

**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

OR

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

For the transition period from April 1, 2013 to December 31, 2013

Commission file number: 1-14131

**ALKERMES PUBLIC LIMITED COMPANY**

(Exact name of registrant as specified in its charter)

**Ireland**

(State or other jurisdiction of  
incorporation or organization)

**98-1007018**

(I.R.S. Employer  
Identification No.)

**Connaught House  
1 Burlington Road  
Dublin 4, Ireland**

(Address of principal executive offices)

(Zip code)

**+353-1-772-8000**

(Registrant's telephone number, including area code)

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

Ordinary shares, \$0.01 par value

NASDAQ Global Select Stock Market

**Title of each class**

**Name of each exchange on which registered**

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

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities

Act. Yes  No

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Exchange

Act. Yes  No

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

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

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 on June 28, 2013, the last business day of the registrant's most recently completed second fiscal quarter (taking into account the registrant's change in fiscal year end), was \$3,850,629,514.

As of February 13, 2014, 144,185,293 ordinary shares were issued and outstanding.

**DOCUMENTS INCORPORATED BY REFERENCE**

The information required by Part III of this Transition Report on Form 10-K, to the extent not set forth herein, is incorporated by reference from portions of the definitive proxy statement for our Annual General Meeting of Shareholders to be held in 2014, which will be filed with the Securities and Exchange Commission within 120 days after the end of the fiscal period to which this Transition Report on Form 10-K relates.

**ALKERMES PLC AND SUBSIDIARIES  
TRANSITION REPORT ON FORM 10-K  
FOR THE NINE MONTHS ENDED DECEMBER 31, 2013  
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## CAUTIONARY NOTE CONCERNING FORWARD-LOOKING STATEMENTS

This document contains and incorporates by reference “forward-looking statements” within the meaning of the Private Securities Litigation Reform Act of 1995, 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 Transition Report on Form 10-K (“Transition 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 review (including expectations about regulatory approval and regulatory timelines) and 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;
- our expectations regarding the financial impact of currency exchange rate fluctuations and valuations;
- our expectations regarding our collaborations and other significant agreements relating to our products;
- our expectations regarding the impact 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 risk factors described in “Item 1A—Risk Factors” in this Transition 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 Transition Report. All written and oral forward-looking statements concerning the matters addressed in this Transition Report and attributable to us or any person acting on our behalf are expressly qualified in their entirety by the cautionary statements contained or referred to in this section. Except as required by applicable law or regulation, we do not undertake any obligation to update publicly or revise any forward-looking statements, whether as a result of new information, future events or otherwise. In light of these risks, uncertainties and assumptions, the forward-looking events discussed in this Transition Report might not occur. For more information regarding the risks and uncertainties of our business, see “Item 1A—Risk Factors.”

Unless otherwise indicated, information contained in this Transition Report concerning the disorders targeted by our products and the markets in which we operate is based on information from various 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 and development products. 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 Transition Report.

#### **NOTE REGARDING COMPANY REFERENCES**

Use of the terms such as “us,” “we,” “our,” “Alkermes” or the “Company” in this Transition 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.” For a more detailed discussion of the Business Combination, please refer to the notes to our consolidated financial statements, including Note 1, *Description of Business and Basis of Presentation*, and Note 3, *Acquisitions*, in the accompanying consolidated financial statements.

#### **NOTE REGARDING TRADEMARKS**

CODAS<sup>®</sup>, IPDAS<sup>®</sup>, LinkeRx<sup>®</sup>, MXDAS<sup>®</sup>, NanoCrystal<sup>®</sup>, SODAS<sup>®</sup>, VERELAN<sup>®</sup> and VIVITROL<sup>®</sup> are registered trademarks of Alkermes. The following are trademarks of the respective companies listed: ABILIFY<sup>®</sup> and ABILIFY MAINTENA<sup>®</sup>—Otsuka Pharmaceutical Co., Ltd.; ADALAT<sup>®</sup>—Bayer AG Corporation; AFEDITAB<sup>®</sup>—Actavis, Inc.; AMPYRA<sup>®</sup>, FAMPYRA<sup>®</sup>, ZANAFLEX<sup>®</sup> and ZANAFLEX CAPSULES<sup>®</sup>—Acorda Therapeutics, Inc.; ANTABUSE<sup>®</sup>—Teva Women’s Health, Inc.; AUBAGIO<sup>®</sup>—Sanofi Societe Anonyme France; AVINZA<sup>®</sup>—King Pharmaceuticals Research and Development, Inc.; AVONEX<sup>®</sup>, TECFIDERA<sup>®</sup> and TYSABRI<sup>®</sup>—Biogen Idec MA, Inc.; BETASERON<sup>®</sup>—Bayer Pharma AG; BYDUREON<sup>®</sup> and BYETTA<sup>®</sup>—Amylin Pharmaceuticals, LLC; CAMPRAL<sup>®</sup>—Merck Sante; CARDIZEM<sup>®</sup>—Valeant International Bermuda; COPAXONE<sup>®</sup>—Teva Pharmaceutical Industries Ltd.; DILZEM<sup>®</sup>—Cephalon (UK) Limited or Warner-Lambert Company LLC (depending on the jurisdiction); DILTELAN<sup>®</sup>—Elan Corporation plc or Cephalon Limited (depending on the jurisdiction); EMEND<sup>®</sup>—Merck Sharp & Dohme Corp.; EXTAVIA<sup>®</sup>, FOCALIN XR<sup>®</sup>, GILENYA<sup>®</sup> and RITALIN LA<sup>®</sup>—Novartis AG; INVEGA<sup>®</sup> SUSTENNA<sup>®</sup>, RISPERDAL<sup>®</sup> CONSTA<sup>®</sup> and XEPLION<sup>®</sup>—Johnson & Johnson Corp. (or its affiliate); LUVOX CR<sup>®</sup>—Abbott Laboratories; MEGACE<sup>®</sup>—E.R. Squibb & Sons, LLC; NAPRELAN<sup>®</sup>—Alvogen Pharma US Inc.; RAPAMUNE<sup>®</sup>—Wyeth LLC; REBIF<sup>®</sup>—Ares Trading S.A.; SUBOXONE<sup>®</sup> and SUBUTEX<sup>®</sup>—Reckitt Benckiser Healthcare (UK) Ltd.; SUPRALIP<sup>®</sup> and TRICOR<sup>®</sup>—Fournier Industrie et Sante Corporation; UNIVER<sup>®</sup>—various non-Alkermes entities (depending on the jurisdiction); VICTOZA<sup>®</sup>—Novo Nordisk A/S LLC; ZOHYDRO<sup>™</sup>—Zogenix, Inc.; and ZYPREXA<sup>®</sup> and ZYPREXA<sup>®</sup> RELPREVV<sup>®</sup>—Eli Lilly and Company. Other trademarks, trade names and service marks appearing in this Transition Report are the property of their respective owners.

## 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 Transition 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 Transition 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 commercial drug products and a clinical pipeline of product candidates that address central nervous system (“CNS”) disorders such as addiction, schizophrenia and depression.

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.” Our principal offices are located at Connaught House, 1 Burlington Road, Dublin 4, Ireland. We have 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.

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 Transition Report on Form 10-K covers the nine month transition period ended December 31, 2013 and reflects our financial results for the nine month period from April 1, 2013 through December 31, 2013 (the “Transition Period”). Prior to this Transition Report, our two most recent Annual Reports on Form 10-K, as amended, cover the fiscal years ended March 31, 2013 and March 31, 2012, respectively, and reflect financial results for the respective twelve-month periods from April 1 to March 31. Unless otherwise noted, all references to “fiscal years” in this Transition Report refer to the twelve month fiscal years that, prior to the Transition Period ended December 31, 2013, ended on March 31.

## Products

### Marketed Products

We earn manufacturing and/or royalty revenues on net sales of products marketed 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 marketed products are described in the table below, including, among other things, the territory in which the marketer has the right to sell the product and the source of revenues for us:

Product	Indication(s)	Technology	Territory	Revenue Source	Marketer
RISPERDAL CONSTA	Schizophrenia Bipolar I Disorder	Extended-release microsphere	Worldwide	Manufacturing and Royalty	Ortho-McNeil-Janssen Pharmaceuticals, Inc. and Janssen Pharmaceutica International, a division of Cilag International AG (taken together, "Janssen")
INVEGA SUSTENNA/ XEPLION	Schizophrenia	NanoCrystal	United States (U.S.)  Rest of World ("ROW")	Royalty	Janssen
AMPYRA/ FAMPYRA	Treatment to improve walking in patients with multiple sclerosis ("MS"), as demonstrated by an increase in walking speed	Oral Controlled Release ("OCR") Matrix Drug Absorption System (MXDAS)	U.S.  ROW	Manufacturing and Royalty	Acorda Therapeutics, Inc. ("Acorda")  Biogen Idec International GmbH ("Biogen Idec"), under sublicense from Acorda
BYDUREON	Type 2 diabetes	Extended-release microsphere	Worldwide	Royalty	AstraZeneca plc ("AstraZeneca")
VIVITROL	Alcohol dependence Opioid dependence	Extended-release microsphere	U.S.  Russia and Commonwealth of Independent States ("CIS")	Product sales  Manufacturing and Royalty	Alkermes  Cilag GmbH International ("Cilag")
TRICOR LIPANTHYL LIPIDIL SUPRALIP (and other trade names under which fenofibrate 48 mg and 145 mg are sold)	Cholesterol lowering	NanoCrystal	Worldwide	Royalty	AbbVie Inc. Abbott Laboratories
ZANAFLEX CAPSULES ZANAFLEX TABLETS TIZANIDINE HYDROCHLORIDE (AB Rated to ZANAFLEX CAPSULES)	Muscle spasticity	OCR Spheroidal Oral Drug Absorption System (SODAS)	U.S.	Manufacturing (capsules only) and Royalty	Acorda; Actavis, Inc. (formerly Watson Pharmaceutical)
AVINZA	Chronic moderate to severe pain	OCR (SODAS)	U.S.	Manufacturing and Royalty	Pfizer Inc. ("Pfizer")
EMEND	Nausea associated with chemotherapy and surgery	NanoCrystal	Worldwide	Manufacturing and Royalty	Merck & Co. Inc. ("Merck")
FOCALIN XR RITALIN LA	Attention Deficit Hyperactivity Disorder	OCR (SODAS)	Worldwide	Manufacturing and Royalty	Novartis AG ("Novartis")
MEGACE ES	Anorexia, Cachexia associated with AIDS	NanoCrystal	U.S.	Royalty	Strativa Pharmaceuticals (a business division of Par Pharmaceutical Companies, Inc.)

<b>Product</b>	<b>Indication(s)</b>	<b>Technology</b>	<b>Territory</b>	<b>Revenue Source</b>	<b>Marketer</b>
<i>LUVOX CR</i>	Obsessive-compulsive disorder	OCR (SODAS)	U.S.	Royalty	Jazz Pharmaceuticals plc (“Jazz”)
<i>RAPAMUNE</i>	Prevention of renal transplant rejection	NanoCrystal	Worldwide	Manufacturing	Pfizer
<i>NAPRELAN</i>	Various mild to moderate pain indications	OCR Intestinal Protective Drug Absorption System (IPDAS)	U.S. Canada	Manufacturing	Shionogi
<i>VERAPAMIL SR</i> <i>VERELAN</i> <i>VERELAN PM</i> <i>VERAPAMIL PM</i> <i>VERACAPS</i> <i>UNIVER</i>	Hypertension	OCR (SODAS)	Licensed on country/region basis throughout the world	Manufacturing and Royalty (on select formulations)	Kremers-Urban; Cephalon; Aspen Pharma; Actavis, Inc.
<i>DILZEM SR</i> <i>DILZEM XL</i> <i>DILTELAN</i> <i>CARDIZEM CD</i>	Hypertension and/or Angina	OCR (SODAS)	Licensed on country/region basis throughout the world	Manufacturing and Royalty (for CARDIZEM CD only)	Cephalon; Kun-Wha Pharmaceutical Co. Ltd; Sanofi; Valeant Pharmaceuticals International Inc.
<i>AFEDITAB CR</i> <i>(AB Rated to ADALAT CC)</i>	Hypertension	OCR (MXDAS)	U.S.	Manufacturing	Actavis, Inc.
<i>ZOHYDRO ER</i>	Severe pain	OCR (SODAS)	U.S.	Manufacturing and royalty	Zogenix, Inc.

Our key marketed products are expected to generate significant revenues for us in the near- and medium-term. 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 Transition Report for information with respect to the intellectual property protection for our marketed products. These products are discussed below:

### ***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. They are products of Janssen.

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 is marketed and sold by Janssen worldwide. It was first approved for the treatment of schizophrenia in the U.S. in 2003 and in countries in Europe in 2002. The U.S. Food and Drug Administration (“FDA”) approved RISPERDAL CONSTA as both monotherapy and adjunctive therapy to lithium or valproate in the maintenance treatment of bipolar I disorder in May 2009. RISPERDAL CONSTA is also approved for the maintenance treatment of bipolar I disorder in over 25 other countries worldwide.

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 was approved for the acute and maintenance treatment of schizophrenia in adults in the U.S. in 2009. Paliperidone palmitate extended-release for injectable suspension is also approved in the European Union (“EU”) and other countries worldwide, and is marketed and sold in the EU under the trade name XEPLION. INVEGA SUSTENNA/XEPLION is manufactured and commercialized worldwide by Janssen.



Revenues from Janssen accounted for approximately 44%, 35% and 48% of our consolidated revenues for the Transition Period and our fiscal years 2013 and 2012, respectively. See “*Collaborative Arrangements*” below 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.

***AMPYRA/FAMPYRA***

Dalfampridine extended-release tablets are marketed and sold in the U.S. under the trade name AMPYRA by Acorda. In January 2010, the FDA approved AMPYRA as a treatment to improve walking in patients with MS as demonstrated by an increase in walking speed. It is the first and, currently, only product to be approved for this indication. Prolonged-release fampridine tablets are marketed and sold outside the U.S. under the trade name FAMPYRA by Biogen Idec. 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 July 2013. The product incorporates our OCR technology. AMPYRA and FAMPYRA are manufactured by us.

*What is multiple sclerosis?*

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

***BYDUREON***

BYDUREON was approved by the FDA in January 2012, and received marketing authorization in the EU in June 2011, for the treatment of type 2 diabetes. BYDUREON, a once-weekly formulation of exenatide, the active ingredient in BYETTA (exenatide), uses our polymer-based microsphere injectable extended-release technology. 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.

*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 by the FDA for the treatment of alcohol dependence in April 2006 and for the prevention of relapse to opioid dependence, following opioid detoxification, in October 2010. The medication uses our polymer-based microsphere injectable extended-release technology to deliver and maintain therapeutic medication levels in the body through just one injection every four weeks. We developed, and currently market and sell, VIVITROL in the U.S., and Cilag sells VIVITROL in Russia and the CIS. The Russian regulatory authorities approved VIVITROL for the treatment of alcohol dependence in 2008 and for the treatment of opioid dependence in 2011.

*What are opioid dependence and alcohol dependence?*

Opioid dependence is a serious and chronic brain disease characterized by compulsive, prolonged self-administration of opioid substances that are not used for a medical purpose. According to the 2012 U.S. National Survey on Drug Use and Health, an estimated 1.9 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

Except for ZOHYDRO, which received FDA approval in October 2013, we generally expect revenues from our other commercial products, taken together, to decrease in the future due to existing and expected competition from generic manufacturers. For a more detailed discussion of current and expected future revenue contributions from such products, please see "Management's Discussion and Analysis of Financial Condition and Results of Operations" elsewhere in this Transition Report.

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 entailed the termination of manufacturing services for certain older products becoming uneconomic to produce due to decreasing demand from our customers resulting from generic competition, and the implementation of a corresponding reduction in headcount of up to 130 employees at our Athlone, Ireland manufacturing facility. We commenced this restructuring plan in April 2013, and expect it to be substantially complete by the end of 2015.

## Key Development Programs

We leverage our formulation expertise and proprietary product platforms to develop, both with partners and on our own, competitively advantaged medications designed to enhance patient outcomes in major therapeutic areas. As part of our ongoing research and development efforts, we have devoted significant resources to conducting clinical studies to advance the development of new pharmaceutical products. The discussion below highlights our current research and development programs for our product candidates. 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 Transition Report for information with respect to the intellectual property protection for our product candidates.

### *Aripiprazole Lauroxil*

We are studying aripiprazole lauroxil for the treatment of schizophrenia. Aripiprazole lauroxil is designed to provide once-monthly dosing of a medication that converts *in vivo* into aripiprazole, a molecule that is commercially available under the name ABILIFY. Aripiprazole lauroxil is our first product candidate to leverage our proprietary LinkeRx technology. In October 2013, we announced the completion of patient enrollment in our phase 3 trial to assess the efficacy, safety and tolerability of aripiprazole lauroxil in patients experiencing acute exacerbation of schizophrenia. The clinical data from this study, expected in the first half of 2014, may form the basis of a New Drug Application (“NDA”) to the FDA for aripiprazole lauroxil for the treatment of schizophrenia.

In January 2014, we announced plans to commence clinical testing of aripiprazole lauroxil two-month, a new product candidate for the treatment of schizophrenia, in 2014. If approved, aripiprazole lauroxil two-month would be the first and only long-acting atypical antipsychotic medication dosed every two months. The two-month form of aripiprazole lauroxil also utilizes our proprietary LinkeRx technology.

### *ALKS 33*

ALKS 33 is a proprietary oral opioid modulator characterized by limited hepatic metabolism and durable pharmacologic activity in modulating brain opioid receptors. ALKS 33 has completed a phase 2 study in alcohol dependence and is currently being evaluated as a component of ALKS 5461 and ALKS 3831.

### *ALKS 5461*

ALKS 5461 is a proprietary combination of ALKS 33 and buprenorphine that we are developing to be a non-addictive therapy for the treatment of major depressive disorder (“MDD”) in patients who have an inadequate response to standard antidepressant therapies. In April 2013, we announced positive results from a phase 2 study in which ALKS 5461 met its primary endpoint, met key secondary endpoints and demonstrated significant reduction in depressive symptoms versus placebo. In October 2013, we announced that we had successfully completed our End-of-Phase 2 interactions with the FDA and that the FDA had granted ALKS 5461 Fast Track status for the adjunctive treatment of MDD in patients with an inadequate response to standard therapies. Fast Track is a process designed to facilitate the development, and expedite the review of drugs to treat serious conditions with the potential to address an unmet medical need. The phase 3 clinical program for ALKS 5461 is expected to commence in the first quarter of 2014. This pivotal clinical program will include three core phase 3 efficacy studies and is expected to enroll a total of approximately 1,500 patients with MDD who have had an inadequate response to standard therapies. The primary efficacy endpoint for all phase 3 studies will be the change in Montgomery-Åsberg Depression Rating Scale (“MADRS”) scores from baseline. The pivotal program will also evaluate remission as a secondary endpoint. In addition to the three core

efficacy studies, the program will also include studies to evaluate the long-term safety, pharmacokinetic profile, titration schedule and human abuse liability of ALKS 5461.

