,367
Unrealized gains on marketable securities, net of tax of \$7,739				(13,710)					(13,710)
Net loss					(30,061)				(30,061)
BALANCE December 31, 2014	148,545,150	\$ 1,482	\$ 1,942,878	\$ (3,136)	\$ (512,335)	(1,006,631)	\$ (32,052)	\$	1,396,837

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





Table of Contents

## ALKERMES PLC AND SUBSIDIARIES

## CONSOLIDATED STATEMENTS OF CASH FLOWS

Year Ended December 31, 2014, Nine Months Ended December 31, 2013 and Year Ended March 31, 2013

	Year Ended December 31, 2014	Nine Months Ended December 31, 2013	Year Ended March 31, 2013
	(In thousands)		
<b>CASH FLOWS FROM OPERATING ACTIVITIES:</b>			
Net (loss) income	\$ (30,061)	\$ 17,649	\$ 24,983
Adjustments to reconcile net (loss) income to cash flows from operating activities:			
Depreciation and amortization	98,087	70,765	73,751
Share-based compensation expense	59,579	33,409	34,716
(Gain) loss on sale of property, plant and equipment	(40,099)	129	373
Excess tax benefit from share-based compensation	(32,367)	(11,394)	(8,867)
Gain on sale of investment in Civitas Therapeutics, Inc.	(29,564)		
Deferred income taxes	(19,192)	(15,393)	(2,113)
Gain on sale of investment in Acceleron Pharmaceuticals, Inc.	(15,296)		
Impairment of long-lived assets			3,346
Loss on debt refinancing transaction			19,670
Prepayment penalty in connection with debt refinancing			(6,533)
Principal payments on long-term debt attributable to original issue discount			(2,657)
Other non-cash charges	9,192	(5,860)	5,325
Changes in assets and liabilities:			
Receivables	(17,397)	(9,534)	(28,239)
Inventory, prepaid expenses and other assets	(31,237)	(6,345)	(6,577)
Accounts payable and accrued expenses	56,896	16,126	19,406
Deferred revenue	(996)	4,051	(3,351)
Other long-term liabilities	3,594	(1,382)	3,318
Cash flows provided by operating activities	11,139	92,221	126,551
<b>CASH FLOWS FROM INVESTING ACTIVITIES:</b>			
Additions of property, plant and equipment	(33,651)	(19,054)	(22,217)
Proceeds from the sale of equipment	44,365	52	193
Investment in Civitas Therapeutics, Inc.	27,190	(1,191)	
Promissory note issued to Civitas Therapeutics, Inc.			(1,116)
Purchases of investments	(642,455)	(135,643)	(303,945)
Sales and maturities of investments	341,154	90,470	258,937
Cash flows used in investing activities	(263,397)	(65,366)	(68,148)
<b>CASH FLOWS FROM FINANCING ACTIVITIES:</b>			
Proceeds from the issuance of ordinary shares, net	248,406		
Proceeds from the issuance of ordinary shares under share-based compensation arrangements	47,577	49,077	34,360
Excess tax benefit from share-based compensation	32,367	11,394	8,867
Proceeds from the issuance of long-term debt			366,483
Employee taxes paid related to net share settlement of equity awards	(12,840)	(11,665)	(4,809)
Principal payments of long-term debt	(6,750)	(5,060)	(449,944)
Cash flows provided by (used in) financing activities	308,760	43,746	(45,043)
NET INCREASE IN CASH AND CASH EQUIVALENTS	56,502	70,601	13,360
CASH AND CASH EQUIVALENTS Beginning of period	167,562	96,961	83,601
CASH AND CASH EQUIVALENTS End of period	\$ 224,064	\$ 167,562	\$ 96,961

## Edgar Filing: Alkermes plc. - Form 10-K

### SUPPLEMENTAL CASH FLOW DISCLOSURE:

Cash paid for interest	\$	12,489	\$	9,596	\$	7,656
Cash paid for taxes	\$	2,799	\$	704	\$	5,921
Non-cash investing and financing activities:						
Purchased capital expenditures included in accounts payable and accrued expenses	\$	3,483	\$	1,969	\$	2,450
Investment in Civitas Therapeutics, Inc.	\$		\$	1,160	\$	

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

F-5

---

Table of Contents

**ALKERMES PLC AND SUBSIDIARIES**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**1. DESCRIPTION OF BUSINESS AND BASIS OF PRESENTATION**

Alkermes plc (the "Company") is a fully integrated, global biopharmaceutical company that applies its scientific expertise and proprietary technologies to research, develop and commercialize, both with partners and on its own, pharmaceutical products that are designed to address unmet medical needs of patients in major therapeutic areas. The Company has a diversified portfolio of more than 20 commercial drug products and a clinical pipeline of product candidates that address central nervous system ("CNS") disorders such as addiction, schizophrenia and depression. Headquartered in Dublin, Ireland, the Company has a research and development ("R&D") center in Waltham, Massachusetts; R&D and manufacturing facilities in Athlone, Ireland; and manufacturing facilities in Gainesville, Georgia and Wilmington, Ohio.

*Change in Fiscal Year*

On May 21, 2013, the Company's Audit and Risk Committee, with such authority delegated to it by the Company's Board of Directors, approved a change to its fiscal year-end from March 31 to December 31. This Annual Report reflects the Company's financial results for the twelve month period from January 1, 2014 through December 31, 2014. The period ended December 31, 2013 reflects the Company's financial results for the nine month period from April 1, 2013 through December 31, 2013 (the "Transition Period"). The period ended March 31, 2013 reflects the Company's financial results for the twelve month period from April 1, 2012 to March 31, 2013.

**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; Daravita Limited; Daravita Pharma Ireland Limited; Alkermes Science Four Limited; Alkermes Science Five Limited; Alkermes Pharma Ireland Limited; Alkermes U.S. Holdings, Inc.; Alkermes, Inc.; Eagle Holdings USA, Inc.; Alkermes Controlled Therapeutics, Inc.; Alkermes Europe, Ltd.; Alkermes Gainesville LLC; Alkermes Science Six Limited; Alkermes Finance Ireland Limited; Alkermes Finance S.à r.l.; Alkermes Finance Ireland (No. 2) Limited; and Alkermes Finance Ireland (No. 3) Limited. Intercompany accounts and transactions have been eliminated.

*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, 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.

Table of Contents

**ALKERMES PLC AND SUBSIDIARIES**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)**

***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 so near their maturity, generally three months from the date of purchase, that they present insignificant risk of change in value because of interest rate changes 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 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 December 31, 2014, substantially all these investments are classified as available-for-sale and are recorded at fair value.

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

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

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 long-term", in the accompanying consolidated balance sheets.

***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

Table of Contents

**ALKERMES PLC AND SUBSIDIARIES**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)**

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 at December 31, 2014 include U.S. treasury securities. At December 31, 2013, the Company had investments in money market funds, U.S. treasury securities and the common stock of a publicly-traded company that utilized Level 1 inputs;

*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 and liabilities utilizing Level 2 inputs include U.S. government agency debt securities, debt securities issued by foreign agencies and backed by foreign governments and investments in corporate debt securities that are trading in the credit markets. At December 31, 2013, the Company had an interest rate swap contract that utilized Level 2 inputs; and

*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. During the nine months ended December 31, 2013, the Company's Level 3 investment consisted of warrants to purchase the common stock of a publicly-traded company.

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

***Inventory***

Inventory is stated at the lower of cost or market value. Cost is determined using the first-in, first-out method. Included in inventory are raw materials used in production of pre-clinical and clinical products, which have alternative future use and are charged to R&D expense when consumed. The cost elements included within inventory include three primary categories for commercial products: cost of raw materials; direct labor; and overhead. Overhead is based on the normal capacity of the Company's production facilities and does not include costs from abnormally low production or idle capacity, which are expensed directly to the consolidated statement of operations.

***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

Table of Contents**ALKERMES PLC AND SUBSIDIARIES****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)****2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)**

renewals and improvements are capitalized. Depreciation is calculated using the straight-line method over the following estimated useful lives of the assets:

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

***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 consists solely of goodwill created as a result of the Company's acquisition of Elan Drug Technologies ("EDT") from Elan Corporation, plc in September 2011 and has been assigned to one reporting unit. A reporting unit is an operating segment or sub-segment to which goodwill is assigned when initially recorded.

Goodwill is not amortized but is reviewed for impairment on an annual basis, as of October 31, and whenever events or changes in circumstances indicate that the carrying value of the goodwill might not be recoverable. The Company has the option to first assess qualitative factors to determine whether it is necessary to perform the two-step impairment test. If the Company elects this option and believes, as a result of the qualitative assessment, that it is more-likely-than-not that the fair value of its reporting unit is less than its carrying amount, the quantitative two-step impairment test is required; otherwise, no further testing is required. Alternatively, the Company may elect to not first assess qualitative factors and immediately perform the quantitative two-step impairment test. In the first step, the Company compares the fair value of its reporting unit to its carrying value. If the carrying value of the net assets assigned to the reporting unit exceeds the fair value of its reporting unit, then the second step of the impairment test is performed in order to determine the implied fair value of the Company's reporting unit's goodwill. If the carrying value of the Company's reporting unit's goodwill exceeds its implied fair value, then the Company would record an impairment loss equal to the difference.

The Company performed its annual goodwill impairment test as of October 31, 2014. The Company elected to assess qualitative factors to determine whether it was necessary to perform the two-step impairment test. Based on the weight of all available evidence, the Company determined that the fair value of the reporting unit more-likely-than-not exceeded its carrying value.

The Company's finite-lived intangible assets consist of core developed technology and collaboration agreements acquired as part of the acquisition of EDT, were recorded at fair value at the time of their acquisition and are stated within the Company's consolidated balance sheets net of accumulated amortization and impairments. The finite-lived intangible assets are amortized over their estimated useful lives 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.