#### ***ALKS 3831***

ALKS 3831 is a proprietary investigational medicine designed as a broad spectrum treatment for schizophrenia. ALKS 3831 is composed of ALKS 33, an oral opioid modulator, in combination with the established antipsychotic drug olanzapine, which is generally available under the name ZYPREXA (olanzapine). ALKS 3831 is designed to attenuate olanzapine-induced metabolic side effects, including weight gain, and to have utility in patients with schizophrenia exacerbated by alcohol use disorders. In July 2013, we announced the initiation of a double-blind, active-controlled, dose-ranging phase 2 study of ALKS 3831 in patients with schizophrenia. In addition to safety and tolerability, the phase 2 study is designed to evaluate the impact of ALKS 3831 on weight and other metabolic factors and to confirm the attenuation of olanzapine-induced weight gain observed in the phase 1 study of ALKS 3831. We expect to complete enrollment in this study in 2014. A second, planned phase 2 study will investigate the potential utility of ALKS 3831 for the large number of patients with schizophrenia exacerbated by alcohol use disorders.

#### ***MMF Prodrug ALKS 8700***

ALKS 8700 is a proprietary, small-molecule prodrug of monomethyl fumarate (“MMF”) for the treatment of multiple sclerosis. It is designed to rapidly and efficiently convert to MMF in the body and to offer differentiated dosing and tolerability as compared to the currently marketed dimethyl fumarate prodrug, TECFIDERA. We expect to file an Investigational New Drug (“IND”) application with the FDA and initiate a phase 1 study of ALKS 8700 in mid-2014.

#### ***ALKS 7106***

ALKS 7106 is our novel and proprietary small-molecule product candidate derived from our opioid modulator platform. ALKS 7106 is a potent oral opioid analgesic designed for the treatment of pain with intrinsically low potential for abuse and overdose death, two liabilities associated with opioid medicines. In July 2013, we presented preclinical data showing that ALKS 7106 had more potent analgesic properties than morphine and was well tolerated at doses far in excess of those required for analgesic action. Additional preclinical data for ALKS 7106 demonstrated a ceiling effect on neurotransmitter release over a broad concentration range, suggesting low potential for abuse and overdose death. We expect to file an IND and initiate clinical studies in mid-2014.

#### ***RDB 1419***

In July 2013, we presented preclinical data showing that RDB 1419, a proprietary biologic cancer immunotherapy candidate based on interleukin-2 and its receptors, preferentially expanded the number of tumor-killing cells involved in immunotherapeutic effects on cancer. Additional preclinical data demonstrated that RDB 1419 inhibited lung metastases in a model of lung cancer. RDB 1419 was engineered using our proprietary fusion protein technology platform to modulate the natural mechanism of action of a biologic. We expect to conduct IND-enabling activities for RDB 1419 in 2014.

#### ***Other***

A phase 3 clinical research program for a three-month formulation of INVEGA SUSTENNA was initiated by Janssen Research & Development, LLC in 2012. Two phase 3 studies are underway, involving approximately 1,800 patients with schizophrenia, to assess the efficacy, safety and tolerability of the three-month injectable formulation. Janssen is expected to submit an NDA to the FDA and an

application with the EMA in 2015. This investigational product is being developed by Janssen Pharmaceutica, NV, licensee to our proprietary technology for nanoparticles.

AstraZeneca is developing line extensions for BYDUREON, including a dual-chamber pen device, and weekly and monthly suspension formulations using our proprietary technology for extended-release microspheres. In January 2014, AstraZeneca stated that they expect the BYDUREON dual-chamber pen to be approved in the U.S. in the second quarter of 2014 and in the EU in the fourth quarter of 2014, and that they plan to file for approval of the dual-chamber pen in Japan during the second quarter of 2014. In December 2013, AstraZeneca announced its expectation to file for approval of the BYDUREON once-weekly suspension in the U.S. and EU in 2015.

### ***Our Research and Development Expenditures***

We devote significant resources to R&D programs. We focus our R&D efforts on identifying novel therapeutics in areas of high unmet medical need. Please see “Management’s Discussion and Analysis of Financial Condition and Results of Operations—Results of Operations of Alkermes” for our R&D expenditures for the Transition Period and our fiscal years 2013 and 2012.

### **Collaborative Arrangements**

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

#### ***Janssen***

##### **RISPERDAL CONSTA**

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

Under license agreements, we granted Janssen and an affiliate of Janssen exclusive worldwide licenses to use and sell RISPERDAL CONSTA. Under our license agreements with Janssen, we receive royalty payments equal to 2.5% of Janssen’s net sales of RISPERDAL CONSTA in each country where the license is in effect based on the quarter when the product is sold by Janssen. This royalty may be reduced in any country based on lack of patent coverage and significant competition from generic versions of the product. Janssen can terminate the license agreements upon 30 days’ prior written notice to us. 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 receive certain development milestone payments from Janssen and aggregate 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.

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 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, 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 license agreement upon 90 days' written notice. We have the right to terminate the license agreement for countries in which Acorda fails to launch a product within a specified time after obtaining the necessary regulatory approval or fails to file regulatory approvals within a commercially reasonable time after completion 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 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 license agreement, licenses granted under the license agreement terminate on a country-by-country basis on the later of (i) September 2018 or (ii) the expiration of the last to expire of our patents or the existence of a threshold level of competition in the marketplace.

Under our commercial manufacturing supply agreement with Acorda, we manufacture and supply AMPYRA/FAMPYRA for Acorda (and its sub-licensees). Under the terms of the agreement, Acorda may obtain up to 25% of its total annual requirements of product from a second-source manufacturer. We receive 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 supply agreement upon 12 months' prior written notice to Acorda, and either party may terminate the supply agreement following a material and uncured breach of the supply or license agreement or the entry into bankruptcy or dissolution proceedings by the other party. In addition, subject to early termination of the supply agreement noted above, the supply agreement terminates upon the expiry or termination of the license agreement.

In January 2011, we entered into a development and supplemental agreement to our amended and restated license agreement with Acorda. Under the terms of this agreement, we granted Acorda the right, either with us or with a third party, in each case in accordance with certain terms and conditions, to develop new formulations of dalfampridine or other aminopyridines. Under the terms of the agreement, Acorda has the right to select either a formulation developed by us or by a third party for commercialization. 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. 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. 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 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 received a \$7.0 million milestone payment in July 2011 upon the first commercial sale of BYDUREON in the EU, and we received a \$7.0 million milestone payment upon the first commercial sale of BYDUREON in the U.S. in February 2012.

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. Civitas undertook a subsequent Series A Preferred Stock sale, in which we did not participate. Civitas also entered into an agreement to sublease our pulmonary manufacturing facility located in Chelsea, Massachusetts and has an option to purchase our pulmonary manufacturing equipment located at this facility. In addition, we have a seat on the Civitas board of directors. In December 2012, we paid Civitas \$1.1 million for a promissory note which is convertible into shares of its Series B Preferred Stock. In September 2013, we paid Civitas \$1.2 million for additional shares of its Series B Preferred Stock.



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

### **Proprietary Product Platforms**

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

#### ***Injectable Extended-Release Microsphere Technology***

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

#### ***LinkeRx Technology***

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

#### ***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 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, IPDAS technology, CODAS technology and the MXDAS drug absorption system, each as described below:

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

- **CODAS Technology:** CODAS (Chronotherapeutic Oral Drug Absorption System) enables the delayed onset of drug release incorporating the use of specific polymers, resulting in a drug release profile that more accurately complements circadian patterns.
- **IPDAS Technology:** IPDAS (Intestinal Protective Drug Absorption System) technology conveys gastrointestinal protection by a wide dispersion of drug candidates in a controlled and gradual manner, through the use of numerous high-density controlled-release beads compressed into a tablet form. Release characteristics are modified by the application of polymers to the micro matrix and subsequent coatings, which form a rate-limiting semi-permeable membrane.
- **MXDAS Technology:** MXDAS (Matrix Drug Absorption System) formulates the drug candidate in a hydrophilic matrix and incorporates one or more hydrophilic matrix-forming polymers into a solid oral dosage form, which controls the release of drug through a process of diffusion and erosion in the gastrointestinal tract.

### **Manufacturing and Product Supply**

We own and occupy manufacturing, office and laboratory facilities in: Wilmington, Ohio; Athlone, Ireland; and Gainesville, Georgia. We either purchase active drug product from third parties or receive it from our third-party collaborators to formulate product using our technologies. The manufacture of our 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 drug products are currently available from a single source or a limited number of qualified sources, we attempt to acquire an adequate inventory of such materials, establish alternative sources and/or negotiate long-term supply arrangements. We believe we do not have any significant issues 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 products or product candidates, including as a result of a failure of our facilities or the facilities or operations of third parties to pass any regulatory agency inspection, could significantly impair our ability to sell our products or advance our development efforts, as the case may be. For information about risks relating to the manufacture of our products and product candidates, see “Item 1A—Risk Factors” and specifically those sections entitled “—Our revenues largely depend on the actions of our third-party collaborators and, if they are not effective, our revenues could be materially adversely affected,” “—We rely heavily on collaborative partners in the commercialization and continued development of our products,” “—We are subject to risks related to the manufacture of our products,” “—We rely on third parties to provide services in connection with the manufacture and distribution of our products,” “—If we or our third-party providers fail to meet the stringent requirements of governmental regulation in the manufacture of our products, we could incur substantial remedial costs and a reduction in sales and/or revenues” and

### ***Commercial Products***

We manufacture RISPERDAL CONSTA, VIVITROL and polymer for BYDUREON in our Wilmington, Ohio facility. We are currently operating two RISPERDAL CONSTA lines and one VIVITROL line at commercial scale. Janssen has granted us an option, exercisable upon 30 days’ advance written notice, to purchase the most recently constructed and validated RISPERDAL

CONSTA manufacturing line at its then-current net book value. We source our packaging operations for VIVITROL to a third-party contractor. Janssen is responsible for packaging operations for RISPERDAL CONSTA. The facility has been inspected by U.S., European (“MHRA”), 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 and Korean regulatory authorities for compliance with required cGMP standards for continued commercial manufacturing.

We manufacture FOCALIN XR, RITALIN LA, AVINZA, VERAPAMIL and other products in our Gainesville, Georgia facility. The facility has been inspected by U.S., Danish, 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.”

### ***Clinical Products***

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

### ***Research & Development***

We devote significant resources to 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—Results of Operations of Alkermes” for our R&D expenditures for the Transition Period and our fiscal years 2013 and 2012.

### **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. M516), an Investigational Medicinal Products Manufacturers Authorization (No. IMP008) and Certificates of Good Manufacturing Practice Compliance of a Manufacturer (Ref. 2010-096 and 2010-097) from the Irish Medicines Board (“IMB”) in respect of our Athlone facility, and a number of Controlled Substance Licenses granted by the IMB. 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 (“DMF”), or the chemistry, manufacturing and controls data to the relevant regulator to prove adequate manufacturing

data in respect of the product. We would generally update this information annually with the relevant regulator. In other cases where we are developing proprietary product candidates, such as VIVITROL, we may hold the appropriate regulatory documentation ourselves.

### **Marketing, Sales and Distribution**

We 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 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 Transition Period to McKesson Corporation, CVS Caremark Corporation and AmerisourceBergen Drug Corporation represented approximately 16%, 13%, and 13%, respectively, of total VIVITROL sales.

Effective April 1, 2009, we entered into an agreement with Cardinal Health Specialty Pharmaceutical Services (“Cardinal SPS”), a division of Cardinal, to provide warehouse, shipping and administrative services for VIVITROL. Our expectation for 2014 is to continue to distribute VIVITROL through Cardinal SPS.

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

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

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

product candidates. Our collaborative partners could choose a competing technology to use with their drugs instead of one of our product platforms and could develop products that compete with our products.

With respect to our proprietary injectable product platform, we are aware that there are other companies developing extended-release delivery systems for pharmaceutical products. RISPERDAL CONSTA and INVEGA SUSTENNA may compete with a number of other injectable products including ZYPREXA RELPREVV ((olanzapine) For Extended Release Injectable Suspension), which is marketed and sold by Lilly; a once-monthly injectable formulation of ABILIFY (aripiprazole) developed by Otsuka Pharmaceutical Co., Ltd. (“Otsuka”), which was approved by the FDA in February 2013 and is commercialized under the name ABILIFY MAINTENA; oral compounds currently on the market, including generic versions of many branded products; and other products currently in development.

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 and that, if approved by the FDA, would compete with VIVITROL.

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

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

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

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



## Patents and Proprietary Rights

Our success will be dependent, in part, on our ability to obtain and maintain patent protection for our 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. We have filed numerous patent applications in the U.S. and in other countries directed to compositions of matter as well as processes of preparation and methods of use, including applications relating to each of our delivery technologies. We own more than 200 issued U.S. patents. In the future, we plan to file additional patent applications in the U.S. and in other countries directed to new or improved products and processes. We intend to file additional patent applications when appropriate and defend our patent position aggressively.

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

Our NanoCrystal technology patent portfolio contains a number of patents granted throughout the world, including the U.S. and countries outside of the U.S. We also have a significant number of pending patent applications covering our NanoCrystal technology. The latest of the patents covering INVEGA SUSTENNA expires in 2019 in the U.S. and 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, which issued in April 2013, covers a class of compounds that includes aripiprazole lauroxil and expires in 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 Application 11/760,039, for which a Notice of Allowance was granted by the U.S. Patent and Trademark Office (“USPTO”), contains method of treatment claims that will cover ALKS 5461, ALKS 3831 and ALKS 7106 and will expire in 2029. U.S. Patent Application 14/032,736 for which a Notice of Allowance was granted by the USPTO, 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 products and product candidates. The manufacture, use, offer for sale, sale or import of some of our product candidates might be found to infringe on the claims of these patents. A party might file an infringement action against us. The cost of defending such an action is likely to be high, and we might not receive a favorable ruling.

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

We try to protect our proprietary position by filing patent applications in the U.S. and in other countries related to our proprietary technology, inventions and improvements that are important to the development of our business. Because the patent position of biotechnology and pharmaceutical companies involves complex legal and factual questions, enforceability of patents cannot be predicted with certainty. The ultimate degree of patent protection that will be afforded to 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.

There are currently a few Paragraph IV litigations in the U.S. and other proceedings in Europe involving our patents in respect of FOCALIN XR, TRICOR, RITALIN LA and MEGACE ES.

We also rely on trade secrets, know-how and technology, which are not protected by patents, to maintain our competitive position. We try to protect this information by entering into confidentiality agreements with parties that have access to it, such as our corporate partners, collaborators, employees and consultants. Any of these parties may breach the agreements and disclose our confidential information or our competitors might learn of the information in some other way. If any trade secret, know-how or other technology not protected by a patent were to be disclosed to, or independently developed by, a competitor, such event could materially adversely affect our business, results of operations, cash flows and financial condition. For more information, see “Item 1A—Risk Factors.”

Our trademarks, including VIVITROL, are important to us and are generally covered by trademark applications or registrations in the USPTO 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.



## Revenues and Assets by Region

For the Transition Period ended December 31, 2013 and fiscal years 2013 and 2012, our revenue and assets are presented below by geographical area.

(In thousands)	Nine Months Ended December 31, 2013	Twelve Months Ended March 31,	
		2013	2012
Revenue by region:			
U.S. . . . .	\$269,005	\$380,565	\$212,859
Ireland . . . . .	5,722	14,455	12,695
Rest of world . . . . .	158,184	180,528	164,423
Assets by region:			
Current assets:			
U.S. . . . .	\$382,571	\$248,441	\$209,683
Ireland . . . . .	187,023	159,544	122,077
Rest of world . . . . .	544	603	7,393
Long-term assets:			
U.S.:			
Intangible assets . . . . .	\$ —	\$ —	\$ —
Goodwill . . . . .	3,677	3,677	3,677
Other . . . . .	225,559	229,691	213,729
Ireland:			
Intangible assets . . . . .	\$537,565	\$575,993	\$617,845
Goodwill . . . . .	89,063	89,063	89,063
Other . . . . .	151,586	163,279	171,750

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

*Non-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. Clinical trials must be conducted under protocols that detail the objectives of the 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 tolerance, absorption, bio-distribution, metabolism, excretion and clinical pharmacology and, if possible, to gain early evidence regarding efficacy.
- Phase 2 clinical trials—involve a 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 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 inform the applicant of the reason for the refusal. The applicant may then resubmit the application and include the supplemental information.

Once an application for an NME 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). In some cases, the FDA has available 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; there are currently four defined pathways for such review, depending on the results of clinical testing of the product, the condition(s) treated, and the currently available therapies for such conditions: Fast Track, Breakthrough Therapy, Accelerated Approval and Priority Review.

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 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, deny the application if it determines the application does not provide an adequate basis for approval, or issue a complete response letter to communicate to the applicant the reason the application cannot be approved in the current 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 preclinical 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, centrally acting pharmaceutical products 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 a use other than that initially approved. Such regulatory reviews can result in denial or modification of the planned changes, or requirements to conduct additional tests or evaluations that can substantially delay or increase the cost of the planned changes.

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

**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. Any pharmaceutical product that acts on the CNS has the potential to become a controlled substance, and scheduling by the DEA 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 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 U.S.*

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 Committee for Medicinal Products for Human Use (“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 party to comply with GCP can likewise result in rejection of our clinical trial data or other sanctions.

### *Hatch-Waxman Act*

Under the U.S. Drug Price Competition and Patent Term Restoration Act of 1984 (the “Hatch-Waxman Act”), Congress created an abbreviated FDA review process for generic versions of pioneer, or brand-name, drug products. The law also provides incentives by awarding, in certain circumstances, non-patent-related marketing exclusivities to pioneer drug manufacturers. Newly approved drug products and changes to the conditions of use of approved products may benefit from periods of non-patent-related marketing exclusivity in addition to any patent protection the drug product may have. The Hatch-Waxman Act provides five years of new chemical entity (“NCE”) marketing exclusivity to the first applicant to gain approval of a NDA for a product that contains an active ingredient not found in any other approved product. The FDA is prohibited from accepting any abbreviated NDA (“ANDA”) for a generic drug or 505(b)(2) application for five years from the date of approval of the NCE, or four years in the case of an ANDA or 505(b)(2) application containing a patent challenge. A 505(b)(2) application is an NDA wherein the applicant relies in part on data from clinical studies not conducted by or for it and for which the applicant has not obtained a right of reference; this type of application allows the sponsor to rely, at least in part, on the FDA’s findings of safety and/or effectiveness for a previously approved drug. This exclusivity will not prevent the submission or approval of a full NDA, as opposed to an ANDA or 505(b)(2) application, for any drug, including, for example, a drug with the same active ingredient, dosage form, route of administration, strength and conditions of use.

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

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

### *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 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 “—Product liability claims may adversely affect our business.”

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, with manufacturer reporting to commence 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 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 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. 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 Veterans Administration, 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 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 receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

#### *Outside the U.S.*

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 Bribery Act. Penalties under the Bribery Act include potentially unlimited fines for corporations and criminal sanctions for corporate officers under certain circumstances.

**Environmental, Health and Safety Laws:** Our operations are subject to complex and increasingly stringent environmental, health and safety laws and regulations in the countries where we operate and, in particular, where we have manufacturing facilities, namely the U.S. and Ireland. Environmental and health and safety authorities in the relevant jurisdictions, including the Environmental Protection Agency and the Occupational Safety and Health Administration in the U.S. and the Environmental Protection Agency and the Health and Safety Authority in Ireland, administer laws which regulate, among other matters, the emission of pollutants into the air (including the workplace), the discharge of

pollutants into bodies of water, the storage, use, handling and disposal of hazardous substances, the exposure of persons to hazardous substances, and the general health, safety and welfare of employees and members of the public. In certain cases, such laws and regulations may impose strict liability for pollution of the environment and contamination resulting from spills, disposals or other releases of hazardous substances or waste and/or any migration of such hazardous substances or waste. Costs, damages and/or fines may result from the presence, investigation and remediation of such contamination at properties currently or formerly owned, leased or operated by us and/or off-site locations, including where we have arranged for the disposal of hazardous substances or waste. In addition, we may be subject to third-party claims, including for natural resource damages, personal injury and property damage, in connection with such contamination.

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

### **Employees**

As of February 13, 2014, we had approximately 1,250 full-time employees. A significant number of our management and professional employees have prior experience with pharmaceutical, biotechnology or medical product companies. We believe that we have been successful in attracting skilled and experienced scientific and senior management personnel; however, competition for such personnel is intense. None of our employees is covered by a collective bargaining agreement. We consider our relations with our employees to be good.

### **Available Information**

We were incorporated in Ireland on May 4, 2011 as a private limited company, under the name Antler Science Two Limited (registration number 498284). On July 25, 2011, Antler Science Two Limited was re-registered as a public limited company under the name Antler Science Two plc. On September 14, 2011, Antler Science Two plc was re-named Alkermes plc. On September 16, 2011, the business of Alkermes, Inc. and the drug technologies business of Elan were combined under Alkermes plc.

Our principal executive offices are located at Connaught House, 1 Burlington Road, Dublin 4, Ireland. Our telephone number is +353-1-772-8000 and our website address is [www.alkermes.com](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 Transition Report. We make available free of charge through the Investors section of our website our Transition Report on Form 10-K, Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and all amendments to those reports as soon as reasonably practicable after such material is electronically filed with, or furnished to, the SEC. We also make available on our website (i) the charters for the committees of our Board of Directors, including the Audit and Risk Committee, Compensation Committee, and Nominating and Corporate Governance Committee, and (ii) our Code of Business Conduct and Ethics governing our directors, officers and employees. We intend to disclose on our website any amendments to, or waivers from, our Code of Business Conduct and Ethics that are required to be disclosed pursuant to the rules of the SEC. You may read and copy materials we file with the SEC at the SEC’s Public Reference Room at 100 F Street, N.E., Washington, D.C. 20549. You may obtain information on the operation of the Public Reference Room by calling the SEC at 1-800-SEC-0330. The SEC maintains an internet site that contains reports, proxy and information statements and other information regarding issuers that file electronically with the SEC at [www.sec.gov](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 Transition Report, including the matters addressed under the caption “Forward-Looking Statements.” If any events described by the following risks actually occur, they could materially adversely affect our business, financial condition, 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.*

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

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

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

While we manufacture RISPERDAL CONSTA and AMPYRA/FAMPYRA, we are not involved in the commercialization efforts for these products or for BYDUREON or INVEGA SUSTENNA. 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. Our revenues, from manufacturing fees and/or royalties, depend upon sales of these products by or on behalf of our partners. Accordingly, our revenues will depend in large part on the efforts of our partners, which are outside of our control. For these and other reasons outside of our control, our revenues from the sale of RISPERDAL CONSTA, AMPYRA/FAMPYRA, BYDUREON and INVEGA SUSTENNA/XEPLION may not meet our or our partners’ expectations, or those of investors.

### *VIVITROL*

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

### *REMAINING COMMERCIAL PORTFOLIO*

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

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

We depend substantially upon continued sales of RISPERDAL CONSTA and INVEGA SUSTENNA by our partner, Janssen, and upon continued sales of AMPYRA/FAMPYRA by our partner Acorda, and its sublicensee, Biogen. 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.

***We rely heavily on collaborative partners in the commercialization and continued development of our products.***

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

Our collaborative partners may 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.

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.

***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;

- 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.

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

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

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

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

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

Our manufacturing facilities also require specialized personnel and are expensive to operate and maintain. Any delay in the regulatory approval or market launch of product candidates, or suspension of the sale of our products, to be manufactured in our facilities, may cause operating losses as we continue to operate these facilities and retain specialized personnel. In addition, any interruption in manufacturing could result in delays in meeting contractual obligations and could damage our relationships with our collaborative partners, including the loss of manufacturing and supply rights.

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

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

The manufacture of products and product components, including the procurement of bulk drug product, packaging, storage and distribution of our products, 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 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 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



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. The 2010 Patient Protection and Affordable Care Act encourages the development of comparative effectiveness research, and 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 not only limit the marketing of products within that country, but may also adversely affect the ability to obtain acceptable prices in other markets.

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

***Patent protection for our products is important and uncertain.***

The following factors are important to our success:

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

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

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

Because the patent positions of pharmaceutical and biotechnology companies involve complex legal and factual questions, enforceability of patents cannot be predicted with certainty. The ultimate degree of patent protection that will be afforded to 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 and sale of our products.

In part as a result of this uncertainty, there has been, and we expect that there may continue to be, significant litigation in the 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 a few Paragraph IV litigations in the U.S. and other proceedings in Europe in respect of some of our products. These litigations could result in new or additional generic competition to our marketed products and a potential reduction in product revenue.

Litigation and administrative proceedings concerning patents and other intellectual property rights may be expensive, distracting to management and protracted with no certainty of success. Competitors may sue us as a way of delaying the introduction of our products. Any litigation, including any interference or derivation proceedings to determine priority of inventions, oppositions or other post-grant review proceedings to patents in the U.S. or in countries outside the U.S., or litigation against our partners may be costly and time-consuming and could harm our business. We expect that

litigation may be necessary in some instances to determine the validity and scope of certain of our proprietary rights. Litigation may be necessary in other instances to determine the validity, scope and/or non-infringement of certain patent rights claimed by third parties to be pertinent to the manufacture, use or sale of our products. Ultimately, the outcome of such litigation could adversely affect the validity and scope of our patent or other proprietary rights or hinder our ability to manufacture and market our products.

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

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 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 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.

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

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

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

***We have limited experience in the commercialization of products.***

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

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

***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 (“cGCP”).

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.

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

***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.”

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

- a product candidate may not demonstrate safety and efficacy for each target indication in accordance with FDA standards or standards of other regulatory agencies;
- poor rate of patient enrollment, including limited availability of patients who meet the criteria for certain clinical trials;
- data from preclinical testing and clinical trials may be interpreted by the FDA or other regulatory agencies in different ways than we or our partners interpret it;
- the FDA or other regulatory agencies might not approve our or our partners’ manufacturing processes or facilities;
- the FDA or other regulatory agencies may not approve accelerated development timelines for our product candidates;
- the failure of third-party 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, stock 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 stock price could decline significantly.

Even if regulatory approval to market a drug product is granted, the approval may impose limitations on the indicated use for which the drug product may be marketed and additional post-approval requirements with which we would need to comply in order to maintain the approval of such products. Our business could be seriously harmed if we do not complete these studies and the FDA, as a result, requires us to change related sections of the marketing label for our products. In addition, adverse medical events that occur during clinical trials or during commercial marketing of our products could result in legal claims against us and the temporary or permanent withdrawal of our products from commercial marketing, which could seriously harm our business and cause our stock price to decline. Further, even if the FDA provides regulatory approval, centrally acting drugs 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. DEA scheduling can negatively impact the ability or willingness of healthcare professionals to prescribe or dispense products, the likelihood that patients will use them and other aspects of our ability to commercialize such products.

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

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

Our 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 have opened clinical sites and are enrolling patients in a number of countries where our experience is more limited. For example, the phase 3 study of aripiprazole lauroxil 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 new drugs have shown promising results in early clinical trials but subsequently failed to establish sufficient safety and efficacy data to obtain necessary regulatory approvals. Clinical trials conducted by us, by our collaborative partners or by third parties on our behalf may not demonstrate sufficient safety and efficacy to obtain the requisite regulatory approvals for our product candidates.

If a product candidate fails to demonstrate safety and efficacy in clinical trials, or if third parties fail to conduct clinical trials in accordance with their obligations, the development, approval and commercialization of our product candidates may be delayed or prevented, 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 stock 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 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 stock price to decline or experience periods of volatility.

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

Our activities, and the activities of our collaborators and third-party providers, are subject to comprehensive government regulation. Government regulation by various national, state and local agencies, which includes detailed inspection of, and controls over, research and laboratory procedures, clinical investigations, product approvals and manufacturing, marketing and promotion, adverse event reporting, sampling, distribution, recordkeeping, storage, and disposal practices, and achieving compliance with these regulations, substantially increases the time, difficulty and costs incurred in obtaining and maintaining the approval to market newly developed and existing products. Government regulatory actions can result in delay in the release of products, seizure or recall of products, suspension or revocation of the authority necessary for their production and sale, and other civil or criminal sanctions, including fines and penalties. Pharmaceutical and biotechnology companies 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 new products, require additional safety monitoring, labeling changes, restrictions on product distribution or other measures that could increase our costs of doing business and adversely affect the market for our products. The enactment in the U.S. of healthcare reform, new legislation or implementation of existing statutory provisions on importation of lower-cost competing drugs from other jurisdictions and legislation on comparative

effectiveness research are examples of previously enacted and possible future changes in laws that could adversely affect our business.

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

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

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

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

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

With respect to our proprietary injectable product platform, we are aware that there are other companies developing extended-release delivery systems for pharmaceutical products. RISPERDAL CONSTA and INVEGA SUSTENNA may compete with a number of other injectable products including ZYPREXA RELPREVV ((olanzapine) For Extended Release Injectable Suspension), which is marketed and sold by Lilly; a once-monthly injectable formulation of ABILIFY (aripiprazole)

developed by Otsuka, which was approved by the FDA in February 2013 and is commercialized under the name ABILIFY MAINTENA; oral compounds currently on the market, including generic versions of many branded products; and other products currently in development.

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 and that, if approved by the FDA, would compete with VIVITROL.

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

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

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

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, 2013, our accumulated deficit was \$482.3 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 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.

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

- obtain and maintain regulatory approval for our products and product candidates, and for our partnered products, both in the U.S. and in other countries;
- efficiently manufacture our products;
- support the commercialization of our products by our collaborative partners;
- successfully market and sell VIVITROL in the U.S.;
- support the commercialization of VIVITROL in Russia and the countries of the CIS by our partner Cilag;
- enter into agreements to develop and commercialize our products and product candidates;
- develop, have manufactured or expand our capacity to manufacture and market our products and product candidates;
- obtain adequate reimbursement coverage for our products from insurance companies, government programs and other third-party 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 and for our partnered product candidates, including clinical trials;
- the time and expense that will be required to pursue FDA and/or non-U.S. regulatory approvals for our products and whether such approvals are obtained;
- the time that will be required for the DEA to provide its final scheduling designation for our products 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;
- 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 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 stockholders. 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.

***Product liability claims may adversely affect our business.***

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 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 the litigation and, as a result, our business could be materially harmed. These lawsuits may result in large judgments or settlements against us, any of which could have a negative effect on our financial condition and business if in excess of our insurance coverage. Additionally, lawsuits can be expensive to defend, whether or not they have merit, and the defense of these actions may divert the attention of our management and other resources that would otherwise be engaged in managing our business.

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

***Our business involves environmental, health and safety risks.***

Our business involves the controlled use of hazardous materials and chemicals and is subject to numerous environmental, health and safety laws and regulations and to periodic inspections for possible violations of these laws and regulations. Under certain of those laws and regulations, we could be liable



for any contamination at our current or former properties or third-party waste disposal sites. In addition to significant remediation costs, contamination can give rise to third-party claims for fines, penalties, natural resource damages, personal injury and damage (including property damage). The costs of compliance with environmental, health and safety laws and regulations are significant. Any violations, even if inadvertent or accidental, of current or future environmental, health or safety laws or regulations, the cost of compliance with any resulting order or fine and any liability imposed in connection with any contamination for which we may be responsible could 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 the recent tightening of global credit and the volatility in the financial markets, there may be a disruption or delay in the performance of our third-party contractors, suppliers or collaborative partners. If such third parties are unable to pay amounts owed to us or satisfy their commitments to us, or if there are reductions in the availability or extent of reimbursement available to us, our business, 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.

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, including the Business Combination, 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.

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

The pro forma financial data contained in this Transition Report are presented for illustrative purposes only and may not be an indication of what our financial condition or results of operations would have been had the Business Combination been completed on the dates indicated. The pro forma financial data have been derived from the audited and unaudited historical financial statements of Alkermes, Inc. and EDT, and certain adjustments and assumptions have been made regarding the combined company after giving effect to the Business Combination. Accordingly, the actual financial condition and results of operations of the combined company following the Business Combination may not be consistent with, or evident from, this pro forma financial data.

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

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

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

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

As of December 31, 2013, 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, 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 it is expected that 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. 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.

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

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

investigation has merit, and the defense of these actions may divert the attention of our management and other resources that would otherwise be engaged in running our business.

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

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

- responding to proxy contests and other actions by activist shareholders can be costly and time-consuming, disrupting operations and diverting the attention of management and employees, and can lead to uncertainty;
- perceived uncertainties as to future direction may result in the loss of potential acquisitions, collaborations or in-licensing opportunities, and may make it more difficult to attract and retain qualified personnel and business partners; and
- if individuals are elected to our board of directors with a specific agenda, it may adversely affect our ability to effectively and 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 may, from time to time, work with Janssen, Acorda and AstraZeneca to address certain issues related to these products. In doing so, we have established relationships with members of the management teams of Janssen, Acorda and AstraZeneca in relevant functional areas.

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.

***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. 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 stockholders.***

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 stockholders for the foreseeable future.

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

None.

**Item 2. *Properties***

We lease approximately 8,500 square feet of corporate office space in Dublin, Ireland, which houses our corporate headquarters. This lease expires in 2022 and includes a tenant option to terminate in 2017. We lease approximately 115,000 square feet of space in Waltham, Massachusetts, which houses corporate offices, administrative areas and laboratories. We have the right to lease an additional approximately 31,000 square feet of space at this location commencing June 2014, with such



commencement date subject to extension. This lease expires in 2021 and includes a tenant option to extend the term for up to two five-year periods.

We own manufacturing, office and laboratory sites in Wilmington, Ohio (approximately 195,000 square feet); Athlone, Ireland (approximately 460,000 square feet); and Gainesville, Georgia (approximately 90,000 square feet). In January 2014, we agreed to sell, subject to customary closing conditions, certain of our land, buildings (approximately 56,000 square feet) and equipment at our Athlone, Ireland facility.

We have a sublease agreement in place for a commercial manufacturing facility we lease in Chelsea, Massachusetts designed for clinical and commercial manufacturing of inhaled products based on our pulmonary technology that we are currently sub-letting. 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 a few Paragraph IV litigations in the U.S. and other proceedings in Europe involving our patents in respect of FOCALIN XR, TRICOR, RITALIN LA and MEGACE ES. 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.

## 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.

	Nine Months Ended December 31, 2013		Twelve Months Ended March 31, 2013	
	High	Low	High	Low
1st Quarter . . . . .	\$33.72	\$22.35	\$18.64	\$15.12
2nd Quarter . . . . .	35.35	28.66	20.87	17.22
3rd Quarter . . . . .	41.12	30.17	20.88	18.08
4th Quarter . . . . .	—	—	23.81	19.28

There were 246 shareholders of record for our ordinary shares on February 13, 2014. In addition, the last reported sale price of our ordinary shares as reported on the NASDAQ Global Select Stock Market on February 13, 2014 was \$52.13.

#### *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 2013 Annual Meeting of Shareholders (the "2013 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 nine months ended December 31, 2013. As of December 31, 2013, 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, 2014, and on discussions and correspondence with the Irish Revenue Commissioners. Legislative, administrative or judicial changes may modify the tax consequences described below.

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

*Withholding 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 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.