Table of Contents**ALKERMES PLC AND SUBSIDIARIES****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)****2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)***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.

*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 manufacturing facility located in Chelsea, Massachusetts, which it presently subleases. The carrying amount of the asset retirement obligation at December 31, 2014 and 2013 was \$2.4 million and \$2.2 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 at December 31, 2014 and 2013:

<b>(In thousands)</b>	<b>Carrying Amount</b>
Balance, April 1, 2013	\$ 2,049
Accretion expense	151
Balance, December 31, 2013	\$ 2,200
Accretion expense	220
Balance, December 31, 2014	\$ 2,420

*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® and AstraZeneca for BYDUREON®. Substantially all of the products developed under the Company's collaborative arrangements are currently being marketed as approved products. The Company receives payments for manufacturing services and/or royalties on product sales.

*Manufacturing revenues* The Company recognizes manufacturing revenues from the sale of products it manufactures for resale by its collaborative partners. Manufacturing revenues are recognized

Table of Contents

**ALKERMES PLC AND SUBSIDIARIES**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)**

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. The sales price for certain of the Company's manufacturing revenues is based on the end-market sales price earned by its collaborative partners. As the end-market sale occurs after the Company has shipped its product and the risk of loss has passed to its collaborative partner, the Company estimates the sales price for its product based on information supplied to it by the Company's collaborative partners, its historical transaction experience and other third-party data. Differences between the actual manufacturing revenues and estimated manufacturing revenues are reconciled and adjusted for in the period in which they become known, which is generally the following quarter. The difference between actual and estimated manufacturing revenues has not been material.

*Royalty revenues* The Company recognizes royalty revenues related to the sale of products by its collaborative partners that incorporates the Company's technologies. Royalties, with the exception of those from AMPYRA, 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. Royalties on AMPYRA are earned in the period the product is shipped to Acorda. 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, which is generally the following quarter. The difference between actual and estimated royalty revenues has not been material.

*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 with its collaborative partners. The Company generally bills its collaborative partners under R&D arrangements using a full-time equivalent ("FTE") or hourly rate, plus direct external costs, if any.

Certain 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," and are recognized in their entirety in the period in which the milestone is achieved. Consideration received from the achievement of milestones that are not considered to be "substantive milestones" are recognized under the proportional performance method whereby revenue is limited to the lesser of the cumulative amount of payments received or the cumulative amount of revenue earned.

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.



**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:

*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. 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 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 the Company the difference between the price initially paid by the wholesaler and the contracted price paid to the wholesaler 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;

*Product Discounts* 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. To date, actual product discounts have not differed materially from the Company's estimates;

*Co-pay Assistance* the Company has a program whereby a patient can receive up to \$500 per month toward their co-payment, co-insurance or deductible, provided the patient meets certain eligibility criteria. Reserves are recorded upon the sale of VIVITROL. To date, actual co-pay assistance has not differed materially from the Company's estimates; and

*Product Returns* in August 2012, the Company changed the way in which revenue is recognized on VIVITROL product sales. Prior to August 1, 2012, the Company did not have sufficient history to reasonably estimate returns related to VIVITROL shipments and, therefore, the Company deferred the recognition of revenue on shipments of VIVITROL until the product left the distribution channel. In August 2012, it was determined there was sufficient history to reliably estimate returns, and revenue on the sales of VIVITROL is now recognized upon delivery to wholesalers, distributors and pharmacies, which is the point in time the customer assumes the risks and rewards of ownership. This change in the method of revenue recognition resulted in a one-time \$1.7 million increase to "Product sales, net" in the accompanying consolidated statements of operations and comprehensive (loss) income, which was recognized during the year ended March 31, 2013. Based on this revised revenue recognition policy, a reserve is now estimated for future product returns on VIVITROL gross product sales. This estimate is based on historical return rates as well as specifically identified anticipated returns due to known business conditions and product

Table of Contents

**ALKERMES PLC AND SUBSIDIARIES**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)**

expiry dates. Return amounts are recorded as a deduction to arrive at VIVITROL product sales, net. Once VIVITROL is returned, it is destroyed. At December 31, 2014, the product return reserve was estimated to be approximately 2% of product sales and amounted to \$5.5 million.

Other

The Company recognizes revenues from the license and the sale of intellectual property, deemed to have standalone value, when persuasive evidence of an arrangement exists, delivery has occurred, the sales price is fixed or determinable and collectibility is reasonably assured. The Company considers delivery to have occurred when the buyer has use of, and is able to benefit from, the intellectual property and the Company has no remaining obligations under the arrangement.

***Risk-Management Instruments***

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. At December 31, 2013, the Company's risk management instruments consisted of an interest rate swap agreement which expired during the year ended December 31, 2014. The objective of the interest rate swap agreement was to limit the impact of fluctuations in interest rates in earnings related to the Company's long-term debt. Refer to Note 11, *Derivative Instruments*, for additional information related to the Company's risk management instruments.

***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), net" in the accompanying consolidated statements of operations and comprehensive (loss) income. During the year ended December 31, 2014, the nine months ended December 31, 2013 and the year ended March 31, 2013, the Company recorded a gain on foreign currency translation of \$0.6 million, \$0.2 million and \$0.1 million, 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 December 31, 2014,

Table of Contents

## ALKERMES PLC AND SUBSIDIARIES

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

## 2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

2013 and March 31, 2013 and for the year ended December 31, 2014, the nine months ended December 31, 2013 and the year ended March 31, 2013:

Customer	Year Ended December 31, 2014		Nine Months Ended December 31, 2013		Year Ended March 31, 2013	
	Receivables	Revenue	Receivables	Revenue	Receivables	Revenue
Janssen	44%	41%	46%	44%	32%	35%
Acorda	17%	13%	12%	12%	15%	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.

*Geographic Information*

Company revenues by geographic location, as determined by the location of the customer, and the location of its assets, are as follows:

(In thousands)	Year Ended December 31, 2014		Nine Months Ended December 31, 2013		Year Ended March 31, 2013	
Revenue by region:						
U.S.	\$	398,189	\$	269,005	\$	380,565
Ireland		7,691		5,722		14,455
Rest of world		212,909		158,184		180,528
Assets by region:						
Current assets:						
U.S.	\$	385,715	\$	382,571	\$	248,441
Ireland		490,577		187,023		159,544
Rest of world		501		544		603
Long-term assets:						
U.S.:						
Intangible assets	\$		\$		\$	
Goodwill		3,677		3,677		3,677
Other		228,693		225,559		229,691
Ireland:						
Intangible assets	\$	479,412	\$	537,565	\$	575,993
Goodwill		90,535		89,063		89,063
Other		242,162		151,586		163,279

F-14

Table of Contents

**ALKERMES PLC AND SUBSIDIARIES**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)**

*Research and Development Expenses*

For each of its R&D programs, the Company incurs both external and internal expenses. External R&D expenses include costs related to clinical and non-clinical activities performed by contract research organizations, consulting fees, laboratory services, purchases of drug product materials and third-party manufacturing development costs. Internal R&D expenses include employee-related expenses, occupancy costs, depreciation and general overhead. The Company tracks external R&D expenses for each of its development programs, however, internal R&D expenses are not tracked by individual program as they benefit multiple programs or its technologies in general.

*Selling, General and Administrative Expenses*

Selling, general and administrative expenses are primarily comprised of compensation and benefits associated with sales and marketing, finance, human resources, legal, information technology and other administrative personnel, outside marketing, advertising and legal expenses and other general and administrative costs.

Advertising costs are expensed as incurred. During the year ended December 31, 2014, the nine months ended December 31, 2013 and the year ended March 31, 2013, advertising costs totaled \$8.6 million, \$5.3 million and \$6.0 million, respectively.

*Share-Based Compensation*

The Company's share-based compensation programs grant awards which include stock options and restricted stock units ("RSUs"), which vest with the passage of time and, to a limited extent, vest based on the achievement of certain performance or market criteria. The Company issues new shares upon stock option exercise or the vesting of RSUs. 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 or upon meeting the retirement eligibility criteria, whichever is later.

*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

Table of Contents**ALKERMES PLC AND SUBSIDIARIES****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)****2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)**

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 share 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 is equal to the closing price of the Company's ordinary shares traded on the NASDAQ Global Select Stock 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 December 31, 2014	Nine Months Ended December 31, 2013	Year Ended March 31, 2013
Expected option term	5 - 7 years	5 - 7 years	5 - 7 years
Expected stock volatility	39% - 46%	45% - 48%	47% - 49%
Risk-free interest rate	1.46% - 2.24%	0.75% - 2.15%	0.61% - 1.18%
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 equal to the closing price of the Company's ordinary shares traded on the NASDAQ Global Select Stock Market 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 has RSUs that vest upon the achievement of certain performance criteria. The estimated fair value of these RSUs is based on the market value of the Company's stock on the date of grant. 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 estimate outcome of performance-related conditions until the date results are determined.

*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

Table of Contents

**ALKERMES PLC AND SUBSIDIARIES**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)**

enactment date. 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.

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) Income***

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

***(Loss) Earnings Per Share***

Basic (loss) earnings per share is calculated based upon net (loss) income available to holders of ordinary shares divided by the weighted average number of ordinary shares outstanding. For the calculation of diluted earnings per share, the Company uses the weighted average number of ordinary 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 ("IRS") limitations. The Company

Table of Contents

**ALKERMES PLC AND SUBSIDIARIES**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)**

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 year ended December 31, 2014, the nine months ended December 31, 2013 and the year ended March 31, 2013, the Company contributed \$4.7 million, \$3.1 million and \$4.1 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%, depending upon their age, of their total taxable earnings subject to an earnings cap of €115,000. The Company provides a match of up to 18% of taxable earnings depending upon an individual's contribution level. During the year ended December 31, 2014, the nine months ended December 31, 2013 and the year ended March 31, 2013, the Company contributed \$3.7 million, \$2.9 million and \$3.7 million, respectively, in contributions to the defined contribution plan.