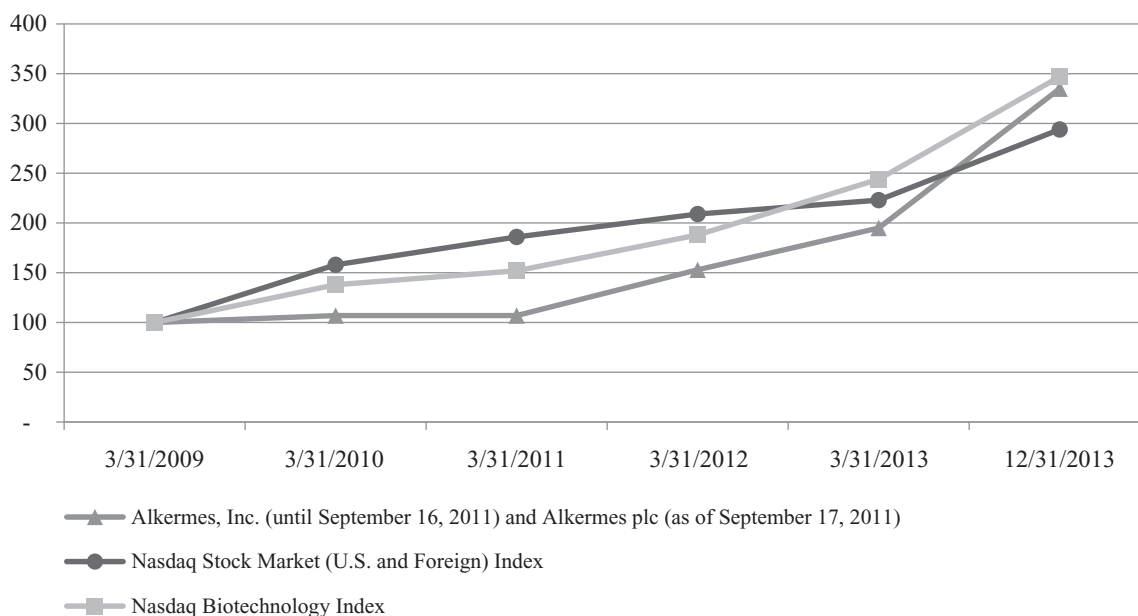
A shareholder who holds ordinary shares outside of DTC may transfer those ordinary shares into DTC without giving rise to Irish stamp duty provided that the shareholder would be the beneficial owner of the related book-entry interest in those ordinary shares recorded in the systems of DTC, and in exactly 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, 2009 through December 31, 2013 (the end of the nine-month transition period covered by this Transition Report) with the cumulative total return on the Nasdaq Stock Market (U.S. and Foreign) Index and the Nasdaq Biotechnology Index. It is important to note that information set forth in the graph below with respect to the time period prior to September 16, 2011 refers to the common stock performance of 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, 2009 in our common stock and in each of the foregoing indices and further assumes reinvestment of any dividends. We did not declare or pay any dividends on our common stock or ordinary shares during the comparison period.

**Comparison of Cumulative Total Returns**



	Twelve Months Ended March 31,					Nine Months Ended December 31,
	2009	2010	2011	2012	2013	2013
Alkermes . . . . .	100	107	107	153	195	335
NASDAQ Stock Market (U.S.) Index . . . . .	100	158	186	209	223	294
NASDAQ Biotechnology Index . . . . .	100	138	152	188	244	347

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

The selected historical financial data set forth below at December 31, 2013 and March 31, 2013 and for the nine months ended December 31, 2013 and the twelve months ended March 31, 2013 and 2012 are derived from our audited consolidated financial statements, which are included elsewhere in this Transition Report. The selected historical financial data set forth below at March 31, 2012, 2011 and 2010 and for the twelve months ended March 31, 2011 and 2010 are derived from audited consolidated financial statements, which are not included in this Transition 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. 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. As a result of this change to the fiscal year end, this Transition Report covers a nine-month transition period consisting of the period from April 1, 2013 to December 31, 2013, and our 2014 fiscal year will begin on January 1, 2014 and end on December 31, 2014.

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 Transition Report. The historical results are not necessarily indicative of the results to be expected for any future period.

	Nine Months Ended December 31, 2013	Twelve Months Ended March 31,			
		2013	2012(1)	2011	2010
(In thousands, except per share data)					
<b>Consolidated Statements of Operations Data:</b>					
REVENUES:					
Manufacturing and royalty revenues . . . . .	\$ 371,039	\$ 510,900	\$ 326,444	\$156,840	\$149,917
Product sales, net . . . . .	57,215	58,107	41,184	28,920	20,245
Research and development revenue . . . . .	4,657	6,541	22,349	880	3,117
Net collaborative profit . . . . .	—	—	—	—	5,002
Total revenues . . . . .	<u>432,911</u>	<u>575,548</u>	<u>389,977</u>	<u>186,640</u>	<u>178,281</u>
EXPENSES:					
Cost of goods manufactured and sold . . . . .	134,306	170,466	127,578	52,185	49,438
Research and development . . . . .	128,125	140,013	141,893	97,239	95,363
Selling, general and administrative(2) . . . . .	116,558	125,758	137,632	82,847	76,514
Amortization of acquired intangible assets . . . . .	38,428	41,852	25,355	—	—
Restructuring(3) . . . . .	—	12,300	—	—	—
Impairment of long-lived assets(4) . . . . .	—	3,346	45,800	—	—
Total expenses . . . . .	<u>417,417</u>	<u>493,735</u>	<u>478,258</u>	<u>232,271</u>	<u>221,315</u>
OPERATING INCOME (LOSS) . . . . .	15,494	81,813	(88,281)	(45,631)	(43,034)
OTHER EXPENSE, NET . . . . .	(10,097)	(46,372)	(26,111)	(860)	(1,667)
INCOME (LOSS) BEFORE INCOME TAXES . . . . .	<u>5,397</u>	<u>35,441</u>	<u>(114,392)</u>	<u>(46,491)</u>	<u>(44,701)</u>
(BENEFIT) PROVISION FOR INCOME TAXES . . . . .	(12,252)	10,458	(714)	(951)	(5,075)
NET INCOME (LOSS) . . . . .	<u>\$ 17,649</u>	<u>\$ 24,983</u>	<u>\$ (113,678)</u>	<u>\$ (45,540)</u>	<u>\$ (39,626)</u>
EARNINGS (LOSS) PER COMMON SHARE:					
BASIC . . . . .	<u>\$ 0.13</u>	<u>\$ 0.19</u>	<u>\$ (0.99)</u>	<u>\$ (0.48)</u>	<u>\$ (0.42)</u>
DILUTED . . . . .	<u>\$ 0.12</u>	<u>\$ 0.18</u>	<u>\$ (0.99)</u>	<u>\$ (0.48)</u>	<u>\$ (0.42)</u>
WEIGHTED AVERAGE NUMBER OF COMMON SHARES OUTSTANDING:					
BASIC . . . . .	<u>135,960</u>	<u>131,713</u>	<u>114,702</u>	<u>95,610</u>	<u>94,839</u>
DILUTED . . . . .	<u>144,961</u>	<u>137,100</u>	<u>114,702</u>	<u>95,610</u>	<u>94,839</u>
<b>Consolidated Balance Sheet Data:</b>					
Cash, cash equivalents and investments . . . . .	\$ 449,995	\$ 304,179	\$ 246,138	\$294,730	\$350,193
Total assets . . . . .	1,577,588	1,470,291	1,435,217	452,448	515,600
Long-term debt . . . . .	364,293	369,008	444,460	—	—
Shareholders' equity . . . . .	1,065,186	952,374	853,852	392,018	412,616

- (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 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 twelve months 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 twelve months 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 twelve months 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 Transition 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 Transition Report.

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. As a result of this change to the fiscal year end, this Transition Report covers a nine-month transition period consisting of the period from April 1, 2013 to December 31, 2013, and our 2014 fiscal year will begin on January 1, 2014 and end on December 31, 2014.

### **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.

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. For a more detailed discussion of the Business Combination, refer to Note 1, *Description of Business and Basis of Presentation*, and Note 3, *Acquisitions*, in the accompanying Notes to Consolidated Financial Statements.

### **Executive Summary**

We and our pharmaceutical and biotechnology partners have more than 20 commercialized products sold worldwide, including in the U.S. We earn manufacturing and/or royalty revenues on net sales of products commercialized by our partners and earn revenue on net sales of VIVITROL, which is a proprietary product that we manufacture, market and sell in the U.S. Our 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 are: RISPERDAL CONSTA and INVEGA SUSTENNA/XEPLION; AMPYRA/FAMPYRA; BYDUREON; and VIVITROL.

For the nine months ended December 31, 2013, we reported \$432.9 million in revenues, an increase of 5% over the prior comparative period. Revenues from our key marketed products accounted for 74% of our total revenues in the nine months ended December 31, 2013, an increase of 14% over the prior comparative period. Excluding the \$20.0 million of revenue from the sale of intellectual property, unrelated to our key development programs, from the nine months ended December 31, 2012, our total revenue increased by 10%.

For the nine months ended December 31, 2013, we generated cash flows from operations of \$92.2 million, and our total cash and investments increased by \$145.8 million from March 31, 2013 to \$450.0 million.

During the nine months ended December 31, 2013, we had a number of developments in our product pipeline including:

- We completed patient enrollment in our phase 3 study of aripiprazole lauroxil;
- We announced positive results from our phase 2 study of ALKS 5461, completed our End-of-Phase 2 interactions with the FDA and received Fast Track status from the FDA for this product candidate;
- We announced the initiation of a phase 2 study of ALKS 3831; and
- We added three programs, ALKS 8700, ALKS 7106 and RDB 1419 to our key development program portfolio. These programs are planned for IND-enabling activities or clinical studies in 2014.

## Results of Operations

### Nine Months Ended December 31, 2013 and 2012

#### 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 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 . . . . .	<u>\$371.0</u>	<u>\$364.0</u>	<u>\$ 7.0</u>

Our long-acting, antipsychotic franchise consists of RISPERDAL CONSTA and INVEGA SUSTENNA/XEPLION. 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. 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 beginning of each calendar-year to 5%.

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.

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, and we also earn royalty revenues upon third-party shipments of AMPYRA to Acorda. 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 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.

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 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 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.

During the nine months ended December 31, 2012, we sold a license to certain of our intellectual property that is not used in our key clinical development programs or commercial products for \$20.0 million.

A number of our mature products, including TRICOR 145, RITALIN LA and FOCALIN XR, currently face generic competition. As a result of these generic entries, we expect sales of these products to decline over the next few fiscal years.

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 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(1) . . . . .	(0.9)	(1.1)%	0.4	0.7%
Other . . . . .	(2.9)	(3.6)%	(2.4)	(4.2)%
Total adjustments . . . . .	(21.9)	(27.7)%	(14.7)	(25.3)%
Product sales, net . . . . .	<u>\$ 57.2</u>	<u>72.3%</u>	<u>\$ 43.5</u>	<u>74.7%</u>

(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. 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 VIVITROL, which may negatively impact future sales of VIVITROL. Increased competition may lead to reduced unit sales of VIVITROL, as well as increasing pricing pressure. VIVITROL is covered by a patent that will expire in the U.S. in 2029 and in Europe in 2021 and, as such, we do not anticipate any generic versions of this product in the near-term.

### 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 . . . . .	<u>\$134.3</u>	<u>\$122.5</u>	<u>\$(11.8)</u>

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 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 ended December 31, 2015.

### *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)	Nine Months Ended December 31,		Change Favorable/ (Unfavorable)
	2013	2012 (unaudited)	
External R&D Expenses:			
Key development programs:			
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)
Total external expenses . . . . .	<u>65.0</u>	<u>50.5</u>	<u>(14.5)</u>
Internal R&D expenses:			
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
Total internal R&D expenses . . . . .	<u>63.1</u>	<u>53.7</u>	<u>(9.4)</u>
Research and development expenses . . . . .	<u>\$128.1</u>	<u>\$104.2</u>	<u>\$(23.9)</u>

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.

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.

We expect an increase in R&D expenses in 2014 primarily due to increased R&D investment as certain of our key development programs, most notably ALKS 5461 and ALKS 3831, continue to advance through the pipeline and as aripiprazole lauroxil nears completion of its phase 3 clinical trial.

*Selling, General and Administrative Expenses*

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

The increase in selling, general and administrative (“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 due primarily to 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 . . . . .	<u>\$38.4</u>	<u>\$31.5</u>	<u>\$(6.9)</u>

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. Based on our most recent analysis, amortization of intangible assets included within our consolidated balance sheet at December 31, 2013 is expected to be approximately \$60.0 million, \$65.0 million, \$70.0 million, \$70.0 million and \$70.0 million in the years ended December 31, 2014 through 2018, respectively.

### *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 . . . . .	<u>\$ (10.1)</u>	<u>\$ (35.3)</u>	<u>\$ 25.2</u>

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 twelve months 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.

### *Provision for Income Taxes*

(In millions)	Nine Months Ended December 31,		Change Favorable/ (Unfavorable)
	2013	2012 (unaudited)	
Income tax (benefit) expense . . . . .	<u>\$ (12.3)</u>	<u>\$ 5.6</u>	<u>\$ (17.9)</u>

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.

At December 31, 2013, we maintained a valuation allowance of \$10.7 million against certain U.S. federal and state deferred tax assets and \$58.9 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. \$9.1 million of the \$10.7 million valuation allowance held against certain U.S. tax assets, when recognized, will be accounted for as a credit to additional paid-in capital rather than a reduction of income tax expense.

As of December 31, 2013, we had \$494.6 million of Irish Net Operating Loss (“NOL”) carryforwards, \$77.1 million of U.S. federal NOL carryforwards and \$9.8 million of U.S. state NOL carryforwards, \$22.3 million of federal research and development credits, \$7.5 million of alternative minimum tax credits and \$0.6 million of U.S. state tax credits which either expire on various dates through 2033 or can be carried forward indefinitely. These loss carryforwards and credits are available to reduce certain future Irish and U.S. taxable income, if any. These loss carryforwards are subject to review and possible adjustment by the appropriate taxing authorities. These loss carryforwards, which may be utilized in any future period, may be subject to limitations based upon changes in the ownership of our stock. We have performed a review of ownership changes in accordance with the U.S. Internal Revenue Code and have determined that it is more-likely-than-not that, as a result of the

Business Combination, we 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.

**Twelve months Ended March 31, 2013 and 2012**

***Manufacturing and Royalty Revenues***

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

(In millions)	Twelve Months 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 . . . . .	<u>\$510.9</u>	<u>\$326.4</u>	<u>\$184.5</u>

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 twelve months ended March 31, 2012 to \$1,399.1 million during the twelve months 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 twelve months 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 twelve months ended March 31, 2012 to \$920.0 million in the twelve months 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 twelve months 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 is sold. Acorda’s end-market sales of AMPYRA/FAMPYRA in the twelve months ended March 31, 2013 and 2012 were \$329.4 million and \$249.7 million, respectively.

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 is 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 twelve months ended March 31, 2013 and 2012:

(In millions)	Twelve Months Ended March 31, 2013		Twelve Months 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)	Twelve Months 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 twelve months 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 twelve months ended March 31, 2012, we also received a \$3.0 million milestone payment upon receipt of regulatory approval for VIVITROL in Russia for the opioid dependence indication.

## Costs and Expenses

### Cost of Goods Manufactured and Sold

(In millions)	Twelve Months 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 twelve months 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)	Twelve Months Ended March 31,		Change Favorable/ (Unfavorable)
	2013	2012	
External R&D Expenses:			
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
Internal R&D expenses:			
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 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)	Twelve Months Ended March 31,		Change Favorable/ (Unfavorable)
	2013	2012	
Selling, general and administrative . . . . .	<u>\$125.8</u>	<u>\$137.6</u>	<u>\$11.8</u>

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 twelve months 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 twelve months 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)	Twelve Months Ended March 31,		Change Favorable/ (Unfavorable)
	2013	2012	
Amortization of acquired intangible assets . . . . .	<u>\$41.9</u>	<u>\$25.4</u>	<u>\$(16.5)</u>

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

*Restructuring*

(In millions)	Twelve Months Ended March 31,		Change Favorable/ (Unfavorable)
	2013	2012	
Restructuring . . . . .	<u>\$12.3</u>	<u>\$—</u>	<u>\$(12.3)</u>

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, expected to be implemented over a two-year period, calls for us to terminate manufacturing services for certain older products that are 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 from the manufacturing of these products during 2014 and, 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 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)	Twelve Months Ended March 31,		Change Favorable/ (Unfavorable)
	2013	2012	
Impairment of long-lived assets . . . . .	<u>\$3.3</u>	<u>\$45.8</u>	<u>\$42.5</u>

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 twelve months 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)	Twelve Months 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 . . . . .	<u>1.8</u>	<u>0.5</u>	<u>1.3</u>
Total other expense, net . . . . .	<u>\$(46.4)</u>	<u>\$(26.1)</u>	<u>\$(20.3)</u>

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 twelve months 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 twelve months 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)	<u>September 2012 Refinancing</u>	<u>February 2013 Repricing</u>	<u>Total</u>
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
Total . . . . .	<u>\$12.2</u>	<u>\$7.5</u>	<u>\$19.7</u>

***Provision for Income Taxes***

(In millions)	<u>Twelve Months Ended March 31,</u>		<u>Change Favorable/ (Unfavorable)</u>
	<u>2013</u>	<u>2012</u>	
Income tax expense (benefit) . . . . .	<u>\$10.5</u>	<u>\$(0.7)</u>	<u>\$(11.2)</u>

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.

## Liquidity and Capital Resources

Our financial condition is summarized as follows:

(In millions)	December 2013	March 2013
Cash and cash equivalents . . . . .	\$167.6	\$ 97.0
Investments—short-term . . . . .	194.6	124.4
Investments—long-term . . . . .	87.8	82.8
Total cash and investments . . . . .	<u>\$450.0</u>	<u>\$304.2</u>
Working capital . . . . .	\$469.2	\$322.7
Outstanding borrowings—current and long-term . . . . .	\$364.3	\$369.0

### Sources and Uses of Cash

We expect that funds generated by 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. Subsequent to December 31, 2013, we sold approximately 5.9 million of our ordinary shares through a registered direct offering for net proceeds of \$248.4 million.

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 nine months ended December 31, 2013 and the twelve months ended December 31, 2013 and 2012:

(In millions)	Nine Months Ended December 31, 2013	Twelve Months Ended March 31,	
		2013	2012
Cash and cash equivalents, beginning of period . . . . .	\$ 97.0	\$ 83.6	\$ 38.4
Cash provided by (used in) operating activities . . . . .	92.2	126.5	(2.5)
Cash (used in) investing activities . . . . .	(65.4)	(68.1)	(417.1)
Cash provided by (used in) financing activities . . . . .	43.8	(45.0)	464.8
Cash and cash equivalents, end of period . . . . .	<u>\$167.6</u>	<u>\$ 97.0</u>	<u>\$ 83.6</u>

### Operating Activities

We continued to generate cash flows from operating activities in the nine months ended December 31, 2013 with cash provided from net income of \$89.3 million and cash provided by working capital of \$2.9 million. Cash provided from net income in the twelve months ended March 31, 2013 was \$142.0 million, an increase of \$147.7 million from the twelve months ended March 31, 2012. Cash used for working capital was \$15.4 million in the twelve months ended March 31, 2013, an increase of \$16.2 million from the twelve months ended March 31, 2012, most notably from a decrease in cash from accounts receivable of \$14.2 million and a decrease in cash from deferred revenue of \$9.4 million.

### Investing Activities

During the nine months ended December 31, 2013, our net purchases of available-for-sale investments were \$45.2 million and we invested an additional \$1.2 million in Civitas during this period. We also had \$19.1 million in purchases of property, plant and equipment. The increase in cash flows

provided by investing activities in the twelve months ended March 31, 2013, as compared to the twelve months ended March 31, 2012, was primarily due to \$500.0 million of cash used in the purchase of the former EDT business in September 2011, partially offset by an increase in the net purchase of investments of \$139.8 million. During the twelve months ended March 31, 2013, we made net purchases of investments of \$45.0 million whereas in the twelve months ended March 31, 2012, we made net sales of investments of \$94.8 million due in part to fund the purchase of the former EDT business.