*Reclassifications*

At December 31, 2014, the Company elected to display "Deferred tax assets - current" separately rather than include it as a component of "Prepaid expenses and other current assets." Accordingly, the balance of \$12.8 million that was previously classified within "Prepaid expenses and other current assets" at December 31, 2013 has been reclassified to "Deferred tax assets - current" in the accompanying consolidated balance sheets.

*New Accounting Pronouncements*

From time to time, new accounting pronouncements are issued by the Financial Accounting Standards Board ("FASB") or other standard-setting bodies that are adopted by the Company as of the specified effective date. Unless otherwise discussed, the Company believes that the impact of recently issued standards that are not yet effective will not have a material impact on its financial position or results of operations upon adoption.

In July 2013, the FASB adopted clarifying guidance on the presentation of unrecognized tax benefits when various qualifying tax credits exist. The amendment requires that unrecognized tax benefits be presented on the consolidated balance sheet as a reduction to deferred tax assets created by net operating losses ("NOLs") or other tax credits from prior periods that occur in the same taxing jurisdiction. To the extent that the unrecognized tax benefit exceeds these NOLs or other tax credits, it shall be presented as a liability. This update, required to be adopted for all annual periods and interim reporting periods beginning after December 15, 2013, was adopted by the Company on January 1, 2014. The adoption of this standard did not have a material impact on the presentation of the Company's financial position.

In April 2014, the FASB adopted guidance that amends the requirements for reporting discontinued operations. Under the amendment, only those disposals of components of an entity that represent a strategic shift that has (or will have) a major effect on an entity's operations and financial results will be reported as discontinued operations in the financial statements. Currently, many disposals, some of which may be routine in nature and not a change in an entity's strategy, are reported in discontinued operations. The guidance also requires expanded disclosures for discontinued

Table of Contents

**ALKERMES PLC AND SUBSIDIARIES**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)**

operations. This guidance became effective for the Company on January 1, 2015 and is not expected to have a material impact on the Company's results of operations, cash flows or financial condition.

In June 2014, the FASB issued guidance that clarifies the accounting for share-based payments when the terms of an award provide that a performance target could be achieved after the requisite service period. Existing GAAP does not contain explicit guidance on how to account for these share-based payments. The new guidance requires that a performance target that affects vesting and that could be achieved after the requisite service period be treated as a performance condition. Entities have the option of prospectively applying the guidance to awards granted or modified after the effective date or retrospectively applying the guidance to all awards with performance targets that are outstanding as of the beginning of the earliest annual period presented in the financial statements. The guidance becomes effective for the Company in its year ending December 31, 2016, and early adoption is permitted. The Company is currently assessing the impact that this standard will have on its consolidated financial statements.

In May 2014, the FASB issued guidance that outlines a single comprehensive model for entities to use in accounting for revenue arising from contracts with customers and supersedes most current revenue recognition guidance, including industry-specific guidance. The guidance is based on the principle that an entity should recognize revenue to depict the transfer of goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. The guidance also requires additional disclosure about the nature, amount, timing and uncertainty of revenue and cash flows arising from customer contracts, including significant judgments and changes in judgments and assets recognized from costs incurred to fulfill a contract. Entities have the option of using either a full retrospective or a modified retrospective approach for the adoption of the new standard. The guidance becomes effective for the Company in its year ending December 31, 2017, and early adoption is not permitted. The Company is currently assessing the impact that this standard will have on its consolidated financial statements.



Table of Contents

## ALKERMES PLC AND SUBSIDIARIES

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

## 3. INVESTMENTS

Investments consist of the following:

	Amortized Cost	Gains	Gross Unrealized Losses		Estimated Fair Value
			Less than One Year	Greater than One Year	
<b>December 31, 2014</b>					
Short-term investments:					
Available-for-sale securities:					
U.S. government and agency debt securities	\$ 226,387	\$ 88	\$ (15)	\$	\$ 226,460
Corporate debt securities	140,900	26	(66)		140,860
International government agency debt securities	39,774	13	(5)		39,782
<b>Total short-term investments</b>	<b>407,061</b>	<b>127</b>	<b>(86)</b>		<b>407,102</b>
Long-term investments:					
Available-for-sale securities:					
U.S. government and agency debt securities	100,429		(196)	(40)	100,193
Corporate debt securities	61,187		(84)		61,103
International government agency debt securities	7,568		(2)	(1)	7,565
	169,184		(282)	(41)	168,861
Held-to-maturity securities:					
Certificates of deposit	1,619				1,619
<b>Total long-term investments</b>	<b>170,803</b>		<b>(282)</b>	<b>(41)</b>	<b>170,480</b>
<b>Total investments</b>	<b>\$ 577,864</b>	<b>\$ 127</b>	<b>\$ (368)</b>	<b>\$ (41)</b>	<b>\$ 577,582</b>

**December 31, 2013**

Short-term investments:					
Available-for-sale securities:					
U.S. government and agency debt securities	\$ 130,669	\$ 80	\$ (1)	\$	\$ 130,748
Corporate debt securities	38,614	64	(30)		38,648
International government agency debt securities	24,097	8	(33)		24,072
	193,380	152	(64)		193,468
Money market funds	1,201				1,201
<b>Total short-term investments</b>	<b>194,581</b>	<b>152</b>	<b>(64)</b>		<b>194,669</b>
Long-term investments:					
Available-for-sale securities:					

Edgar Filing: Alkermes plc. - Form 10-K

Equity securities	8,732	21,253			29,985
U.S. government and agency debt securities	28,503		(61)	(3)	28,439
Corporate debt securities	20,266		(30)	(75)	20,161
International government agency debt securities	7,691		(5)		7,686
	65,192	21,253	(96)	(78)	86,271
Held-to-maturity securities:					
Certificates of deposit	1,493				1,493
Total long-term investments	66,685	21,253	(96)	(78)	87,764
Total investments	\$ 261,266	\$ 21,405	\$ (160)	\$ (78)	\$ 282,433

F-20

---

Table of Contents

## ALKERMES PLC AND SUBSIDIARIES

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

## 3. INVESTMENTS (Continued)

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

(In thousands)	Year Ended December 31, 2014	Nine Months Ended December 31, 2013	Year Ended March 31, 2013
Proceeds from the sales and maturities of marketable securities	\$ 341,154	\$ 90,470	\$ 258,937
Realized gains	\$ 15,364	\$ 16	\$ 39
Realized losses	\$ (31)	\$	\$ (5)

During the year ended December 31, 2014, the Company sold its investment in Acceleron Pharma Inc. ("Acceleron"), which consisted of common stock and warrants to purchase the common stock of Acceleron. The Company received net proceeds of \$24.0 million and realized a gain of \$15.3 million from the sale of this investment. The Company reclassified the gain from accumulated other comprehensive (loss) income to gain on sale of investment in Acceleron in its consolidated statements of operations and comprehensive (loss) income.

The Company's available-for-sale and held-to-maturity securities at December 31, 2014 had 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	\$ 323,500	\$ 323,475	\$ 1,619	\$ 1,619
After 1 year through 5 years	252,745	252,488		
Total	\$ 576,245	\$ 575,963	\$ 1,619	\$ 1,619

At December 31, 2014, the Company believed that the unrealized losses on its available-for-sale investments were temporary. The investments with unrealized losses consisted primarily of corporate debt securities and U.S. Government and agency 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; 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 Civitas Therapeutics, Inc. ("Civitas") was zero and \$2.0 million at December 31, 2014 and December 31, 2013, respectively, which was recorded within "Other Assets" in the accompanying consolidated balance sheets. In October 2014, Civitas was acquired by Acorda for \$525.0 million. As a result of this transaction, the Company received \$27.2 million and has the right to receive up to an additional \$2.4 million, subject to release of all amounts held in escrow, for its approximate 6% equity interest in Civitas. Prior to its acquisition by Acorda, the Company's investment in Civitas consisted of various issues of preferred stock, certain of which were accounted for under the cost method or equity method, depending upon if the preferred stock was considered to be "in-substance" common stock and the Company's belief that it may have been able to exercise

Table of Contents**ALKERMES PLC AND SUBSIDIARIES****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)****3. INVESTMENTS (Continued)**

significant influence over the operating and financial policies of Civitas. During the year ended December 31, 2014, the nine months ended December 31, 2013 and the year ended March 31, 2013, the Company recorded a reduction in its investment in Civitas of \$6.8 million, \$1.2 million and \$1.2 million, respectively, which represented the Company's proportionate share of Civitas' net losses for these periods.

In May 2014, the Company entered into an agreement whereby it is committed to provide up to €7.4 million to a partnership, Fountain Healthcare Partners II, L.P. of Ireland ("Fountain"), which was created to carry on the business of investing exclusively in companies and businesses engaged in healthcare, pharmaceutical and life sciences sectors. The Company's commitment represents approximately 10% of the partnership's total funding, and the Company is accounting for its investment in Fountain under the equity method. At December 31, 2014, the Company had made payments of, and its investment is equal to, \$1.2 million (€0.9 million), which is included within "Other assets" in the accompanying consolidated balance sheets. During the year ended December 31, 2014, the Company recorded a reduction in its investment in Fountain of \$0.1 million, which represented the Company's proportionate share of Fountain's net loss for this period.

**4. FAIR VALUE**

The following table presents information about the Company's assets and liabilities 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)	<b>December 31,</b>			
	<b>2014</b>	<b>Level 1</b>	<b>Level 2</b>	<b>Level 3</b>
<b>Assets:</b>				
U.S. government and agency debt securities	\$ 326,653	\$ 189,030	\$ 137,623	\$
Corporate debt securities	201,963		201,963	
International government agency debt securities	47,347		47,347	
<b>Total</b>	<b>\$ 575,963</b>	<b>\$ 189,030</b>	<b>\$ 386,933</b>	<b>\$</b>

Table of Contents

## ALKERMES PLC AND SUBSIDIARIES

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

## 4. FAIR VALUE (Continued)

	December 31, 2013	Level 1	Level 2	Level 3
<b>Assets:</b>				
Cash equivalents	\$ 1,201	\$ 1,201	\$	\$
U.S. government and agency debt securities	159,187	63,213	95,974	
Corporate debt securities	58,809		58,809	
International government agency debt securities	31,758		31,758	
Equity securities	29,985	28,459		1,526
<b>Total</b>	<b>\$ 280,940</b>	<b>\$ 92,873</b>	<b>\$ 186,541</b>	<b>\$ 1,526</b>
<b>Liabilities:</b>				
Interest rate swap contract	\$ (275)	\$	\$ (275)	\$
<b>Total</b>	<b>\$ (275)</b>	<b>\$</b>	<b>\$ (275)</b>	<b>\$</b>

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.

There were no transfers of any securities from Level 1 to Level 2 or from Level 2 to Level 1 during the year ended December 31, 2014. 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 December 31, 2014:

(In thousands)	Fair Value
Balance, January 1, 2014	\$ 1,526
Total unrealized losses included in other comprehensive (loss) income	(383)
Sale of equity securities	(1,143)
Balance, December 31, 2014	\$

During the year ended December 31, 2014, the Company sold its Level 3 investment, which consisted of warrants to purchase the common stock of Acceleron.

The Company's investments in U.S. government and agency debt securities, international government agency debt securities and corporate debt securities classified as Level 2 within the fair value hierarchy 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 included reportable trades, benchmark yields, credit spreads, broker/dealer quotes, bids, offers, current spot rates and other industry and economic events. The Company validated 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 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. The fair value of the remaining financial

## Edgar Filing: Alkermes plc. - Form 10-K

instruments not currently recognized at fair value on the Company's consolidated balance sheets consisted of the \$300.0 million, seven-year term loan bearing interest at LIBOR plus 2.75% with a LIBOR floor of 0.75% ("Term Loan B-1") and the \$75.0 million, four-year term loan bearing interest at LIBOR plus 2.75%, with no LIBOR floor ("Term Loan B-2" and together with Term Loan B-1, the "Term Loan Facility"). The

F-23

---

Table of Contents

## ALKERMES PLC AND SUBSIDIARIES

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

**4. FAIR VALUE (Continued)**

estimated fair value of these term loans, which was based on quoted market price indications (Level 2 in the fair value hierarchy) and may not be representative of actual values that could have been or will be realized in the future, was as follows at December 31, 2014:

(In thousands)	Carrying Value	Estimated Fair Value
Term Loan B-1	\$ 291,476	\$ 289,218
Term Loan B-2	\$ 66,494	\$ 65,897

**5. INVENTORY**

Inventory consists of the following:

(In thousands)	December 31, 2014	December 31, 2013
Raw materials	\$ 21,101	\$ 18,410
Work in process	14,824	15,581
Finished goods(1)	15,432	12,227
Total inventory	\$ 51,357	\$ 46,218

(1)

At December 31, 2014 and December 31, 2013, the Company had \$4.4 million and \$1.1 million, respectively, of finished goods inventory located at its third-party warehouse and shipping service provider.

**6. PROPERTY, PLANT AND EQUIPMENT**

Property, plant and equipment consist of the following:

(In thousands)	December 31, 2014	December 31, 2013
Land	\$ 8,163	\$ 8,440
Building and improvements	149,158	148,044
Furniture, fixture and equipment	225,834	220,984
Leasehold improvements	12,971	23,980
Construction in progress	39,774	26,688
Subtotal	435,900	428,136
Less: accumulated depreciation	(170,160)	(153,646)
Total property, plant and equipment, net	\$ 265,740	\$ 274,490

In April 2014, the Company sold certain of its land, buildings and equipment at its Athlone, Ireland facility that had a carrying value of \$2.2 million, in exchange for \$17.5 million. \$3.0 million of the sale proceeds will remain in escrow pending the completion of certain additional services the Company is obligated to perform, and will be recognized as "Gain on sale of property, plant and equipment" as the services are

Edgar Filing: Alkermes plc. - Form 10-K

provided. In October 2014, the Company sold certain commercial-scale pulmonary manufacturing equipment located at its Chelsea, Massachusetts manufacturing facility, which

F-24

---



Table of Contents**ALKERMES PLC AND SUBSIDIARIES****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)****6. PROPERTY, PLANT AND EQUIPMENT (Continued)**

had a carrying value of \$0.4 million in exchange for \$30.0 million. The gain of \$29.6 million resulting from this transaction is included in "Gain on sale of property, plant and equipment" in the accompanying statements of operations and comprehensive (loss) income.

Depreciation expense was \$39.9 million, \$32.3 million and \$31.9 million for the year ended December 31, 2014, the nine months ended December 31, 2013 and the year ended March 31, 2013, respectively. Also, during the year ended December 31, 2014, the nine months ended December 31, 2013 and the year ended March 31, 2013, the Company wrote off furniture, fixtures and equipment that had a carrying value of \$1.4 million, less than \$0.1 million and less than \$0.1 million, respectively, at the time of disposition.

Amounts included as construction in progress in the consolidated balance sheets primarily include capital expenditures at the Company's manufacturing facility 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. The Company continues to periodically evaluate whether facts and circumstances indicate that the carrying value of its long-lived assets to be held and used may not be recoverable.

**7. GOODWILL AND INTANGIBLE ASSETS**

Goodwill and intangible assets consist of the following:

(In thousands)	Weighted Amortizable Life	Year Ended December 31, 2014			Nine Months Ended December 31, 2013		
		Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount	Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount
Goodwill		\$ 94,212	\$	\$ 94,212	\$ 92,740	\$	\$ 92,740
Finite-lived intangible assets:							
Collaboration agreements	12	\$ 499,700	\$ (127,393)	\$ 372,307	\$ 499,700	\$ (80,655)	\$ 419,045
NanoCrystal technology	13	74,600	(13,243)	61,357	74,600	(8,506)	66,094
OCR technologies	12	66,300	(20,552)	45,748	66,300	(13,874)	52,426
Total		640,600	(161,188)	479,412	640,600	(103,035)	537,565

The Company's finite-lived intangible assets consist of collaborative agreements and the NanoCrystal and OCR technologies acquired as part of the EDT acquisition. The Company recorded \$58.2 million, \$38.4 million and \$41.9 million of amortization expense related to its finite-lived intangible assets during the year ended December 31, 2014, the nine months ended December 31, 2013 and the year ended March 31, 2013, respectively. Based on the Company's most recent analysis, amortization of intangible assets included within its consolidated balance sheets at December 31, 2014 is expected to be approximately \$65.0 million, \$70.0 million, \$70.0 million, \$70.0 million and \$60.0 million in the years ending December 31, 2015 through 2019, respectively. Although the Company believes such available information and assumptions are reasonable, given the inherent risks and uncertainties underlying its expectations regarding such future revenues, there is the potential for the Company's actual results to vary significantly from such expectations. If revenues are projected to change, the related amortization of the intangible assets will change in proportion to the change in revenues.



Table of Contents

## ALKERMES PLC AND SUBSIDIARIES

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

## 8. ACCOUNTS PAYABLE AND ACCRUED EXPENSES

Accounts payable and accrued expenses consist of the following:

(In thousands)	December 31, 2014	December 31, 2013
Accounts payable	\$ 32,335	\$ 19,493
Accrued compensation	36,854	28,101
Accrued restructuring	2,004	7,296
Accrued other	50,065	36,283
<b>Total accounts payable and accrued expenses</b>	<b>\$ 121,258</b>	<b>\$ 91,173</b>

## 9. RESTRUCTURING

On April 4, 2013, the Company approved a restructuring plan at its Athlone, Ireland manufacturing facility consistent with the evolution of the Company's product portfolio and designed to improve operational performance for the future. The restructuring plan calls for the Company to terminate manufacturing services for certain older products that are expected to no longer be economically practicable to produce due to decreasing demand from its customers resulting from generic competition. The Company expects to continue to generate revenues from the manufacturing of these products into the year ending December 31, 2015.

As a result of the termination of these services, it was contemplated that the Company would also implement a corresponding reduction in headcount of up to 130 employees. In connection with this restructuring plan, during the year ended March 31, 2013, the Company recorded a restructuring charge of \$12.3 million, which consisted of severance and outplacement services. The Company has paid in cash \$11.1 million and recorded an adjustment of \$0.1 million due to changes in foreign currency since inception of this restructuring plan. Restructuring activity during the year ended December 31, 2014 was as follows:

(In thousands)	Severance and Outplacement Services
Balance, January 1, 2014	\$ 10,578
Payments	(8,772)
Adjustments	(478)
<b>Balance, December 31, 2014</b>	<b>\$ 1,328</b>

At December 31, 2014 and 2013, \$1.3 million and \$6.8 million, respectively, of this restructuring accrual were included within "Accounts payable and accrued expenses," and none and \$3.8 million, respectively, were included within "Other long-term liabilities" in the accompanying consolidated balance sheets.