We expect to spend approximately \$30.0 million during the twelve months ended December 31, 2014 for capital expenditures. Amounts included as construction in progress in the consolidated balance sheets 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.

#### *Financing Activities*

During the nine months ended December 31, 2013, we received \$49.1 million from our employees upon the exercise of stock option awards and \$11.4 million in excess tax-benefit from share-based compensation expense. These amounts were offset by \$11.7 million in cash used to buyback our ordinary shares to pay employee withholdings related to stock awards and principal payments of \$5.1 million on our long-term debt. The increase in cash flows used in financing activities in the twelve months ended March 31, 2013, as compared to the twelve months ended March 31, 2012, was primarily due to the \$444.1 million of cash received upon the issuance of the 2011 Term Loans in September 2011. During the twelve months ended March 31, 2013, we used \$74.2 million of cash in the Refinancing attributable to financing activities, and \$4.2 million of cash for principal payments on our long-term debt, which was offset by a \$13.5 million increase in cash received from our employees upon the exercise of stock awards.

At December 31, 2013, our investments consisted of the following:

(In millions)	Amortized Cost	Gross Unrealized		Estimated Fair Value
		Gains	Losses	
Investments—short-term . . . . .	\$194.6	\$ 0.2	\$(0.1)	\$194.7
Investments—long-term available-for-sale . . . . .	65.2	21.2	(0.2)	86.2
Investments—long-term held-to-maturity . . . . .	1.5	—	—	1.5
Total . . . . .	<u>\$261.3</u>	<u>\$21.4</u>	<u>\$(0.3)</u>	<u>\$282.4</u>

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. However, the value of these securities may be adversely affected by the instability of the global financial markets, which could, in turn, adversely impact our financial position and our overall liquidity. Our available-for-sale investments consist primarily of short- and long-term U.S. government and agency debt securities, debt securities issued by foreign agencies and backed by foreign governments, corporate debt securities and equity securities. The equity securities consist of common stock and warrants of Acceleron, which we reclassified from a cost method investment to an available-for-sale investment, following Acceleron's IPO in September 2013. Our held-to-maturity

investments consist of investments that are restricted and held as collateral under certain letters of credit related to certain of our lease agreements.

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, 2013, we performed an analysis of our investments with unrealized losses for impairment and determined that they were temporarily impaired.

At December 31, 2013 and March 31, 2013, \$1.5 million and none of our investments were valued using Level 3 inputs, respectively. Level 3 inputs are unobservable and are significant to the overall fair value measurement and require a significant degree of judgment.

### ***Borrowings***

At December 31, 2013, our borrowings consisted of \$366.6 million outstanding under our Term Loan Facility. Please refer to Note 11, *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, 2013:

<u>Contractual Obligations</u>	<u>Total</u>	<u>Less Than One Year (2014)</u>	<u>One to Three Years (2015 - 2016)</u>	<u>Three to Five Years (2017 - 2018)</u>	<u>More than Five Years (After 2019)</u>
			(In thousands)		
Term Loan Facility—Principal . . . . .	\$366,563	\$ 6,750	\$ 72,563	\$ 6,000	\$281,250
Term Loan Facility—Interest . . . . .	63,289	12,364	23,638	19,924	7,363
Operating lease obligations . . . . .	30,416	4,816	9,231	8,960	7,409
Purchase obligations . . . . .	101,825	101,825	—	—	—
Total contractual cash obligations . . . . .	<u>\$562,093</u>	<u>\$125,755</u>	<u>\$105,432</u>	<u>\$34,884</u>	<u>\$296,022</u>

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 0.20%, which was the approximate one-month LIBOR rate at December 31, 2013. 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, 2013, we had \$1.1 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.

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 \$9.1 million upon

certain agreed-upon development events. All amounts paid to RPI to date under this license agreement have been expensed and are included in R&D 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, 2013, 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.

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.

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. 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 AMP. We estimate expected unit sales and rebates per unit under the Medicaid program and adjust our rebate estimates based on actual unit sales and rebates per unit. To date, actual Medicaid rebates have not differed materially from our estimates;
- **Chargebacks**—wholesaler and specialty pharmacy chargebacks are discounts that occur when contracted customers purchase directly from an intermediary wholesale purchaser. Contracted customers, which consist primarily of federal government agencies purchasing under the FSS, generally purchase the product at its contracted price, plus a mark-up from the wholesaler. The wholesaler, in-turn, charges back to us the difference between the price initially paid by the wholesaler and the contracted price paid to the wholesaler by the customer. The allowance for wholesaler chargebacks is based on actual and expected utilization of these programs. Wholesaler chargebacks could exceed historical experience and our estimates of future participation in these programs. To date, actual wholesaler chargebacks have not differed materially from our estimates;
- **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, 2013, our product return reserve is 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 related to products shipped to customers with the associated revenue, we deferred the recognition of the cost of goods to the period in which the associated revenue is 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, 2012</b> .....	\$ 1.5	\$ 0.1	\$ 0.3	\$ 0.1	\$ 3.8	\$ 0.5	\$ 6.3
Provision:							
Current period .....	6.0	5.4	2.7	3.2	3.7	3.4	24.4
Prior period .....	(0.1)	—	—	—	(3.9)	—	(4.0)
Total .....	5.9	5.4	2.7	3.2	(0.2)	3.4	20.4
Actual:							
Current period .....	(4.2)	(5.4)	(2.6)	(3.3)	(0.5)	(3.0)	(19.0)
Prior period .....	(1.3)	(0.1)	—	—	—	(0.3)	(1.7)
Total .....	(5.5)	(5.5)	(2.6)	(3.3)	(0.5)	(3.3)	(20.7)
<b>Balance, March 31, 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)
Total .....	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)
Total .....	(4.6)	(5.2)	(3.4)	(3.8)	(0.2)	(3.2)	(20.4)
<b>Balance, December 31, 2013</b> .....	<u>\$ 2.7</u>	<u>\$ —</u>	<u>\$ 0.8</u>	<u>\$ 0.2</u>	<u>\$ 3.8</u>	<u>\$ —</u>	<u>\$ 7.5</u>

### **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 includes 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 requires us to estimate certain subjective assumptions. These assumptions include 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 15, *Share-Based Compensation*, in our Notes to Consolidated Financial Statements for a complete discussion of our share-based compensation plans.

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 nine months ended December 31, 2013 and the twelve months ended March 31, 2013 and 2012, the ranges in weighted-average assumptions were as follows:

	Nine Months Ended December 31, 2013	Twelve Months Ended March 31,	
		2013	2012
Expected option term . . . . .	5 - 7 years	5 - 7 years	5 - 7 years
Expected stock volatility . . . . .	45% - 48%	47% - 49%	47% - 51%
Risk-free interest rate . . . . .	0.75% - 2.15%	0.61% - 1.18%	0.82% - 2.5%
Expected annual dividend yield . . . . .	—	—	—

In addition to the above, we apply judgment in developing estimates of award forfeitures. For the nine months ended December 31, 2013, 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 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, 2013, is expected to be approximately \$60.0 million, \$65.0 million, \$70.0 million, \$70.0 million and \$70.0 million in the twelve months ending December 31, 2014 through 2018, 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 in the quarter ended December 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, 2013, we have one operating segment and two reporting units. Our goodwill, which solely relates to the EDT acquisition in the twelve months ended March 31, 2012, has been assigned to one reporting unit which consists of the former EDT business.

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.

We worked with a third-party valuation firm and established fair value for the purpose of impairment testing by using an average of the income approach and the market approach. The income approach employs a discounted cash flow model that takes into account: (i) assumptions that market participants would use in their estimates of fair value; (ii) current period actual results; and (iii) forecasted results for future periods that have been vetted by senior management. The discounted cash flow model incorporates the same fundamental pricing concepts used to calculate fair value in an acquisition due diligence process and a discount rate that takes into consideration our estimated cost of capital adjusted for the uncertainty inherent in an acquisition. The market approach employs market multiples for comparable publicly traded companies in the pharmaceutical and biotechnology industries obtained from industry sources, taking into consideration the nature, scope and size of the acquired reporting unit. In the market approach, estimates of fair value are established using an average of both revenue and EBITDA multiples, adjusted for the reporting unit's performance relative to peer companies.

We determined that the fair value of the former EDT business reporting unit was substantially in excess of its carrying value and there was no impairment in the value of this asset as of December 31, 2013. A decline in the estimated fair value of a reporting unit could result in goodwill impairment, and a related non-cash impairment charge against earnings, if the estimated fair value for the reporting unit is less than the carrying value of the net assets of the reporting unit, including its goodwill. A large decline in estimated fair value of a reporting unit could result in an adverse effect on our financial condition and results of operations. In order to evaluate the sensitivity of the fair value calculations relating to our goodwill impairment assessment, we applied a hypothetical decrease to the estimated fair value of the former EDT business reporting unit and we determined that a decrease in fair value of at least 80% would be required before this reporting unit would have a carrying value in excess of its fair value.

#### ***Acquisitions—Purchase Price Allocation***

In accordance with accounting guidance for business combinations, we allocate the purchase price of an acquired business to its identifiable assets and liabilities based on estimated fair values. The excess of the purchase price over the amount allocated to the assets and liabilities, if any, is recorded as goodwill. We adjust the preliminary purchase price allocation as necessary, up to one year after the acquisition closing date as we obtain more information regarding asset values and liabilities assumed.

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

- estimating the timing of and expected costs to complete the in-process projects;
- projecting regulatory approvals;
- estimating future cash flows from product sales resulting from completed products and in-process projects; and
- developing appropriate discount rates and probability rates by project.

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

#### ***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.

#### ***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. Due to the conservative nature of our short-term and long-term investments and our investment policy, we do not believe that we have a material exposure to interest rate risk as our investment policies specify credit quality standards for our investments and limit the amount of credit exposure from any single issue, issuer or type of investment.

We do not believe that inflation and changing prices have had a material impact on our results of operations, and as over 56% 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.

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 0.24% at December 31, 2013, 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, 2014.

Term Loan B-2 bears interest at one-month LIBOR plus 2.75% with no LIBOR floor. At December 31, 2013, the one-month LIBOR rate was 0.17%. A 10% increase in the one-month LIBOR rate would increase our interest expense in the twelve months ended December 31, 2014 by an immaterial amount.

At December 31, 2013, we have an interest rate swap agreement, entered into in connection with a term loan that has since been refinanced, that remains outstanding. The interest rate swap has a notional amount of \$160.0 million and protects us if three-month LIBOR were to reach 2.057% from December 3, 2012 through September 3, 2014.

We do not use derivative financial instruments for speculative trading purposes. The counterparty to our interest rate swap contract is a multinational commercial bank. We believe the risk of counterparty non-performance is remote.

### **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. Also, certain of our R&D revenue is generated in countries other than the U.S. and is denominated in the Euro. 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 nine months ended December 31, 2013, 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 \$16.4 million.

We 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. For the nine months ended December 31, 2013, an average 10% weakening in the USD relative to the Euro would have resulted in an increase to our expenses denominated in Euro of \$6.7 million.

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

**Selected Quarterly Financial Data (unaudited)**

(In thousands, except per share data)	<u>First Quarter</u>	<u>Second Quarter</u>	<u>Third Quarter</u>	<u>Total</u>
<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 . . . . .	<u>138,631</u>	<u>139,802</u>	<u>154,478</u>	<u>432,911</u>
<b>EXPENSES:</b>				
Cost of goods manufactured and sold . . . . .	45,991	45,423	42,892	134,306
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 . . . . .	<u>125,102</u>	<u>143,680</u>	<u>148,635</u>	<u>417,417</u>
OPERATING INCOME (LOSS) . . . . .	13,529	(3,878)	5,843	15,494
OTHER (EXPENSE), NET . . . . .	<u>(3,477)</u>	<u>(3,651)</u>	<u>(2,969)</u>	<u>(10,097)</u>
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) . . . . .	<u>\$ 7,334</u>	<u>\$ (7,762)</u>	<u>\$ 18,077</u>	<u>\$ 17,649</u>
EARNINGS (LOSS) PER SHARE—BASIC . . . . .	<u>\$ 0.05</u>	<u>\$ (0.06)</u>	<u>\$ 0.13</u>	<u>\$ 0.13</u>
EARNINGS (LOSS) PER SHARE—DILUTED . . . . .	<u>\$ 0.05</u>	<u>\$ (0.06)</u>	<u>\$ 0.12</u>	<u>\$ 0.12</u>

(In thousands, except per share data)	First Quarter	Second Quarter	Third Quarter	Fourth Quarter	Total
<b>Twelve Months Ended March 31, 2013</b>					
<b>REVENUES:</b>					
Manufacturing and royalty revenues . . . . .	\$138,380	\$107,327	\$118,274	\$146,919	\$510,900
Product sales, net . . . . .	12,372	15,192	15,917	14,626	58,107
Research and development revenue . . . . .	1,487	1,459	1,718	1,877	6,541
Total revenues . . . . .	<u>152,239</u>	<u>123,978</u>	<u>135,909</u>	<u>163,422</u>	<u>575,548</u>
<b>EXPENSES:</b>					
Cost of goods manufactured and sold . . . . .	42,070	41,491	38,914	47,991	170,466
Research and development . . . . .	37,806	35,088	31,319	35,800	140,013
Selling, general and administrative . . . . .	29,784	31,428	29,867	34,679	125,758
Amortization of acquired intangible assets . .	10,434	10,547	10,549	10,322	41,852
Restructuring . . . . .	—	—	—	12,300	12,300
Impairment of long-lived assets . . . . .	—	—	—	3,346	3,346
Total expenses . . . . .	<u>120,094</u>	<u>118,554</u>	<u>110,649</u>	<u>144,438</u>	<u>493,735</u>
OPERATING INCOME (LOSS) . . . . .	32,145	5,424	25,260	18,984	81,813
OTHER (EXPENSE), NET . . . . .	<u>(8,948)</u>	<u>(21,709)</u>	<u>(4,597)</u>	<u>(11,118)</u>	<u>(46,372)</u>
<b>INCOME (LOSS) BEFORE INCOME TAXES</b>					
TAXES . . . . .	23,197	(16,285)	20,663	7,866	35,441
INCOME TAX PROVISION . . . . .	764	422	4,405	4,867	10,458
NET INCOME (LOSS) . . . . .	<u>\$ 22,433</u>	<u>\$ (16,707)</u>	<u>\$ 16,258</u>	<u>\$ 2,999</u>	<u>\$ 24,983</u>
EARNINGS (LOSS) PER SHARE—BASIC . .	<u>\$ 0.17</u>	<u>\$ (0.13)</u>	<u>\$ 0.12</u>	<u>\$ 0.02</u>	<u>\$ 0.19</u>
<b>EARNINGS (LOSS) PER SHARE—DILUTED</b>					
DILUTED . . . . .	<u>\$ 0.17</u>	<u>\$ (0.13)</u>	<u>\$ 0.12</u>	<u>\$ 0.02</u>	<u>\$ 0.18</u>

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, 2013. 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, 2013 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

#### ***Management's Transition 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
- 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, 2013. In making this assessment, management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (“COSO”) in its 1992 Internal Control—Integrated Framework.

Based on this assessment, our management has concluded that, as of December 31, 2013, our internal control over financial reporting was effective.

The effectiveness of our internal control over financial reporting as of December 31, 2013 has been audited by PricewaterhouseCoopers LLP, an independent registered public accounting firm, as stated in their report, which is included herein.

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

None.



### **PART III**

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

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

### **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 Transition 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.



<u>Signature</u>	<u>Title</u>	<u>Date</u>
<u>/s/ WENDY L. DIXON</u> Wendy L. Dixon	Director	February 27, 2014
<u>/s/ GERALDINE HENWOOD</u> Geraldine Henwood	Director	February 27, 2014
<u>/s/ PAUL J. MITCHELL</u> Paul J. Mitchell	Director	February 27, 2014
<u>/s/ NANCY J. WYSENSKI</u> Nancy J. Wysenski	Director	February 27, 2014

## EXHIBIT INDEX

Exhibit No.	Description of Exhibit
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.)
10.3++	Lease Agreement, dated as of April 22, 2009 between PDM Unit 850, LLC, and Alkermes, Inc. (Incorporated by reference to Exhibit 10.5 to the Alkermes, Inc. Annual Report on Form 10-K for the twelve months ended March 31, 2009 (File No. 001-14131).)
10.4++	First Amendment to Lease Agreement between Alkermes, Inc. and PDM Unit 850, LLC, dated as of June 18, 2009. (Incorporated by reference to Exhibit 10.2 to the Alkermes, Inc. Quarterly Report on Form 10-Q for the quarter ended June 30, 2009 (File No. 001-14131).)
10.5++*	License Agreement, dated as of February 13, 1996, between Medisorb Technologies International L.P. and Janssen Pharmaceutica Inc. (U.S.) (assigned to Alkermes, Inc. in July 2006) (with certain confidential information deleted). (Incorporated by reference to Exhibit 10.19 to the Alkermes, Inc. Annual Report on Form 10-K for the twelve months ended March 31, 1996 (File No. 000-19267).)
10.6++*	License Agreement, dated as of February 21, 1996, between Medisorb Technologies International L.P. and Janssen Pharmaceutica International (worldwide except United States) (assigned to Alkermes, Inc. in July 2006) (with certain confidential information deleted). (Incorporated by reference to Exhibit 10.20 to the Alkermes, Inc. Annual Report on Form 10-K for the twelve months ended March 31, 1996 (File No. 000-19267).)
10.7++**	Manufacturing and Supply Agreement, dated August 6, 1997, by and among Alkermes Controlled Therapeutics Inc. II, Janssen Pharmaceutica International and Janssen Pharmaceutica, Inc. (assigned to Alkermes, Inc. in July 2006) (with certain confidential information deleted). (Incorporated by reference to Exhibit 10.19 to the Alkermes, Inc. Annual Report on Form 10-K for the twelve months ended March 31, 2002 (File No. 001-14131).)
10.8++***	Third Amendment To Development Agreement, Second Amendment To Manufacturing and Supply Agreement and First Amendment To License Agreements by and between Janssen Pharmaceutica International Inc. and Alkermes Controlled Therapeutics Inc. II, dated April 1, 2000 (assigned to Alkermes, Inc. in July 2006) (with certain confidential information deleted). (Incorporated by reference to Exhibit 10.5 to the Alkermes, Inc. Quarterly Report on Form 10-Q for the quarter ended December 31, 2004 (File No. 001-14131).)