Table of Contents**ALKERMES PLC AND SUBSIDIARIES****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)****10. LONG-TERM DEBT**

Long-term debt consists of the following:

(In thousands)	December 31, 2014	December 31, 2013
Term Loan B-1, due September 25, 2019	\$ 291,476	\$ 294,091
Term Loan B-2, due September 25, 2016	66,494	70,202
<b>Total</b>	<b>357,970</b>	<b>364,293</b>
Less: current portion	(6,750)	(6,750)
<b>Long-term debt</b>	<b>\$ 351,220</b>	<b>\$ 357,543</b>

***Term Loans***

Term Loan B-1 was issued with a principal balance of \$300.0 million, interest payable of LIBOR plus 2.75% with a LIBOR floor of 0.75%, and an original issue discount of \$3.0 million. Term Loan B-1 amortizes in equal quarterly amounts of 0.25% of the original principal amount of the loan, with the balance payable at maturity, which is September 25, 2019. Term Loan B-2 was issued with a principal balance of \$75.0 million, interest payable of LIBOR plus 2.75% with no LIBOR floor, and an original issue discount of \$0.4 million. Term Loan B-2 amortizes in equal quarterly amounts of 1.25% of the original principal amount of the loan, with the balance payable at maturity, which is September 25, 2016. The Term Loan Facility is guaranteed by certain subsidiaries of the Company (the "Guarantors") and is secured by a first priority lien on substantially all of the assets and properties of the Company and the Guarantors (subject to certain exceptions and limitations).

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

<b>Year Ended:</b>	
2015	\$ 6,750
2016	65,813
2017	3,000
2018	3,000
2019	281,250
<b>Total</b>	<b>\$ 359,813</b>

Required quarterly principal payments of \$0.8 million on Term Loan B-1 and \$0.9 million on Term Loan B-2 began on December 31, 2012. Beginning on January 1, 2014, the Company became subject to mandatory prepayments of principal if certain excess cash flow thresholds, as defined in the Term Loan Facility, were met. During the year ended December 31, 2014, the Company was not subject to mandatory prepayments of principal. The Company may make prepayments of principal without premium or penalty.

The Term Loan Facility has an incremental facility capacity in an amount of \$140.0 million, plus additional amounts as long as the Company meets certain conditions, including a specified leverage ratio. The Term Loan Facility includes a number of restrictive covenants that, among other things and subject to certain exceptions and baskets, impose operating and financial restrictions on the Company



Table of Contents

**ALKERMES PLC AND SUBSIDIARIES**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**10. LONG-TERM DEBT (Continued)**

and certain of its subsidiaries. The Term Loan Facility also contains customary affirmative covenants and events of default. The Company was in compliance with its debt covenants at December 31, 2014.

***Refinancing and Repricing Transactions***

The Company entered into the Term Loan Facility pursuant to an amendment and restatement, and partial repayment, of its existing long-term debt (such debt, the "2011 Term Loans"). This amendment and restatement represented a restructuring of the 2011 Term Loans (the "Refinancing") and involved multiple lenders who were considered members of a loan syndicate. In determining whether the Refinancing was to be accounted for as a debt extinguishment or modification, the Company considered whether creditors remained the same or changed and whether the change in debt terms was substantial. The terms of the Term Loan Facility were considered substantially different from the 2011 Term Loans if the present value of the cash flows under the Term Loan Facility was at least 10% different from the present value of the remaining cash flows under the 2011 Term Loans (commonly referred to as the "10% Test"). The Company performed a separate 10% Test for each individual creditor participating in the loan syndication. The loans of creditors who did not participate in the Term Loan Facility were accounted for as a debt extinguishment.

In February 2013, the Company further amended the Term Loan Facility (the "Repricing"). The Repricing was a restructuring of the Term Loan Facility and involved multiple lenders who were considered members of a loan syndicate. The Company performed a similar analysis to the analysis described above to determine if the Repricing was to be accounted for as a debt extinguishment or modification. In addition, since the Repricing occurred within twelve months of the Refinancing, for any lenders who participated in the Refinancing, the Company performed the 10% test using the present value of the remaining cash flows under the Term Loan Facility.

As the 2011 Term Loans and the Term Loan Facility have a prepayment option exercisable at any time, the Company assumed the prepayment option was exercised immediately on the date of the Refinancing for purposes of applying the 10% Test. When there was a change in principal balance for individual creditors in the Refinancing and/or the Repricing, in applying the 10% Test, the Company used the cash flows related to the lowest common principal balance (commonly referred to as the "Net Method"). Under the Net Method, any principal in excess of a creditor's rollover money was treated as a new, separate debt issuance, and any decrease in principal was treated as a partial extinguishment of debt.

New costs paid to creditors and third parties in connection with the Refinancing and/or Repricing were allocated to the Term Loan Facility and then further allocated to each creditor. Once these costs were allocated to the individual creditors, an analysis of each creditor was performed and a determination made as to whether the refinancing was accounted for as a debt extinguishment or modification under the 10% Test. For debt considered to be extinguished, the unamortized deferred financing costs and unamortized original issue discount associated with the extinguished debt were expensed. For debt considered to be modified, the unamortized deferred financing costs and unamortized original issue discount associated with the modified debt continue to be amortized, new financing costs were expensed and new third-party fees were capitalized. For new creditors in the Refinancing and/or Repricing, new financing costs and original issue discount fees were capitalized and will be amortized over the estimated repayment period of the new debt.

Table of Contents**ALKERMES PLC AND SUBSIDIARIES****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)****10. LONG-TERM DEBT (Continued)**

The Refinancing and Repricing resulted in a \$12.1 million and \$7.5 million charge, respectively, in the year ended March 31, 2013, which was included in "Interest expense" in the accompanying consolidated statement of operations and comprehensive (loss) income and was comprised of the following:

(In thousands)	September 2012 Refinancing	February 2013 Repricing	Total
Extinguished debt:			
Unamortized deferred financing costs	\$ 4,600	\$ 1,566	\$ 6,166
Unamortized original issue discount	2,657	1,437	4,094
Modified debt:			
Debt financing costs	1,967	805	2,772
Original issue discount	105		105
Prepayment penalty	2,800	3,733	6,533
Total	\$ 12,129	\$ 7,541	\$ 19,670

At December 31, 2014, the Company's balance of unamortized deferred financing costs and unamortized original issue discount costs were \$2.2 million and \$1.8 million, respectively. These costs are being amortized to interest expense over the estimated repayment period of the Term Loan Facility using the effective interest method. During the year ended December 31, 2014, the nine months ended December 31, 2013 and the year ended March 31, 2013, the Company had amortization expense of \$1.0 million, \$0.8 million and \$5.8 million, respectively, related to deferred financing costs and original issue discount.

**11. DERIVATIVE INSTRUMENTS**

In September 2011, the Company entered into an interest rate swap agreement with Morgan Stanley Capital Services LLC ("MSCS") to mitigate the impact of fluctuations in the three-month LIBOR rate at which the Company's long-term debt bears interest. The interest rate swap agreement became effective in December 2012, expired in September 2014 and had a notional value of \$65.0 million. This contract was initially designated as a cash flow hedge, however, in connection with the Refinancing, the cash flow hedge was deemed to no longer be effective for accounting purposes. The Company recorded an immaterial loss, a gain of \$0.3 million and a loss of \$0.6 million within "Other income (expense), net" due to the fluctuations in fair value of this contract during the year ended December 31, 2014, the nine months ended December 31, 2013 and the year ended March 31, 2013, respectively.

In December 2011, the Company entered into an interest rate cap agreement at a cost of \$0.1 million to mitigate the impact of fluctuations in the three-month LIBOR rate at which the Company's long-term debt bears interest. The interest rate cap agreement expired in December 2013, had a notional value of \$160.0 million and was not designated as a hedging instrument. The Company recorded an immaterial amount of loss as "Other income (expense), net" in the accompanying consolidated statements of operations and comprehensive (loss) income due to the decline in value of this contract during the nine months ended December 31, 2013 and the year ended March 31, 2013.

Table of Contents

## ALKERMES PLC AND SUBSIDIARIES

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

## 11. DERIVATIVE INSTRUMENTS (Continued)

The following table summarizes the fair value and presentation in the consolidated balance sheets for the Company's hedging instruments (in thousands):

(In thousands)	Balance Sheet Location	Fair Value	
		December 31, 2014	December 31, 2013
Interest rate swap:			
Liability derivative not designated as a cash flow hedge	Other long-term liabilities	\$	\$ (275)

## 12. (LOSS) EARNINGS PER SHARE

Basic (loss) earnings per ordinary share is calculated based upon net (loss) income available to holders of ordinary shares divided by the weighted average number of shares outstanding. For the calculation of diluted (loss) earnings per ordinary share, the Company uses the weighted average number of ordinary shares outstanding, as adjusted for the effect of potential outstanding shares, including stock options and restricted stock units.

(In thousands)	Year Ended December 31, 2014	Nine Months Ended December 31, 2013	Year Ended March 31, 2013
Numerator:			
Net (loss) income	\$ (30,061)	\$ 17,649	\$ 24,983
Denominator:			
Weighted average number of ordinary shares outstanding	145,274	135,960	131,713
Effect of dilutive securities:			
Stock options		7,653	4,025
Restricted stock units		1,348	1,362
Dilutive ordinary share equivalents		9,001	5,387
Shares used in calculating diluted earnings (loss) per share	145,274	144,961	137,100

The following potential ordinary equivalent shares have not been included in the net (loss) income per ordinary share calculations because the effect would have been anti-dilutive:

(In thousands)	Year Ended December 31, 2014	Nine Months Ended December 31, 2013	Year Ended March 31, 2013
Stock options	9,260	1,404	4,497
Restricted stock units	1,834		
Total	11,094	1,404	4,497



Table of Contents

## ALKERMES PLC AND SUBSIDIARIES

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

## 13. SHAREHOLDERS' EQUITY

*Share Repurchase Program*

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. At December 31, 2014, 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 December 31, 2014 and the nine months ended December 31, 2013, the Company did not acquire any ordinary shares under the repurchase program.