Exhibit No.	Description of Exhibit
10.9+ +***	Fourth Amendment To Development Agreement and First Amendment To Manufacturing and Supply Agreement by and between Janssen Pharmaceutica International Inc. and Alkermes Controlled Therapeutics Inc. II, dated December 20, 2000 (assigned to Alkermes, Inc. in July 2006) (with certain confidential information deleted). (Incorporated by reference to Exhibit 10.4 to the Alkermes, Inc. Quarterly Report on Form 10-Q for the quarter ended December 31, 2004 (File No. 001-14131).)
10.10+ +**	Addendum to Manufacturing and Supply Agreement, dated August 2001, by and among Alkermes Controlled Therapeutics Inc. II, Janssen Pharmaceutica International and Janssen Pharmaceutica, Inc. (assigned to Alkermes, Inc. in July 2006) (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 twelve months ended March 31, 2002 (File No. 001-14131).)
10.11+ +**	Letter Agreement and Exhibits to Manufacturing and Supply Agreement, dated February 1, 2002, by and among Alkermes Controlled Therapeutics Inc. II, Janssen Pharmaceutica International and Janssen Pharmaceutica, Inc. (assigned to Alkermes, Inc. in July 2006) (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 twelve months ended March 31, 2002 (File No. 001-14131).)
10.12+ +***	Amendment to Manufacturing and Supply Agreement by and between JPI Pharmaceutica International, Janssen Pharmaceutica Inc. and Alkermes Controlled Therapeutics Inc. II, dated December 22, 2003 (assigned to Alkermes, Inc. in July 2006) (with certain confidential information deleted). (Incorporated by reference to Exhibit 10.8 to the Alkermes, Inc. Quarterly Report on Form 10-Q for the quarter ended December 31, 2004 (File No. 001-14131).)
10.13+ +***	Fourth Amendment To Manufacturing and Supply Agreement by and between JPI Pharmaceutica International, Janssen Pharmaceutica Inc. and Alkermes Controlled Therapeutics Inc. II, dated January 10, 2005 (assigned to Alkermes, Inc. in July 2006) (with certain confidential information deleted). (Incorporated by reference to Exhibit 10.9 to the Alkermes, Inc. Quarterly Report on Form 10-Q for the quarter ended December 31, 2004 (File No. 001-14131).)
10.14+ +***	Agreement by and between JPI Pharmaceutica International, Janssen Pharmaceutica Inc. and Alkermes Controlled Therapeutics Inc. II, dated December 21, 2002 (assigned to Alkermes, Inc. in July 2006) (with certain confidential information deleted). (Incorporated by reference to Exhibit 10.6 to the Alkermes, Inc. Quarterly Report on Form 10-Q for the quarter ended December 31, 2004 (File No. 001-14131).)
10.15+ +***	Amendment to Agreement by and between JPI Pharmaceutica International, Janssen Pharmaceutica Inc. and Alkermes Controlled Therapeutics Inc. II, dated December 16, 2003 (assigned to Alkermes, Inc. in July 2006) (with certain confidential information deleted). (Incorporated by reference to Exhibit 10.7 to the Alkermes, Inc. Quarterly Report on Form 10-Q for the quarter ended December 31, 2004 (File No. 001-14131).)

Exhibit No.	Description of Exhibit
10.16++****	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).)
10.17++	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).)
10.18++	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).)
10.19++	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).)
10.20++	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).)
10.21++*****	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 twelve months ended March 31, 2013 (File No. 001-35299).)
10.22++*****	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 twelve months ended March 31, 2013 (File No. 001-35299).)



Exhibit No.	Description of Exhibit
10.23++*****	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 twelve months ended March 31, 2013 (File No. 001-35299).)
10.24++	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 twelve months ended March 31, 2013 (File No. 001-35299).)
10.25++*****	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 twelve months ended March 31, 2013 (File No. 001-35299).)
10.26†++	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).)
10.27†++	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).)
10.28†++	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).)
10.29†++	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).)
10.30†++	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).)

Exhibit No.	Description of Exhibit
10.31†++	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 twelve months ended March 31, 2008 (File No. 001-14131).)
10.32†++	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 twelve months ended March 31, 2008 (File No. 001-14131).)
10.33†++	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).)
10.34†++	Alkermes, Inc. 1998 Equity Incentive Plan as Amended and Approved on November 2, 2006. (Incorporated by reference to Exhibit 10.1 to the Alkermes, Inc. Quarterly Report on Form 10-Q for the fiscal quarter ended December 31, 2006 (File No. 001-14131).)
10.35†++	Form of Stock Option Certificate pursuant to Alkermes, Inc. 1998 Equity Incentive Plan. (Incorporated by reference to Exhibit 10.37 to the Alkermes, Inc. Annual Report on Form 10-K for the twelve months ended March 31, 2006 (File No. 001-14131).)
10.36†++	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).)
10.37†++	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 twelve months ended March 31, 2006 (File No. 001-14131).)
10.38†++	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 twelve months ended March 31, 2006 (File No. 001-14131).)
10.39†++	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).)
10.40†++	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).)
10.41†++	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).)

Exhibit No.	Description of Exhibit
10.42†++	Amendment to 2006 Stock Option Plan for Non-Employee Directors. (Incorporated by reference to Appendix C to the Alkermes, Inc. Definitive Proxy Statement on Form DEF 14/A filed on July 27, 2007 (File No. 001-14131).)
10.43†++	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).)
10.44†++	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 twelve months ended March 31, 2010 (File No. 001-14131).)
10.45†++	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 twelve months ended March 31, 2010 (File No. 001-14131).)
10.46†++	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).)
10.47†++	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).)
10.48†++	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).)
10.49++****	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 twelve months ended March 31, 2010 (File No. 001-14131).)
10.50++	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.)

<u>Exhibit No.</u>	<u>Description of Exhibit</u>
10.51++	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.)
10.52++	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 twelve months ended March 31, 2013 (File No. 001-35299).)
10.53++	Intellectual Property Transfer Agreement, dated as of September 15, 2011 between Alkermes, Inc., Alkermes Controlled Therapeutics, Inc. and Alkermes Pharma Holdings Limited. (Incorporated by reference to Exhibit 10.3 to the Alkermes plc Current Report on Form 8-K filed on September 16, 2011.)
10.54†++	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.)
10.55†++	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.)
10.56†++	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.)
10.57†++	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.)
10.58†++	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.)
10.59†++	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.)
10.60†++	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.)
10.61†++	Alkermes plc 2011 Stock Option and Incentive Plan. (Incorporated by reference to Exhibit 10.1 to the Alkermes plc Current Report on Form 8-K filed on December 8, 2011.)

Exhibit No.	Description of Exhibit
10.62†++	Alkermes plc 2011 Stock Option and Incentive Plan, as amended. (Incorporated by reference to Exhibit 10.1 to the Alkermes plc Current Report on Form 8-K filed on August 6, 2012.)
10.63†++	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 twelve months ended March 31, 2013 (File No. 001-35299).)
10.64†++	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 twelve months ended March 31, 2013 (File No. 001-35299).)
10.65†++	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.)
10.66†++	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.)
10.67†++	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.)
10.68†++	Fiscal 2013 Alkermes plc Affiliated Company Reporting Officer Performance Plan. (Incorporated by reference to Exhibit 10.1 to the Alkermes plc Current Report on Form 8-K filed on March 30, 2012.)
10.69†++	Amended and Restated Fiscal 2013 Alkermes plc Affiliated Company Reporting Officer Performance Pay Plan. (Incorporated by reference to Exhibit 10.2 of the Alkermes plc Quarterly Report on Form 10-Q for the quarter ended September 30, 2012.)
10.70†++	Fiscal 2014 Alkermes plc Affiliated Company Reporting Officer Performance Pay Plan. (Incorporated by reference to Exhibit 10.1 of the Alkermes plc Current Report on Form 8-K filed on April 1, 2013.)
10.71†++	Amended and Restated Fiscal Year December 2013 Alkermes plc Affiliated Company Reporting Officer Performance Pay Plan. (Incorporated by reference to Exhibit 10.1 of the Alkermes plc Current Report on Form 8-K filed on May 23, 2013.)
10.72†++	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 August 1, 2013.)
10.73†++	Alkermes plc Affiliated Company Fiscal Year 2014 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 9, 2013.)
10.74#	Second Amendment to Lease Agreement between Alkermes, Inc. and PDM Unit 850, LLC, dated as of November 12, 2013.

Exhibit No.	Description of Exhibit
10.75†#	Alkermes plc 2011 Stock Option and Incentive Plan, Restricted Stock Unit Award Certificate (Time Vesting Only—U.S.), as amended.
10.76†#	Alkermes plc 2011 Stock Option and Incentive Plan, Restricted Stock Unit Award Certificate (Performance Vesting Only—U.S.), as amended.
10.77†#	Alkermes plc 2011 Stock Option and Incentive Plan, Restricted Stock Unit Award Certificate (Time Vesting Only—Irish), as amended.
10.78†#	Alkermes plc 2011 Stock Option and Incentive Plan, Restricted Stock Unit Award Certificate (Performance Vesting Only—Irish), as amended.
10.79†#	Alkermes plc 2011 Stock Option and Incentive Plan, Stock Option Award Certificate (Non-Employee Director).
10.80†#	Alkermes plc 2011 Stock Option and Incentive Plan, Stock Option Award Certificate (Non-Qualified Option—Irish).
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) information is furnished and not filed or a part of a registration statement or prospectus for purposes of Sections 11 or 12 of the Securities Act of 1933, is deemed not filed for purposes of Section 18 of the Securities Exchange Act of 1934, and is not otherwise subject to liability under these Sections.

# Filed herewith.

‡ 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.
- \*\*\* 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.

## Report of Independent Registered Public Accounting Firm

To Board of Directors and Shareholders of Alkermes plc

In our opinion, the accompanying consolidated balance sheets at December 31, 2013 and March 31, 2013, and the related consolidated statements of operations and comprehensive income (loss), of shareholders' equity and of cash flows for the nine months ended December 31, 2013 and for each of the two years in the period ended March 31, 2013 present fairly, in all material respects, the financial position of Alkermes plc and its subsidiaries at December 31, 2013 and March 31, 2013, and the results of their operations and their cash flows for the nine months ended December 31, 2013 and for each of the two years in the period 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, 2013, based on criteria established in *Internal Control—Integrated Framework* (1992) 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 Transition Report on Internal Control over Financial Reporting appearing under Item 9A. Our responsibility is to express opinions on these financial statements and on the Company's internal control over financial reporting based on our integrated audits. We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the financial statements are free of material misstatement and whether effective internal control over financial reporting was maintained in all material respects. Our audits of the financial statements included examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. Our audit of internal control over financial reporting included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audits also included performing such other procedures as we considered necessary in the circumstances. We believe that our audits provide a reasonable basis for our opinions.

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

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

/s/ Pricewaterhouse Coopers LLP

Boston, Massachusetts

February 27, 2014

**ALKERMES PLC AND SUBSIDIARIES**  
**CONSOLIDATED BALANCE SHEETS**  
**December 31, 2013 and March 31, 2013**

	<u>December 31, 2013</u>	<u>March 31, 2013</u>
	<u>(In thousands, except share and per share amounts)</u>	
<b>ASSETS</b>		
<b>CURRENT ASSETS:</b>		
Cash and cash equivalents . . . . .	\$ 167,562	\$ 96,961
Investments—short-term . . . . .	194,669	124,391
Receivables, net . . . . .	134,154	124,620
Inventory . . . . .	46,218	43,483
Prepaid expenses and other current assets . . . . .	27,535	19,133
Total current assets . . . . .	<u>570,138</u>	<u>408,588</u>
PROPERTY, PLANT AND EQUIPMENT, NET . . . . .	274,490	288,435
INTANGIBLE ASSETS—NET . . . . .	537,565	575,993
GOODWILL . . . . .	92,740	92,740
INVESTMENTS—LONG-TERM . . . . .	87,764	82,827
OTHER ASSETS . . . . .	14,891	21,708
<b>TOTAL ASSETS . . . . .</b>	<b><u>\$1,577,588</u></b>	<b><u>\$1,470,291</u></b>
<b>LIABILITIES AND SHAREHOLDERS' EQUITY</b>		
<b>CURRENT LIABILITIES:</b>		
Accounts payable and accrued expenses . . . . .	\$ 91,173	\$ 76,910
Long-term debt—short-term . . . . .	6,750	6,750
Deferred revenue—short-term . . . . .	2,974	2,270
Total current liabilities . . . . .	<u>100,897</u>	<u>85,930</u>
LONG-TERM DEBT . . . . .	357,543	362,258
DEFERRED TAX LIABILITIES, NET—LONG-TERM . . . . .	29,169	37,603
OTHER LONG-TERM LIABILITIES . . . . .	12,580	23,260
DEFERRED REVENUE—LONG-TERM . . . . .	12,213	8,866
Total liabilities . . . . .	<u>512,402</u>	<u>517,917</u>
COMMITMENTS AND CONTINGENCIES (Note 19)		
<b>SHAREHOLDERS' EQUITY:</b>		
Preferred stock, par value, \$0.01 per share; 50,000,000 shares authorized; zero issued and outstanding at December 31, 2013 and March 31, 2013, respectively . . . . .	—	—
Ordinary shares, par value, \$0.01 per share; 450,000,000 shares authorized; 138,482,571 and 134,065,107 shares issued; 137,792,626 and 133,751,610 shares outstanding at December 31, 2013 and March 31, 2013, respectively . . . . .	1,382	1,338
Treasury stock, at cost (689,945 and 313,497 shares at December 31, 2013 and March 31, 2013, respectively) . . . . .	(17,833)	(5,380)
Additional paid-in capital . . . . .	1,553,337	1,458,857
Accumulated other comprehensive income (loss) . . . . .	10,574	(2,518)
Accumulated deficit . . . . .	(482,274)	(499,923)
Total shareholders' equity . . . . .	<u>1,065,186</u>	<u>952,374</u>
<b>TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY . . . . .</b>	<b><u>\$1,577,588</u></b>	<b><u>\$1,470,291</u></b>

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

**ALKERMES PLC AND SUBSIDIARIES**  
**CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE INCOME (LOSS)**  
**Nine months Ended December 31, 2013 and Twelve months Ended March 31, 2013 and 2012**

	Nine Months Ended December 31, 2013	Twelve Months Ended March 31,	
		2013	2012
	(In thousands, except per share amounts)		
REVENUES:			
Manufacturing and royalty revenues . . . . .	\$371,039	\$510,900	\$ 326,444
Product sales, net . . . . .	57,215	58,107	41,184
Research and development revenue . . . . .	4,657	6,541	22,349
Total revenues . . . . .	432,911	575,548	389,977
EXPENSES:			
Cost of goods manufactured and sold . . . . .	134,306	170,466	127,578
Research and development . . . . .	128,125	140,013	141,893
Selling, general and administrative . . . . .	116,558	125,758	137,632
Amortization of acquired intangible assets . . . . .	38,428	41,852	25,355
Restructuring . . . . .	—	12,300	—
Impairment of long-lived assets . . . . .	—	3,346	45,800
Total expenses . . . . .	417,417	493,735	478,258
OPERATING INCOME (LOSS) . . . . .	15,494	81,813	(88,281)
OTHER EXPENSE, NET:			
Interest income . . . . .	711	841	1,516
Interest expense . . . . .	(10,379)	(48,994)	(28,111)
Other (expense) income, net . . . . .	(429)	1,781	484
Total other expense, net . . . . .	(10,097)	(46,372)	(26,111)
INCOME (LOSS) BEFORE INCOME TAXES . . . . .	5,397	35,441	(114,392)
(BENEFIT) PROVISION FOR INCOME TAXES . . . . .	(12,252)	10,458	(714)
NET INCOME (LOSS) . . . . .	\$ 17,649	\$ 24,983	\$(113,678)
EARNINGS (LOSS) PER COMMON SHARE:			
Basic . . . . .	\$ 0.13	\$ 0.19	\$ (0.99)
Diluted . . . . .	\$ 0.12	\$ 0.18	\$ (0.99)
WEIGHTED AVERAGE NUMBER OF COMMON SHARES OUTSTANDING:			
Basic . . . . .	135,960	131,713	114,702
Diluted . . . . .	144,961	137,100	114,702
COMPREHENSIVE INCOME (LOSS):			
Net income (loss) . . . . .	\$ 17,649	\$ 24,983	\$(113,678)
Unrealized gains (losses) on marketable securities, net of tax:			
Holding gains, net of tax of \$8,217, none and \$372, respectively . . . . .	13,092	703	627
Less: Reclassification adjustment for gains included in net income (loss) . . . . .	—	(1,030)	—
Unrealized gains (losses) gains on marketable securities . . . . .	13,092	(327)	627
Unrealized (losses) gains on derivative contracts:			
Unrealized losses on derivative contracts, net of tax of none, none and \$(194), respectively . . . . .	—	(72)	(327)
Less: Reclassification adjustment for losses included in net income (loss) . . . . .	—	594	—
Unrealized gains (losses) on derivative contracts . . . . .	—	522	(327)
COMPREHENSIVE INCOME (LOSS) . . . . .	\$ 30,741	\$ 25,178	\$(113,378)

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

**ALKERMES PLC AND SUBSIDIARIES**  
**CONSOLIDATED STATEMENTS OF SHAREHOLDERS' EQUITY**  
**Nine months Ended December 31, 2013 and Twelve months Ended March 31, 2013 and 2012**

	Ordinary Shares		Non-voting Common Stock		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, 2011	105,771,507	\$1,055	382,632	\$ 4	\$ 936,295	\$ (3,013)	\$(411,228)	(10,069,208)	\$(131,095)	\$ 392,018
Issuance of common stock to Elan Corporation, plc in connection with the purchase of Elan Drug Technologies	31,900,000	319	—	—	524,755	—	—	—	—	525,074
Issuance of ordinary shares under employee stock plans	2,398,422	24	—	—	20,840	—	—	—	—	20,864
Receipt of Alkermes' stock for the purchase of stock options or to satisfy minimum tax withholding obligations related to stock based awards	—	—	—	—	—	—	—	(205,901)	(3,676)	(3,676)
Share-based compensation expense	—	—	—	—	28,615	—	—	—	—	28,615
Excess tax benefit from share-based compensation	—	—	—	—	4,335	—	—	—	—	4,335
Conversion of non-voting common stock to common stock	382,632	4	(382,632)	(4)	—	—	—	—	—	—
Cancellation of treasury stock	(10,240,031)	(102)	—	—	(134,098)	—	—	10,240,031	134,200	—
Unrealized gains on marketable securities, net of tax of \$372	—	—	—	—	—	627	—	—	—	627
Unrealized loss on cash flow hedge, net of tax of \$(194)	—	—	—	—	—	(327)	—	—	—	(327)
Net loss	—	—	—	—	—	—	(113,678)	—	—	(113,678)
BALANCE—March 31, 2012	130,212,530	\$1,300	—	\$—	\$1,380,742	\$ (2,713)	\$(524,906)	(35,078)	\$ (571)	\$ 853,852
Issuance of common stock 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 common stock 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	—	—	(376,488)	(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)	(689,985)	\$ (17,833)	\$1,065,186