## 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) income:

<b>(In thousands)</b>	<b>Year Ended December 31, 2014</b>	<b>Nine Months Ended December 31, 2013</b>	<b>Year Ended March 31, 2013</b>
Cost of goods manufactured and sold	\$ 6,940	\$ 3,308	\$ 4,375
Research and development	14,422	7,799	9,078
Selling, general and administrative	38,217	22,302	21,263
Total share-based compensation expense	\$ 59,579	\$ 33,409	\$ 34,716

At December 31, 2014 and 2013 and March 31, 2013, \$0.8 million, \$0.4 million and \$0.6 million, respectively, of share-based compensation expense was capitalized and recorded as "Inventory" in the accompanying consolidated balance sheets.

*Share-based Compensation Plans*

The Company has two compensation plans pursuant to which awards are currently being made: (i) the 2011 Stock Option and Incentive Plan (the "2011 Plan"); and (ii) the 2008 Stock Option and Incentive Plan (the "2008 Plan"). The Company has three 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 Stock Option Plan for Non-Employee Directors (the "1996 Plan"); (ii) the 1999 Stock Option Plan (the "1999 Plan"); and (iii) the 2006 Stock Option Plan for Non-Employee Directors (the "2006 Plan"). The 2011 Plan and the 2008 Plan provide for the 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 December 31, 2014, there were 10.0 million shares of ordinary shares authorized 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

Table of Contents

## ALKERMES PLC AND SUBSIDIARIES

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

## 14. SHARE-BASED COMPENSATION (Continued)

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.

*Stock Options*

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

	Number of Shares	Weighted Average Exercise Price
Outstanding, January 1, 2014	14,688,160	\$ 17.18
Granted	2,036,300	\$ 46.83
Exercised	(3,375,084)	\$ 14.51
Forfeited	(176,750)	\$ 26.59
Outstanding, December 31, 2014	13,172,626	\$ 22.32
Exercisable, December 31, 2014	8,391,987	\$ 16.36

The weighted average grant date fair value of stock options granted during the year ended December 31, 2014, the nine months ended December 31, 2013 and the year ended March 31, 2013 was \$21.44, \$16.27 and \$8.11, respectively. The aggregate intrinsic value of stock options exercised during the year ended December 31, 2014, the nine months ended December 31, 2013 and the year ended March 31, 2013 was \$114.5 million, \$65.6 million and \$28.1 million, respectively.

At December 31, 2014, there were 4.6 million stock options expected to vest with a weighted average exercise price of \$32.50 per share, a weighted average contractual remaining life of 8.3 years and an aggregate intrinsic value of \$121.0 million. At December 31, 2014, the aggregate intrinsic value of stock options exercisable was \$354.1 million with a weighted average remaining contractual term of 5.2 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 December 31, 2014, there was \$38.3 million of unrecognized compensation cost related to unvested stock options, which is expected to be recognized over a weighted average period of approximately 2.0 years. Cash received from option exercises under the Company's award plans during the year ended December 31, 2014, the nine months ended December 31, 2013 and the year ended March 31, 2013 was \$47.6 million, \$49.1 million and \$34.4 million, respectively.

Table of Contents

## 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
Unvested, January 1, 2014	1,987,887	\$ 22.83
Granted	676,475	\$ 47.16
Vested	(770,335)	\$ 19.95
Forfeited	(133,113)	\$ 29.22
Unvested, December 31, 2014	1,760,914	\$ 32.96

The weighted average grant date fair value of time-vested RSUs granted during the year ended December 31, 2014, the nine months ended December 31, 2013 and the year ended March 31, 2013 was \$47.16, \$33.72 and \$16.55, respectively. The total fair value of time-vested RSUs that vested during the year ended December 31, 2014, the nine months ended December 31, 2013 and the year ended March 31, 2013, was \$15.4 million, \$12.5 million and \$9.9 million, respectively.

At December 31, 2014, there was \$27.6 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-Vesting Restricted Stock Units*

In March 2014, the board of directors awarded RSUs to all employees of the Company as of the date of the award, fifty percent of which vest upon the occurrence of the earlier of: (i) FDA approval for aripiprazole lauroxil; or (ii) the achievement of the pre-specified primary endpoint in two phase 3 clinical studies of ALKS 5461; provided that, if such vesting event occurs during the first year after grant, the vesting of the initial 50% of the performance-based restricted stock unit award will not occur until the one-year anniversary of the grant date. In order to build an added retentive component to the grant, the remaining fifty percent of the award will vest on the one-year anniversary of the vesting date of the initial portion. The award will expire if neither of the performance conditions has been met on or before December 31, 2016.

A summary of performance-vesting RSU activity is presented in the following table:

	Number of Shares	Weighted Average Grant Date Fair Value
Unvested, January 1, 2014		\$
Granted	701,600	\$ 47.17
Vested		\$
Forfeited	(44,875)	\$ 47.16
Unvested, December 31, 2014	656,725	\$ 47.17



Table of Contents

## ALKERMES PLC AND SUBSIDIARIES

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

**14. SHARE-BASED COMPENSATION (Continued)**

The grant date fair value of the performance-vesting RSUs was equal to the market value of the Company's stock on the date of grant. At December 31, 2014, the Company does not consider it probable that the performance criteria will be met and has not recognized any share-based compensation expense related to these performance-vesting RSUs. At December 31, 2014, there was \$31.0 million of unrecognized compensation cost related to these performance-vesting RSUs, which would be recognized in accordance with the terms of the award when the Company deems it probable that the performance criteria will be met.

**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 following table is the aggregate for all of the Company's collaborative arrangements:

	Year Ended December 31, 2014	Nine Months Ended December 31, 2013	Year Ended March 31, 2013
	(in thousands)		
<b>MANUFACTURING AND ROYALTY REVENUE:</b>			
Significant collaborative arrangements	\$ 365,904	\$ 261,192	\$ 278,702
All other collaborative arrangements	150,972	109,847	182,198
Total manufacturing and royalty revenue <sup>(1)</sup>	\$ 516,876	\$ 371,039	\$ 460,900
<b>RESEARCH AND DEVELOPMENT REVENUE:</b>			
Significant collaborative arrangements	\$ 501	\$ 921	\$ 1,611
All other collaborative arrangements	7,252	3,736	4,930
Total research and development revenue	\$ 7,753	\$ 4,657	\$ 6,541
<b>COST OF GOODS MANUFACTURED AND SOLD:</b>			
Significant collaborative arrangements	\$ 34,148	\$ 33,454	\$ 36,694
All other collaborative arrangements	127,028	92,534	117,877
Total cost of goods manufactured and sold <sup>(1)</sup>	\$ 161,176	\$ 125,988	\$ 154,571

(1) Includes only manufacturing and royalty revenue and cost of goods manufactured and sold under collaborative arrangements.

The Company's 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.

F-34

---

Table of Contents**ALKERMES PLC AND SUBSIDIARIES****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)****15. COLLABORATIVE ARRANGEMENTS (Continued)**

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. Either party may terminate the license agreements by written notice following a breach which continues for 90 days after the delivery of written notice thereof or the other party's insolvency. 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) 15 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. The Company exclusively manufactures 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%.

Under its agreements with Janssen, the Company recognized manufacturing revenues related to RISPERDAL CONSTA of \$91.0 million, \$82.5 million and \$98.6 million during the year ended December 31, 2014, the nine months ended December 31, 2013 and the year ended March 31, 2013, respectively. Under its agreements with Janssen, the Company recognized royalty revenues related to RISPERDAL CONSTA of \$29.6 million, \$24.7 million and \$35.0 million during the year ended December 31, 2014, the nine months ended December 31, 2013 and the year ended March 31, 2013, respectively.

**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 received milestone payments upon the achievement of certain development goals from Janssen; there are no further milestones to be earned under this agreement. The Company receives 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

Table of Contents

**ALKERMES PLC AND SUBSIDIARIES**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**15. COLLABORATIVE ARRANGEMENTS (Continued)**

determined based on worldwide net sales. The tiered royalty payments consist of a patent royalty and a know-how royalty, both of which are determined on a country-by-country basis. The patent royalty, which equals 1.5% of net sales, is payable until the expiration of the last of the patents claiming the product in such country. The know-how royalty is a tiered royalty of 3.5%, 5.5% and 7.5% on aggregate worldwide net sales of below \$250 million, between \$250 million and \$500 million, and greater than \$500 million, respectively. The know-how royalty is payable for the later of 15 years from first commercial sale of a product in each individual country or March 31, 2019, subject in each case to the expiry of the license agreement. These royalty payments may be reduced in any country based on patent litigation or on competing products achieving certain minimum sales thresholds. The license agreement expires upon the later of: (i) March 31, 2019; or (ii) the expiration of the last of the patents subject to the agreement. 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 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.

Under its agreements with Janssen, the Company recognized royalty revenues from the sale of INVEGA SUSTENNA/XEPLION of \$127.8 million, \$82.9 million and \$63.5 million during the year ended December 31, 2014, the nine months ended December 31, 2013 and the year ended March 31, 2013, respectively.

***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 net 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.

In June 2009, the Company entered into an amendment of the amended and restated license agreement and the supply agreement with Acorda and, pursuant to such amendment, consented to the sublicense by Acorda to Biogen Idec of Acorda's rights to use and sell FAMPYRA in certain territories outside of the U.S. (to the extent that such rights were to be sublicensed to Biogen Idec) pursuant to its separate collaboration and license agreement with Acorda. Under this amendment, the Company agreed to modify certain terms and conditions of the amended and restated license agreement and the supply agreement with Acorda to reflect the sublicense by Acorda to Biogen Idec.