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

**ALKERMES PLC AND SUBSIDIARIES**  
**CONSOLIDATED STATEMENTS OF CASH FLOWS**

**Nine months Ended December 31, 2013 and Twelve months Ended March 31, 2013 and 2012**

	<b>Nine Months Ended December 31, 2013</b>	<b>Twelve Months Ended March 31,</b>	
		<b>2013</b>	<b>2012</b>
	(In thousands)		
<b>CASH FLOWS FROM OPERATING ACTIVITIES:</b>			
Net income (loss) . . . . .	\$ 17,649	\$ 24,983	\$(113,678)
Adjustments to reconcile net income (loss) to cash flows from operating activities:			
Depreciation and amortization . . . . .	70,765	73,751	47,884
Share-based compensation expense . . . . .	33,409	34,716	28,826
Loss on debt refinancing transactions . . . . .	—	19,670	—
Prepayment penalties in connection with debt refinancing transactions . . . . .	—	(6,533)	—
Excess tax benefit from share-based compensation . . . . .	(11,394)	(8,867)	(4,335)
Impairment of long-lived assets . . . . .	—	3,346	45,800
Deferred income taxes . . . . .	(15,393)	(2,113)	(14,556)
Principal payments on long-term debt attributable to original issue discount . . . . .	—	(2,657)	—
Other non-cash charges . . . . .	(5,731)	5,698	4,342
Changes in assets and liabilities, excluding the effect of acquisitions:			
Receivables . . . . .	(9,534)	(28,239)	(14,014)
Inventory, prepaid expenses and other assets . . . . .	(6,345)	(6,577)	(4,879)
Accounts payable and accrued expenses . . . . .	16,126	19,406	15,552
Deferred revenue . . . . .	4,051	(3,351)	6,068
Other long-term liabilities . . . . .	(1,382)	3,318	508
Cash flows provided by (used in) operating activities . . . . .	<u>92,221</u>	<u>126,551</u>	<u>(2,482)</u>
<b>CASH FLOWS FROM INVESTING ACTIVITIES:</b>			
Additions to property, plant and equipment . . . . .	(19,054)	(22,217)	(16,988)
Proceeds from the sale of equipment . . . . .	52	193	35
Acquisition of Elan Drug Technologies, net of cash acquired . . . . .	—	—	(494,774)
Investment in Acceleron Pharmaceuticals, Inc. . . . .	—	—	(231)
Investment in Civitas Therapeutics, Inc. . . . .	(1,191)	—	—
Promissory note issued to Civitas Therapeutics, Inc. . . . .	—	(1,116)	—
Purchases of investments . . . . .	(135,643)	(303,945)	(228,229)
Sales and maturities of investments . . . . .	90,470	258,937	323,028
Cash flows used in investing activities . . . . .	<u>(65,366)</u>	<u>(68,148)</u>	<u>(417,159)</u>
<b>CASH FLOWS FROM FINANCING ACTIVITIES:</b>			
Proceeds from the issuance of ordinary shares for share-based compensation arrangements . . . . .	49,077	34,360	20,864
Excess tax benefit from share-based compensation . . . . .	11,394	8,867	4,335
Proceeds from the issuance of long-term debt . . . . .	—	366,483	444,100
Employee taxes paid related to net share settlement of equity awards . . . . .	(11,665)	(4,809)	(3,676)
Principal payments of long-term debt . . . . .	(5,060)	(449,944)	(775)
Cash flows provided by (used in) financing activities . . . . .	<u>43,746</u>	<u>(45,043)</u>	<u>464,848</u>
<b>NET INCREASE IN CASH AND CASH EQUIVALENTS . . . . .</b>	<b>70,601</b>	<b>13,360</b>	<b>45,207</b>
<b>CASH AND CASH EQUIVALENTS—Beginning of period . . . . .</b>	<b>96,961</b>	<b>83,601</b>	<b>38,394</b>
<b>CASH AND CASH EQUIVALENTS—End of period . . . . .</b>	<b><u>\$ 167,562</u></b>	<b><u>\$ 96,961</u></b>	<b><u>\$ 83,601</u></b>
<b>SUPPLEMENTAL CASH FLOW DISCLOSURE:</b>			
Cash paid for interest . . . . .	\$ 9,596	\$ 7,656	\$ 21,658
Cash paid for taxes . . . . .	\$ 704	\$ 5,921	\$ 10,068
Non-cash investing and financing activities:			
Purchased capital expenditures included in accounts payable and accrued expenses . . . . .	\$ 1,969	\$ 2,450	\$ 3,416
Investment in Civitas Therapeutics, Inc. . . . .	\$ 1,160	\$ —	\$ 1,547
Issuance of common stock used in the acquisition of Elan Drug Technologies . . . . .	\$ —	\$ —	\$ 525,074

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



**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 develop innovative medicines that improve patient outcomes. The Company has a diversified portfolio of more than 20 commercial drug products and a substantial clinical pipeline of product candidates that address central nervous system (“CNS”) disorders such as addiction, schizophrenia and depression. Headquartered in Dublin, Ireland, 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.

On September 16, 2011, the business of Alkermes, Inc. and the drug technologies business (“EDT”) of Elan Corporation, plc (“Elan”) were combined under the Company (this combination is referred to as the “Business Combination”, the “acquisition of EDT” or the “EDT acquisition”) in a transaction accounted for as a reverse acquisition with Alkermes, Inc. treated as the accounting acquirer. As a result, the historical financial statements of Alkermes, Inc. are included in the comparative prior periods. Use of the terms such as “us,” “we,” “our,” “Alkermes” or the “Company” is meant to refer to Alkermes plc and its consolidated subsidiaries, except where context makes it 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 under the symbol “ALKS.”

*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 transition report on Form 10-K (the “Transition Report”) covers the nine-month transition period ended December 31, 2013 and reflects the Company’s financial results for the nine month period from April 1, 2013 through December 31, 2013 (the “Transition Period”). Prior to this Transition Report on Form 10-K, the Company’s two most recent Annual Reports on Form 10-K cover the fiscal years ended March 31, 2013 and March 31, 2012, respectively, and reflect the results of the respective twelve-month periods from April 1 to March 31. Unless otherwise noted, all references to “fiscal years” in this Transition Report refer to the twelve month fiscal years that, prior to the Transition Period ended December 31, 2013 ended on March 31.

**2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES**

*Principles of Consolidation*

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

**ALKERMES PLC AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

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

*Use of Estimates*

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

*Cash and Cash Equivalents*

The Company values its cash and cash equivalents at cost plus accrued interest, which the Company believes approximates their market value. The Company considers only those investments which are highly liquid, readily convertible into cash and 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, corporate debt securities, and common stock and warrants of a public company with which the Company has a collaborative arrangement. The Company generally holds its interest-bearing investments with major financial institutions and in accordance with documented investment policies. The Company limits the amount of credit exposure to any one financial institution or corporate issuer. At December 31, 2013, 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 income (loss)," 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 income (loss).

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

**ALKERMES PLC AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

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

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—short-term" and "Investments—long-term", respectively, in the 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 measurement. The Company's financial assets and liabilities consist of cash equivalents and investments and are classified within the fair value hierarchy as follows:

*Level 1*—these valuations are based on a market approach using quoted prices in active markets for identical assets. Valuations of these products do not require a significant degree of judgment. Assets utilizing Level 1 inputs include investments in money market funds, U.S. treasury securities and the common stock of a publicly-traded company;

*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, investments in corporate debt securities that are trading in the credit markets and an interest rate swap contract; 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 investments 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.

**ALKERMES PLC AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

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

*Property, Plant and Equipment*

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

<u>Asset group</u>	<u>Term</u>
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, which solely relates to the EDT acquisition in the twelve months ended March 31, 2012, has been assigned to a reporting unit which consists of the former EDT business. 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 utilizing a two-step process. The first step requires the Company 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.

The Company's finite-lived intangible assets consist of core developed technology and collaboration agreements, 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. The Company's intangible assets were all acquired as part of the EDT acquisition in the twelve months ended March 31, 2012, as described in Note 3, *Acquisitions*.

*Impairment of Long-Lived Assets*

The Company reviews long-lived assets to be held and used for impairment whenever events or changes in circumstances indicate that the carrying amount of the assets may not be recoverable. Conditions that would necessitate an impairment assessment include a significant decline in the observable market value of an asset, a significant change in the extent or manner in which an asset is

**ALKERMES PLC AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

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

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, 2013 and March 31, 2013 was \$2.2 million and \$2.0 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, 2013 and March 31, 2013:

(In thousands)	<u>Carrying Amount</u>
Balance, April 1, 2012 . . . . .	\$1,862
Accretion expense . . . . .	187
Balance, March 31, 2013 . . . . .	<u>\$2,049</u>
Accretion expense . . . . .	151
Balance, December 31, 2013 . . . . .	<u><u>\$2,200</u></u>

*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® (upon assuming sole responsibility for the development and commercialization of BYDUREON from Bristol-Myers Squibb Company ("Bristol-Myers")). 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 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

**ALKERMES PLC AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

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

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.

*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.

*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.

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



**ALKERMES PLC AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

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

Medicaid program based on a rebate per unit calculation, which is based on its Average Manufacturer Price (“AMP”). The Company estimates expected unit sales and rebates per unit under the Medicaid program and adjusts its rebate estimates based on actual unit sales and rebates per unit;

- *Chargebacks*—wholesaler 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 income (loss), which was recognized during the three months ended September 30, 2012.

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 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, 2013, the product return reserve was estimated to be approximately 2% of product sales and amounts to \$3.8 million.

**ALKERMES PLC AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

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

*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. The objective of the interest rate swap agreement is to limit the impact of fluctuations in interest rates in earnings related to the Company's long-term debt. The interest rate swap agreement is not designated as a hedging instrument and is recorded at fair value. The associated gains and losses related to the interest rate swap are recognized in "Interest expense" during the period of change. Refer to Note 12, *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 (expense) income, net" in the accompanying consolidated statement of operations and comprehensive income (loss). During the nine months ended December 31, 2013 and the twelve months ended March 31, 2013 and 2012, the Company recorded a gain on foreign currency translation of \$0.2 million, \$0.1 million and \$0.5 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, 2013 and March 31, 2013 and 2012, for the nine months ended December 31, 2013 and the twelve months ended March 31, 2013 and 2012:

Customer	Nine Months Ended December 31, 2013		Twelve Months Ended March 31,			
	Receivables	Revenue	2013		2012	
			Receivables	Revenue	Receivables	Revenue
Janssen . . . . .	46%	44%	32%	35%	30%	48%
Acorda . . . . .	12%	12%	15%	11%	11%	—

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

**ALKERMES PLC AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

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

*Geographic Information*

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

(In thousands)	<u>Nine Months Ended December 31, 2013</u>	<u>Twelve Months Ended March 31,</u>	
		2013	2012
Revenue by region:			
U.S. . . . .	\$269,005	\$380,565	\$212,859
Ireland . . . . .	5,722	14,455	12,695
Rest of world . . . . .	158,184	180,528	164,423
Assets by region:			
Current assets:			
U.S. . . . .	\$382,571	\$248,441	\$209,683
Ireland . . . . .	187,023	159,544	122,077
Rest of world . . . . .	544	603	7,393
Long-term assets:			
U.S.:			
Intangible assets . . . . .	\$ —	\$ —	\$ —
Goodwill . . . . .	3,677	3,677	3,677
Other . . . . .	225,559	229,691	213,729
Ireland:			
Intangible assets . . . . .	\$537,565	\$575,993	\$617,845
Goodwill . . . . .	89,063	89,063	89,063
Other . . . . .	151,586	163,279	171,750

*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.

*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.

**ALKERMES PLC AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

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

*Stock Options*

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

The fair value of stock option grants is based on estimates as of the date of grant using a Black-Scholes option valuation model. The Company uses historical data as the basis for estimating option terms and forfeitures. Separate groups of employees that have similar historical stock option exercise and forfeiture behavior are considered separately for valuation purposes. The ranges of expected terms disclosed below reflect different expected behavior among certain groups of employees. Expected stock volatility factors are based on a weighted average of implied volatilities from traded options on the Company's ordinary shares and historical stock price volatility of the Company's ordinary shares, which is determined based on a review of the weighted average of historical daily price changes of the Company's ordinary shares. The risk-free interest rate for periods commensurate with the expected term of the share option is based on the U.S. treasury yield curve in effect at the time of grants. The dividend yield on the Company's ordinary shares is estimated to be zero as the Company has not paid and does not expect to pay dividends. The exercise price of options granted 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:

	Nine Months Ended December 31, 2013	Twelve Months Ended March 31,	
		2013	2012
Expected option term . . . . .	5 - 7 years	5 - 7 years	5 - 7 years
Expected stock volatility . . . . .	45% - 48%	47% - 49%	47% - 51%
Risk-free interest rate . . . . .	0.75% - 2.15%	0.61% - 1.18%	0.82% - 2.5%
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.

**ALKERMES PLC AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

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

*Income Taxes*

The Company recognizes income taxes under the asset and liability method. Deferred income taxes are recognized for differences between the financial reporting and tax bases of assets and liabilities at enacted statutory tax rates in effect for the years in which the differences are expected to reverse. The effect on deferred taxes of a change in tax rates is recognized in income in the period that includes the enactment date. 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 Income (Loss)*

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

*Earnings (Loss) Per Share*

Basic earnings (loss) per share are calculated based upon net income (loss) 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.

**ALKERMES PLC AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

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

*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. Through March 31, 2012, the Company matched 50% of the first 6% of employee pay. Beginning April 1, 2012, the Company matches 100% of employee contributions up to the first 5% of employee pay, up to IRS limits. Employee and Company contributions are fully vested when made. During the nine months ended December 31, 2013 and the twelve months ended March 31, 2013 and 2012, the Company contributed \$3.1 million, \$4.1 million and \$2.5 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 nine months ended December 31, 2013 and the twelve months ended March 31, 2013 and 2012, the Company contributed \$2.9 million, \$3.7 million and \$1.8 million, respectively, in contributions to the defined contribution plan.

*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 is required to be adopted for all annual periods and interim reporting periods beginning after December 15, 2013, with early adoption permitted. The Company does not expect that the adoption of this standard will have a material impact on the presentation of the Company’s financial position.



**ALKERMES PLC AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**3. ACQUISITIONS**

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

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

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

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

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

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

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

**ALKERMES PLC AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**3. ACQUISITIONS (Continued)**

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

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

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

On the acquisition date, EDT had several collaboration agreements in place with third-party pharmaceutical companies related to the development and commercialization of a number of products including INVEGA SUSTENNA/XEPLION, AMPYRA/FAMPYRA, TRICOR 145®, RITALIN LA®, FOCALIN® XR. , EMEND® and VERELAN®/VERAPAMIL®. For a complete listing of commercial products utilizing the NanoCrystal technology and Oral Controlled Release technology, including the product indication, collaborative partner, and revenue source, please refer to our “Commercial Products Table” on page 6 of this Transition Report.

The Company determined the value of each collaboration agreement through the use of the excess earnings method. The Company estimated future revenues to be earned under EDT’s collaboration agreements for the remainder of the year ended March 31, 2012 through the fiscal year ending March 31, 2027, and reduced such future revenues by (i) a projected gross margin percentage, (ii) an estimate of operating expenses to be incurred related to these agreements, and (iii) contributory asset charges for working capital and fixed assets. The Company then applied an estimated tax rate, determined based upon the jurisdictions in which the underlying intangible assets are taxed, to arrive at the excess earnings.

The Company converted the excess earnings attributable to the collaboration agreements to a present value using a discount rate of 14.5%. This discount rate is equal to the Internal Rate of Return (“IRR”) the Company calculated as part of the EDT acquisition. The IRR represents the return a market participant would expect to generate through the acquisition of EDT as well as the level of risk reflected in the financial projections used as the basis for the Company’s valuation analysis. Based on the valuation performed, the Company estimated its collaboration agreements to have a value on the acquisition date of \$499.7 million.

The Company determined the useful life of the collaboration agreements to be 12 years, which is the Company’s best estimate as to the remaining life of the intellectual property for the products underlying the collaboration agreements and the life of the collaboration agreements themselves.

The Company determined the value of the NanoCrystal and OCR technologies through the use of the income approach, specifically the relief-from-royalty method. The Company estimated the savings in royalties that EDT would otherwise have had to pay if it had not owned the NanoCrystal and OCR technologies and had to license it from a third party with rights of use substantially equivalent to ownership. The Company estimated the present value of the stream of future estimated after-tax royalty payments for the remainder of the year ended March 31, 2012 through the fiscal year ending

**ALKERMES PLC AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**3. ACQUISITIONS (Continued)**

March 31, 2027. The Company converted the after-tax royalty payments to a present value using the same discount rate of 14.5% as used in the analysis of the collaboration agreements. Based on the valuation performed, the Company estimated its NanoCrystal and OCR technologies to have a value on the acquisition date of \$74.6 million and \$66.3 million, respectively.

The Company determined the useful life of the NanoCrystal and OCR technologies to be 13 and 12 years, respectively, which is the Company's best estimate as to the remaining life of the intellectual property.

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

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

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

*Pro forma Financial Information (unaudited)*

The following unaudited pro forma information presents the combined results of operations for twelve months ended March 31, 2012 as if the acquisition of EDT had been completed on April 1, 2011. The unaudited pro forma results do not reflect any material adjustments, operating efficiencies or

**ALKERMES PLC AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**3. ACQUISITIONS (Continued)**

potential cost savings which may result from the consolidation of operations but do reflect certain adjustments expected to have a continuing impact on the combined results.