Acorda has the right to terminate the amended and restated license agreement upon 90 days' written notice. The Company has the right to terminate the amended and restated 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 of and receipt of positive data from all preclinical and clinical studies required for filing a marketing authorization application. Either party has the right to terminate the amended and restated license agreement by written notice following a breach of the other party, which is not cured



Table of Contents

**ALKERMES PLC AND SUBSIDIARIES**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**15. COLLABORATIVE ARRANGEMENTS (Continued)**

within a certain time-period, or upon the other party's entry into bankruptcy or dissolution proceedings. 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 amended and restated license agreement, licenses granted under the amended and restated 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 commercial manufacturing supply agreement upon 12 months' prior written notice to Acorda and either party may terminate the commercial manufacturing supply agreement following a material and uncured breach of the commercial manufacturing supply or license agreement or the entry into bankruptcy or dissolution proceedings by the other party. In addition, subject to early termination of the commercial manufacturing supply agreement noted above, the commercial manufacturing supply agreement terminates upon the expiry or termination of the license agreement.

The Company is entitled to receive the following milestone payments under its amended and restated license agreement with Acorda for each of the third and fourth new indications of the product developed thereunder upon the:

initiation of a phase 3 clinical trial: \$1.0 million;

acceptance of an NDA by the FDA: \$1.0 million;

approval of the NDA by the FDA: \$1.5 million; and

the first commercial sale: \$1.5 million.

In January 2011, the Company entered into a development and supplemental agreement to its amended and restated license agreement and commercial manufacturing supply agreement with Acorda. Under the terms of this agreement, the Company granted Acorda the right, either with the Company 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.

The Company is entitled to development fees it incurs in developing formulations under the development and supplemental agreement and, if Acorda selects and commercializes any such formulation, to milestone payments (for new indications if not previously paid), license revenues and royalties in accordance with its amended and restated license agreement for the product, 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.

Table of Contents

**ALKERMES PLC AND SUBSIDIARIES**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**15. COLLABORATIVE ARRANGEMENTS (Continued)**

If, under the development and supplemental agreement, Acorda selects a formulation not developed by the Company, then the Company will be entitled to various compensation payments and has the first option to manufacture such third-party formulation. The development and supplemental agreement expires upon the expiry or termination of the amended and restated license agreement and 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 year ended December 31, 2014, the nine months ended December 31, 2013 and the year ended March 31, 2013, the Company recognized \$81.3 million, \$51.6 million and \$65.0 million, respectively, of revenues from its arrangements with Acorda.

***AstraZeneca***

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, including the once-weekly formulation of exenatide marketed as BYDUREON. In August 2012, Bristol-Myers Squibb Company ("Bristol-Myers") acquired Amylin. From August 2012 through January 2014, Bristol-Myers and AstraZeneca jointly developed and commercialized Amylin's exendin products, including BYDUREON, through their diabetes collaboration. In April 2013, Bristol-Myers completed its assumption of all global commercialization responsibility related to the marketing of BYDUREON from Amylin's former collaborative partner, Eli Lilly & Company. In February 2014, AstraZeneca acquired sole ownership of the intellectual property and global rights related to BYDUREON and Amylin's other exendin products, including Amylin's rights and obligations under the Company's development and license agreement.

Pursuant to the development and license agreement, AstraZeneca 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 will also receive royalty payments based on future product sales. Upon the achievement of certain development and commercialization goals, the Company received milestone payments consisting of cash and warrants for Amylin common stock and there are no further milestones to be earned under the agreement. In October 2005 and in July 2006, the Company amended the development and license agreement. Under the amended agreement: (i) 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; and (ii) the Company transferred certain of its technology related to the manufacture of BYDUREON to Amylin and agreed to the manufacture of BYDUREON by Amylin.

Under the Company's amended agreement, AstraZeneca is responsible for conducting clinical trials, securing regulatory approvals, and commercializing exenatide products including BYDUREON on a worldwide basis.

Table of Contents

## ALKERMES PLC AND SUBSIDIARIES

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

## 15. COLLABORATIVE ARRANGEMENTS (Continued)

Until December 31, 2021, the Company will receive royalties equal to 8% of net sales from the first 40 million units of BYDUREON sold in any particular calendar year and 5.5% of net sales from units sold beyond the first 40 million units for that calendar 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 was entitled to, and received milestone payments related to the first commercial sale of BYDUREON in the EU the first commercial sale of BYDUREON in the U.S.

The development and license agreement expires 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 the Company's patents covering such product. Upon expiration, all licenses become non-exclusive and royalty-free. AstraZeneca 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. Alkermes may terminate the development and license agreement upon AstraZeneca's insolvency or bankruptcy.

During the year ended December 31, 2014, the nine months ended December 31, 2013 and the year ended March 31, 2013, the Company recognized \$36.6 million, \$20.0 million and \$23.8 million, respectively, of revenues from its arrangements with respect to BYDUREON.

## 16. INCOME TAXES

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

(In thousands)	Year Ended December 31, 2014	Nine Months Ended December 31, 2013	Year Ended March 31, 2013
Current income tax provision (benefit):			
U.S. federal	\$ 35,147	\$ 9,224	\$ 8,152
U.S. state	880	2,119	2,588
Rest of world	915	89	1,758
Deferred income tax (benefit) provision:			
Ireland	(17,691)	(3,426)	(1,961)
U.S. federal	(2,654)	(18,317)	
U.S. state	(565)	(1,941)	(79)
Total tax (benefit) provision	\$ 16,032	\$ (12,252)	\$ 10,458

The current income tax provision for the year ended December 31, 2014, the nine months ended December 31, 2013 and year ended March 31, 2013, was primarily due to U.S. federal and state taxes on income earned by the Company in the U.S. A \$32.4 million, \$11.4 million and an \$8.9 million benefit were recorded to additional paid-in capital in the year ended December 31, 2014, nine months ended December 31, 2013 and year ended March 31, 2013, respectively, primarily due to the utilization of current year tax benefits and NOL carryforwards derived from the exercise of employee stock options and vesting of restricted stock units.

The deferred income tax benefit for the year ended December 31, 2014, was primarily due to the creation of a deferred tax asset in Ireland for current year operating losses. The deferred income tax

Table of Contents**ALKERMES PLC AND SUBSIDIARIES****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)****16. INCOME TAXES (Continued)**

benefit in the nine months ended December 31, 2013 was primarily due to the reversal of a valuation allowance on certain of the Company's U.S. federal and state deferred tax assets. The deferred income tax benefit for the year ended March 31, 2013 was primarily due to the unwinding of deferred tax liabilities for intangible assets for which the book basis exceeds the tax basis. These intangible assets are being amortized over the life of the intangible assets.

No provision for income tax has been provided on undistributed earnings of the Company's foreign subsidiaries because such earnings may be repatriated to Ireland without incurring any tax liability. Cumulative unremitted earnings of overseas subsidiaries totaled approximately \$80.4 million at December 31, 2014.

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

(In thousands)	Year Ended December 31, 2014	Nine Months Ended December 31, 2013	Year Ended March 31, 2013
Ireland	\$ (159,538)	\$ (63,975)	\$ (14,722)
U.S.	118,754	49,338	23,503
Rest of world	26,755	20,034	26,660
(Loss) income before provision for income taxes	\$ (14,029)	\$ 5,397	\$ 35,441

The components of the Company's net deferred tax assets (liabilities) were as follows:

(In thousands)	December 31, 2014	December 31, 2013
<b>Deferred tax assets:</b>		
Irish NOL carryforwards	\$ 83,278	\$ 68,459
Share-based compensation	30,655	24,353
Bonus accrual	6,835	4,585
Tax credit carryforwards	1,655	6,247
Tax benefit from the exercise of stock options		9,122
Property, plant and equipment		1,912
Other	9,116	10,538
Less: valuation allowance	(71,796)	(69,659)
Total deferred tax assets	59,743	55,557
 <b>Deferred tax liabilities:</b>		
Intangible assets	(31,169)	(38,238)
Property, plant and equipment	(21,919)	(21,571)
Unrealized gains on investments		(7,719)
Other	(3,849)	(4,421)
Total deferred tax liabilities	(56,937)	(71,949)
Net deferred tax assets (liabilities)	\$ 2,806	\$ (16,392)



Table of Contents**ALKERMES PLC AND SUBSIDIARIES****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)****16. INCOME TAXES (Continued)**

The following table presents the breakdown between current and non-current deferred tax assets (liabilities):

(In thousands)	December 31, 2014	December 31, 2013
Current deferred tax assets	\$ 13,430	\$ 12,777
Non-current deferred tax assets	8,294	
Non-current deferred tax liabilities	(18,918)	(29,169)
Net deferred tax assets (liabilities)	\$ 2,806	\$ (16,392)

In addition to deferred tax assets and liabilities, the Company recorded deferred charges related to intercompany transfers of intellectual property, which will be amortized as income tax expense over the economic life of the intangible assets. Deferred charges are included in the following accounts:

(In thousands)	December 31, 2014	December 31, 2013
Prepaid expenses and other current assets	\$ 1,296	\$ 166
Other assets long-term	8,836	1,431
Total deferred charges	\$ 10,132	\$ 1,597

At December 31, 2014, the Company maintained a valuation allowance of \$1.7 million against certain U.S. state deferred tax assets and \$70.1 million against certain Irish deferred tax assets as the Company has determined that it is more-likely-than-not that these net deferred tax assets will not be realized. If the Company demonstrates consistent profitability in the future, the evaluation of the recoverability of these deferred tax assets could change and the remaining valuation allowances could be released in part or in whole. During the last quarter of the nine months ended December 31, 2013, the Company recognized a benefit of \$26.5 million relating to a reversal of a valuation allowance against substantially all of its U.S. federal and state deferred tax assets. The decision to release this valuation allowance was made as the Company determined it was more-likely-than-not that these deferred tax assets would be realized. This decision was based on an assessment of the relative impact of all positive and negative evidence that existed at December 31, 2013, including an evaluation of cumulative income in recent years, a significant positive factor that overcame substantive prior negative evidence. In addition, the Company considered forecasts of future sources of taxable income and significant risks and uncertainties in the business.

The tax benefit from the exercise of stock options at December 31, 2013 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. During the year ended December 31, 2014 the Company released the \$9.1 million valuation allowance held against these assets and recorded a \$9.1 million benefit to additional paid-in capital. Subsequent to the adoption of ASC 718 on April 1, 2006, an additional \$52.3 million of tax benefits from stock option exercises and the vesting of restricted stock units, in the form of NOL carryforwards and tax credit carryforwards, have not been recognized in the financial statements and will be accounted for as a credit to additional paid-in capital rather than a reduction of income tax expense once they are realized.

Table of Contents

## ALKERMES PLC AND SUBSIDIARIES

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

## 16. INCOME TAXES (Continued)

As of December 31, 2014, the Company had \$574.4 million of Irish NOL carryforwards, \$23.9 million of U.S. federal NOL carryforwards, \$8.3 million of state NOL carryforwards, \$33.8 million of federal R&D credits, \$8.6 million of alternative minimum tax ("AMT") credits and \$4.3 million of state tax credits which will either expire on various dates through 2034 or can be carried forward indefinitely. These loss carryforwards and credits are available to reduce certain future Irish and foreign taxable income and tax, respectively, if any. These loss carryforwards and credits are subject to review and possible adjustment by the appropriate taxing authorities. These loss carryforwards and credits, which may be utilized in any future period, may be subject to limitations based upon changes in the ownership of the company's 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 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.

A reconciliation of the Company's statutory tax rate to its effective tax rate is as follows:

	Year Ended December 31, 2014	Nine Months Ended December 31, 2013	Year Ended March 31, 2013
Statutory tax rate	12.5%	12.5%	12.5%
U.S. state income taxes, net of U.S. federal benefit	(5.2)%	40.8%	4.7%
Foreign rate differential <sup>(1)</sup>	(203.9)%	209.0%	43.4%
R&D credit	99.9%	(29.6)%	(20.5)%
Change in valuation allowance	(79.5)%	(321.4)%	(7.5)%
Intercompany amounts <sup>(2)</sup>	53.2%	(30.0)%	(9.3)%
Irish rate differential <sup>(3)</sup>	34.0%	(81.4)%	(2.9)%
Uncertain tax positions <sup>(4)</sup>	(10.3)%	(58.7)%	2.6%
Share-based compensation	(12.8)%	13.6%	3.3%
Other permanent items <sup>(5)</sup>	(1.8)%	5.1%	(1.5)%
Non-refundable withholding tax	(0.3)%	0.4%	4.7%
State tax law change	%	12.7%	%
Effective tax rate	(114.2)%	(227.0)%	29.5%

(1) Represents income or losses of non-Irish subsidiaries subject to tax at a rate other than the Irish statutory rate.

(2) Intercompany amounts include cross-territory eliminations, the pre-tax effect of which has been eliminated in arriving at the Company's consolidated (loss) income before taxes.

(3) Represents income or losses of Irish companies subject to tax at a rate other than the Irish statutory rate.

(4) Relates to uncertain tax positions adopted by the Company. In June 2013, the Company filed a change in accounting method with the Internal Revenue Service relating to accrued compensation. The method change was automatic and removed the uncertainty around the timing of the deduction for accrued compensation. The effective date of the method change was April 1, 2012.

Table of Contents**ALKERMES PLC AND SUBSIDIARIES****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)****16. INCOME TAXES (Continued)**

As a result, the Company released the uncertain tax position and accounted for the application of the method change in the fiscal year ended March 31, 2013.

(5)

Other permanent items include, but are not limited to, non-deductible meals and entertainment expenses, non-deductible lobbying expenses and non-deductible compensation of senior officers of the Company.

The U.S. federal research and development credit has not yet been enacted for 2015 and, unless retroactively reinstated, will cause an increase to the Company's 2015 effective tax rate.

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

<b>(In thousands)</b>	<b>Unrecognized Tax Benefits</b>
Balance, April 1, 2012	\$ 6,606
Additions based on tax positions related to prior periods	1,065
Decreases due to settlements with tax authorities	(413)
Balance, March 31, 2013	7,258
Additions based on tax positions related to prior periods	881
Additions based on tax positions related to the current period	244
Decreases due to lapse of statute of limitations and settlement of prior period uncertain tax positions	(7,258)
Balance, December 31, 2013	\$ 1,125
Additions based on tax positions related to prior periods	363
Additions based on tax positions related to the current period	1,077
Decreases due to lapse of statute of limitations and settlement of prior period uncertain tax positions	
Balance, December 31, 2014	\$ 2,565

The unrecognized tax benefits at December 31, 2014, if recognized, would affect the Company's effective tax rate. The Company does not anticipate that the amount of existing unrecognized tax benefits will significantly increase or decrease within the next 12 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 December 31, 2014, the nine months ended December 31, 2013 and the year ended March 31, 2013, the Company's accrued interest and penalties related to uncertain tax positions were not material.

The Company's major taxing jurisdictions include Ireland and the U.S. (federal and state). These jurisdictions have varying statutes of limitations. In the U.S., the 2012 through 2014 fiscal years remain subject to examination by the respective tax authorities. In Ireland, fiscal years 2010 to 2014 remain subject to examination by the Irish tax authorities. Additionally, because of the Company's Irish and U.S. loss carryforwards and credit carryforwards, certain tax returns from fiscal years 1999 onward may also be examined. These years generally remain open for three to four years after the loss carryforwards and credit carryforwards have been utilized. During the three months ended June 30, 2013, the IRS completed its review of fiscal years 2007, 2008 and 2010 for Alkermes, Inc., the results of which have been reflected in the financial statements. Fiscal year 2012 for Alkermes, Inc. is currently



Table of Contents

## ALKERMES PLC AND SUBSIDIARIES

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

## 16. INCOME TAXES (Continued)

under examination by the Commonwealth of Massachusetts and fiscal years 2011 through 2013 are currently under examination by the New York State Department of Taxation.

## 17. TRANSITION PERIOD COMPARATIVE DATA

The unaudited information for the year ended December 31, 2013 (which reflects the Company's combined results for the quarter ended March 31, 2013 and the nine-month transition period from April 1, 2013 through December 31, 2013) and the nine months ended December 31, 2012 is presented below for comparative purposes:

(In thousands, except per share amounts)	Year Ended December 31,		Nine Months Ended December 31,	
	2014	2013 (unaudited)	2013	2012 (unaudited)
<b>Statement of Operations Data:</b>				
Revenues	\$ 618,789	\$ 596,333	\$ 432,911	\$ 412,126
Operating expenses	705,933	561,855	417,417	349,297
Operating income	(87,144)	34,478	15,494	62,829
Other expense (net)	73,115	(21,215)	(10,097)	(35,254)
(Loss) income before income taxes	(14,029)	13,263	5,397	27,575
Income tax provision (benefit)	16,032	(7,385)	(12,252)	5,591
Net (loss) income	\$ (30,061)	\$ 20,648	\$ 17,649	\$ 21,984
Earnings per ordinary share basic	\$ (0.21)	\$ 0.15	\$ 0.13	\$ 0.17
Earnings per ordinary share diluted	\$ (0.21)	\$ 0.14	\$ 0.12	\$ 0.16
Weighted average ordinary shares outstanding basic	145,274	135,297	135,960	131,202
Weighted average ordinary shares outstanding diluted	145,274	144,012	144,961	136,216
<b>Statement of Cash Flows Data:</b>				
Cash flows provided by operations	\$ 11,139	\$ 147,525	\$ 92,221	\$ 71,247
Cash flows (used in) provided by investing activities	(263,397)	(177,194)	(65,366)	43,680
Cash flows provided by (used in) financing activities	308,760	61,339	43,746	(62,636)

Increase in cash and cash equivalents	\$	56,502	\$	31,670	\$	70,601	\$	52,291
---------------------------------------	----	--------	----	--------	----	--------	----	--------

**18. COMMITMENTS AND CONTINGENCIES***Lease Commitments*

The Company leases certain of its offices, research laboratories and manufacturing facilities under operating leases that expire through the year 2022. 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, R&D and manufacturing facilities in

Table of Contents

## ALKERMES PLC AND SUBSIDIARIES

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

## 18. COMMITMENTS AND CONTINGENCIES (Continued)

Massachusetts. As of December 31, 2014, the total future annual minimum lease payments under the Company's non-cancelable operating leases are as follows:

(In thousands)	Payment Amount
Year Ended:	
2015	\$ 5,837
2016	5,139
2017	5,301
2018	5,385
2019	5,420
Thereafter	4,222
	31,304
Less: estimated sublease income	(722)
Total future minimum lease payments	\$ 30,582

Rent expense related to operating leases charged to operations was \$5.9 million, \$3.7 million and \$5.0 million for the year ended December 31, 2014, the nine months ended December 31, 2013 and year ended March 31, 2013, respectively. These amounts were net of sublease income of \$0.7 million, \$0.7 million and \$2.6 million, respectively. In addition to its lease commitments, the Company had open purchase orders totaling \$272.2 million at December 31, 2014.

*Litigation*

From time to time, the Company may be subject to legal proceedings and claims in the ordinary course of business. For example, there are currently Paragraph IV litigations in the U.S. and other proceedings in Europe involving the Company's patents in respect of TRICOR, MEGACE ES, AMPYRA and ZOHYDRO ER. 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 the Company's business, financial condition, cash flows and results of operations.