	<u>Twelve Months Ended March 31, 2012</u>
<b>(In thousands, except per share data)</b>	
Revenues . . . . .	\$ 500,105
Net loss . . . . .	\$(108,782)
Basic and diluted loss per ordinary share . . . . .	\$ (0.84)

**ALKERMES PLC AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**4. INVESTMENTS**

Investments consist of the following:

<u>December 31, 2013</u>	<u>Amortized Cost</u>	<u>Gains</u>	<u>Gross Unrealized</u>		<u>Estimated Fair Value</u>
			<u>Less than One Year</u>	<u>Greater than One Year</u>	
			<u>Losses</u>		
			<u>(In thousands)</u>		
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
Total short-term investments . . . . .	194,581	152	(64)	—	194,669
Long-term investments:					
Available-for-sale securities:					
U.S. government and agency debt securities . . . .	28,503	—	(61)	(3)	28,439
Equity securities . . . . .	8,732	21,253	—	—	29,985
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
<b>March 31, 2013</b>					
Short-term investments:					
Available-for-sale securities:					
U.S. government and agency debt securities . . . .	\$102,093	\$ 29	\$ (1)	\$ —	\$102,121
Corporate debt securities . . . . .	10,946	27	—	—	10,973
International government agency debt securities . .	10,089	8	(1)	—	10,096
	123,128	64	(2)	—	123,190
Money market funds . . . . .	1,201	—	—	—	1,201
Total short-term investments . . . . .	124,329	64	(2)	—	124,391
Long-term investments:					
Available-for-sale securities:					
U.S. government and agency debt securities . . . .	60,047	—	(17)	—	60,030
Corporate debt securities . . . . .	18,725	—	(26)	(162)	18,537
International government agency debt securities . .	3,060	—	—	—	3,060
	81,832	—	(43)	(162)	81,627
Held-to-maturity securities:					
Certificates of deposit . . . . .	1,200	—	—	—	1,200
Total long-term investments . . . . .	83,032	—	(43)	(162)	82,827
Total investments . . . . .	\$207,361	\$ 64	\$ (45)	\$(162)	\$207,218

**ALKERMES PLC AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**4. 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)	Nine Months Ended December 31, 2013	Twelve Months Ended March 31,	
		2013	2012
Proceeds from the sales and maturities of marketable securities . . . . .	\$90,470	\$258,937	\$323,028
Realized gains . . . . .	\$ 16	\$ 39	\$ 47
Realized losses . . . . .	\$ —	\$ 5	\$ 11

The Company's available-for-sale and held-to-maturity securities at December 31, 2013 have contractual maturities in the following periods:

(In thousands)	Available-for-sale		Held-to-maturity	
	Amortized Cost	Estimated Fair Value	Amortized Cost	Estimated Fair Value
Within 1 year . . . . .	\$107,374	\$107,354	\$1,493	\$1,493
After 1 year through 5 years . . . . .	142,466	142,400	—	—
Total . . . . .	<u>\$249,840</u>	<u>\$249,754</u>	<u>\$1,493</u>	<u>\$1,493</u>

At December 31, 2013, 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 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; and the Company's intent not to sell these securities, and the assessment that it is more-likely-than-not that the Company would not be required to sell these securities before the recovery of their amortized cost basis.

The Company's equity securities at December 31, 2013 included common stock and warrants of Acceleron Pharma, Inc. ("Acceleron"), which the Company accounts for as available-for-sale marketable securities. In September 2013, Acceleron successfully closed on an initial public offering ("IPO") and as a result, the Company's investment in preferred stock was converted to common stock. Prior to the IPO, the Company's investment in Acceleron was accounted for under the cost method as Acceleron was a privately held company over which the Company did not exercise significant influence. The Company's investment in Acceleron was \$8.7 million at March 31, 2013 and was included within "Other Assets" in the accompanying consolidated balance sheets.

The Company's investment in Civitas Therapeutics, Inc. ("Civitas") was \$2.0 million and \$0.8 million at December 31, 2013 and March 31, 2013, respectively, which was recorded within "Other assets" in the accompanying condensed consolidated balance sheets. In September 2013, the Company invested an additional \$1.2 million and converted a promissory note in the amount of \$1.2 million into 844,415 shares of Civitas Series B preferred stock. The Company is accounting for its investment in Civitas Series B preferred stock under the cost method of accounting as the Series B preferred stock is not considered to be "in-substance" common stock. The Company is accounting for its investment in



**ALKERMES PLC AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**4. INVESTMENTS (Continued)**

Civitas' Series A preferred stock under the equity method as the Series A preferred stock is considered to be "in-substance" common stock and the Company believes it may be able to exercise significant influence over the operating and financial policies of Civitas. During the nine months ended December 31, 2013 and the twelve months ended March 31, 2013 and 2012, the Company recorded a reduction in its investment in Civitas of \$1.2 million, \$1.2 million and \$0.8 million, respectively, which represented the Company's proportionate share of Civitas' net losses for these periods. The Company will continue to record its proportionate share of Civitas' net income or loss in future periods.

**5. 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)	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
Total . . . . .	<u>\$280,940</u>	<u>\$92,873</u>	<u>\$186,541</u>	<u>\$1,526</u>
<b>Liabilities:</b>				
Interest rate swap contract . . . . .	\$ (275)	\$ —	\$ (275)	\$ —
Total . . . . .	<u>\$ (275)</u>	<u>\$ —</u>	<u>\$ (275)</u>	<u>\$ —</u>
	March 31, 2013	Level 1	Level 2	Level 3
<b>Assets:</b>				
Cash equivalents . . . . .	\$ 1,201	\$ 1,201	\$ —	\$—
U.S. government and agency debt securities . . . . .	162,151	75,025	87,126	—
Corporate debt securities . . . . .	29,510	—	29,510	—
International government agency debt securities . . . . .	13,156	—	13,156	—
Total . . . . .	<u>\$206,018</u>	<u>\$76,226</u>	<u>\$129,792</u>	<u>\$—</u>
<b>Liabilities:</b>				
Interest rate swap contract . . . . .	\$ (541)	\$ —	\$ (541)	\$—
Total . . . . .	<u>\$ (541)</u>	<u>\$ —</u>	<u>\$ (541)</u>	<u>\$—</u>

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 nine months ended December 31, 2013. The following table is a rollforward of the fair value

**ALKERMES PLC AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**5. FAIR VALUE (Continued)**

of the Company's investments whose fair value was determined using Level 3 inputs at December 31, 2013:

(In thousands)	<u>Fair Value</u>
Balance, April 1, 2013 . . . . .	\$ —
Conversion of investment from cost method to available-for-sale . . . . .	807
Total unrealized gains included in other comprehensive income (loss) . .	719
Balance, December 31, 2013 . . . . .	<u>\$1,526</u>

During the nine months ended December 31, 2013, our Level 3 investment consisted of warrants to purchase the common stock of Acceleron. The Company used a Black-Scholes model to determine the fair value of these warrants. The assumptions used in the Black-Scholes model included the following:

Current stock price . . . . .	\$39.60
Warrant strike price . . . . .	\$ 5.88
Expected term (years) . . . . .	6.50
Risk-free rate . . . . .	2.45%
Volatility . . . . .	70.4%

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 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 include reportable trades, benchmark yields, credit spreads, broker/dealer quotes, bids, offers, current spot rates and other industry and economic events. The Company validates the prices developed using the market-observable data by obtaining market values from other pricing sources, analyzing pricing data in certain instances and confirming that the relevant markets are active.

The Company entered into an interest rate swap agreement in September 2011 which is described in greater detail in Note 12, *Derivative Instruments*. The fair value of the Company's interest rate swap agreement was based on an income approach, which excludes accrued interest, and takes into consideration then-current interest rates and the then-current creditworthiness of the Company or the counterparty, as applicable.

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 instruments not currently recognized at fair value on the Company's consolidated balance sheets consists 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 estimated fair value of these term loans, which was based on quoted market price indications (Level 2

**ALKERMES PLC AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**5. FAIR VALUE (Continued)**

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, 2013:

(In thousands)	<u>Carrying Value</u>	<u>Estimated Fair Value</u>
Term Loan B-1 . . . . .	\$294,091	\$296,398
Term Loan B-2 . . . . .	\$ 70,202	\$ 70,313

**6. INVENTORY**

Inventory consists of the following:

(In thousands)	<u>December 31, 2013</u>	<u>March 31, 2013</u>
Raw materials . . . . .	\$18,410	\$13,506
Work in process . . . . .	15,581	13,842
Finished goods(1) . . . . .	<u>12,227</u>	<u>16,135</u>
Total inventory . . . . .	<u>\$46,218</u>	<u>\$43,483</u>

(1) At December 31, 2013 and March 31, 2013, the Company had \$1.1 million and \$0.6 million, respectively, of finished goods inventory located at its third-party warehouse and shipping service provider.

**7. PROPERTY, PLANT AND EQUIPMENT**

Property, plant and equipment consist of the following:

(In thousands)	<u>December 31, 2013</u>	<u>March 31, 2013</u>
Land . . . . .	\$ 8,440	\$ 8,357
Building and improvements . . . . .	148,044	141,092
Furniture, fixture and equipment . . . . .	220,984	197,743
Leasehold improvements . . . . .	23,980	24,137
Construction in progress . . . . .	<u>26,688</u>	<u>39,399</u>
Subtotal . . . . .	428,136	410,728
Less: accumulated depreciation . . . . .	<u>(153,646)</u>	<u>(122,293)</u>
Total property, plant and equipment, net . . . . .	<u>\$ 274,490</u>	<u>\$ 288,435</u>

Depreciation expense was \$32.3 million, \$31.9 million and \$22.5 million for the nine months ended December 31, 2013 and the twelve months ended March 31, 2013 and 2012, respectively. Also, during the nine months ended December 31, 2013 and the twelve months ended March 31, 2013, the Company wrote off furniture, fixtures and equipment that had a carrying value of less than \$0.1 million at the time of disposition and received proceeds from the sales of furniture, fixtures and equipment of less than \$0.1 million.

**ALKERMES PLC AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**7. PROPERTY, PLANT AND EQUIPMENT (Continued)**

During the twelve months ended March 31, 2013, the Company performed an impairment analysis on certain of its manufacturing equipment dedicated to the production of VIVITROL. This equipment was originally purchased by Cephalon in connection with the VIVITROL collaboration and later acquired by the Company upon the termination of the VIVITROL collaboration with Cephalon. The Company 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 based on the selling prices of the assets.

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.

**8. GOODWILL AND INTANGIBLE ASSETS**

Goodwill and intangible assets consists of the following:

(In thousands)	Weighted Amortizable Life	Nine Months Ended December 31, 2013			Twelve Months Ended March 31, 2013		
		Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount	Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount
Goodwill . . . . .		\$ 92,740	\$ —	\$ 92,740	\$ 92,740	\$ —	\$ 92,740
Finite-lived intangible assets:							
Collaboration agreements . . . . .	12	\$499,700	\$ (80,655)	\$419,045	\$499,700	\$(50,143)	\$449,557
NanoCrystal technology . . . . .	13	74,600	(8,506)	66,094	74,600	(5,373)	69,227
OCR technologies . . . . .	12	66,300	(13,874)	52,426	66,300	(9,091)	57,209
Total . . . . .		<u>640,600</u>	<u>(103,035)</u>	<u>537,565</u>	<u>640,600</u>	<u>(64,607)</u>	<u>575,993</u>

During the three months ended December 31, 2013, the Company performed its annual goodwill impairment test. The Company worked with a third-party valuation firm and established fair value for the purpose of impairment testing by using an average of the income approach and the market approach. The income approach employs a discounted cash flow model that takes into account: (i) assumptions that market participants would use in their estimates of fair value; (ii) current period actual results; and (iii) forecasted results for future periods that have been vetted by senior management. The discounted cash flow model incorporates the same fundamental pricing concepts used to calculate fair value in an acquisition due diligence process and a discount rate that takes into consideration the Company's estimated cost of capital adjusted for the uncertainty inherent in an acquisition. The market approach employs market multiples for comparable publicly traded companies in the pharmaceutical and biotechnology industries obtained from industry sources, taking into consideration the nature, scope and size of the acquired reporting unit. In the market approach, estimates of fair value are established using an average of both revenue and EBITDA multiples, adjusted for the reporting unit's performance relative to peer companies.

At December 31, 2013, the Company's goodwill, which solely relates to the EDT acquisition, was assigned to one reporting unit. The Company determined that the fair value of its reporting unit,

**ALKERMES PLC AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**8. GOODWILL AND INTANGIBLE ASSETS (Continued)**

subject to the impairment test, was substantially in excess of its respective carrying value and there was no impairment in the value of this asset as of October 31, 2013.

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 \$38.4 million, \$41.9 million and \$25.4 million of amortization expense related to its finite-lived intangible assets during the nine months ended December 31, 2013 and the twelve months ended March 31, 2013 and 2012, respectively. Based on the Company's most recent analysis, amortization of intangible assets included within its condensed consolidated balance sheet at December 31, 2013 is expected to be approximately \$60.0 million, \$65.0 million, \$70.0 million, \$70.0 million and \$70.0 million in the years ending December 31, 2014 through 2018, 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.

**9. ACCOUNTS PAYABLE AND ACCRUED EXPENSES**

Accounts payable and accrued expenses consist of the following:

(In thousands)	<u>December 31, 2013</u>	<u>March 31, 2013</u>
Accounts payable . . . . .	\$19,493	\$18,282
Accrued compensation . . . . .	28,101	30,432
Accrued restructuring . . . . .	7,296	602
Accrued other . . . . .	<u>36,283</u>	<u>27,594</u>
Total accounts payable and accrued expenses . . . . .	<u>\$91,173</u>	<u>\$76,910</u>

During the three months ended June 30, 2013, the Company recorded a \$1.0 million out-of-period adjustment to correct an over-accrued liability from the prior year. The Company believes the impact of this out-of-period adjustment is immaterial to both the previously issued and current period financial statements.

**10. 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 will also implement a corresponding reduction in headcount of up to 130 employees. In connection with this restructuring plan, during the twelve months ended March 31, 2013, the Company recorded a restructuring charge of \$12.3 million, which consisted of severance and outplacement services. During

**ALKERMES PLC AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**10. RESTRUCTURING (Continued)**

the nine months ended December 31, 2013, the Company had paid in cash \$2.3 million in connection with this restructuring plan and recorded an adjustment to the restructuring accrual due to changes in foreign currency of \$0.6 million. Restructuring activity during the nine months ended December 31, 2013 was as follows:

(In thousands)	<u>Severance and Outplacement Services</u>
Balance, April 1, 2013 . . . . .	\$12,300
Payments . . . . .	(2,279)
Adjustments . . . . .	557
Balance, December 31, 2013 . . . . .	<u>\$10,578</u>

At December 31, 2013 and March 31, 2013, \$6.8 million and none, respectively, of this restructuring accrual were included within “Accounts payable and accrued expenses,” and \$3.8 million and \$12.3 million, respectively, were included within “Other long-term liabilities” in the accompanying consolidated balance sheets.

**11. LONG-TERM DEBT**

Long-term debt consists of the following:

(In thousands)	<u>December 31, 2013</u>	<u>March 31, 2013</u>
Term Loan B-1, due September 25, 2019 . . . . .	\$294,091	\$296,029
Term Loan B-2, due September 25, 2016 . . . . .	70,202	72,979
Total . . . . .	364,293	369,008
Less: current portion . . . . .	<u>(6,750)</u>	<u>(6,750)</u>
Long-term debt . . . . .	<u>\$357,543</u>	<u>\$362,258</u>

***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).



**ALKERMES PLC AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

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

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

<b>Year Ended:</b>	
2014 .....	\$ 6,750
2015 .....	6,750
2016 .....	65,813
2017 .....	3,000
2018 .....	3,000
Thereafter .....	<u>281,250</u>
Total .....	<u>\$366,563</u>

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 is subject to mandatory prepayments of principal if certain excess cash flow thresholds, as defined in the Term Loan Facility, are met. 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 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, 2013.

***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.

**ALKERMES PLC AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

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

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.

The Refinancing and Repricing resulted in a \$12.1 million and \$7.5 million charge, respectively, in the twelve months ended March 31, 2013, which was included in “Interest expense” in the accompanying consolidated statement of operations and comprehensive income (loss) 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, 2013, the Company’s balance of unamortized deferred financing costs and unamortized original issue discount costs were \$2.7 million and \$2.3 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 nine months ended December 31, 2013 and the twelve months ended March 31, 2013 and 2012, the Company had amortization expense of \$0.8 million, \$5.8 million and \$3.5 million, respectively, related to deferred financing costs and original issue discount.

**ALKERMES PLC AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**12. DERIVATIVE INSTRUMENTS**

In December 2011, the Company entered into an interest rate cap agreement with Morgan Stanley Capital Services LLC (“MSCS”) at a cost of \$0.1 million to mitigate the impact of fluctuations in the three-month LIBOR rate at which the Company’s 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 income (loss) due to the decline in value of this contract during the nine months ended December 31, 2013 and the twelve months ended March 31, 2013 and 2012.

In September 2011, the Company entered into an interest rate cap agreement with HSBC Bank USA at a cost of less than \$0.1 million to mitigate the impact of fluctuations in the three-month LIBOR rate at which the Company’s long-term debt bears interest. The interest rate cap agreement became effective on September 16, 2011 and expired in December 2012. The interest rate cap agreement had a notional value of \$65.0 million and was not designated as a hedging instrument. The Company recorded an immaterial amount of loss within “Other income (expense), net” in the consolidated statements of operations and comprehensive income (loss) due to the decline in value of this contract during the twelve months ended March 31, 2013 and 2012.

In September 2011, the Company entered into an interest rate swap agreement with MSCS to mitigate the impact of fluctuations in the three-month LIBOR rate at which the Company’s long-term debt bears interest. The interest rate swap agreement became effective in December 2012, expires in December 2014 and has 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 \$0.3 million within “Other income (expense), net” due to the decline in fair value of this contract during the nine months ended December 31, 2013. The Company recorded a realized loss of \$0.6 million upon the reclassification of unrealized losses to realized losses during the twelve months ended March 31, 2013.

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, 2013	March 31, 2012
<i>Interest rate swap</i>			
Liability derivative not designated as a cash flow hedge . . . . .	Other long-term liabilities	\$(275)	\$(541)

**13. EARNINGS (LOSS) PER SHARE**

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

**ALKERMES PLC AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**13. EARNINGS (LOSS) PER SHARE (Continued)**

number of ordinary shares outstanding, as adjusted for the effect of potential outstanding shares, including stock options and restricted stock units.

(In thousands)	Nine Months Ended December 31, 2013	Twelve Months Ended March 31,	
		2013	2012
Numerator:			
Net income (loss) . . . . .	\$ 17,649	\$ 24,983	\$(113,678)
Denominator:			
Weighted average number of ordinary shares outstanding . . . . .	135,960	131,713	114,702
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 . . . . .	<u>144,961</u>	<u>137,100</u>	<u>114,702</u>

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

(In thousands)	Nine Months Ended December 31, 2013	Twelve Months Ended March 31,	
		2013	2012
Stock options . . . . .	1,404	4,497	8,299
Restricted stock units . . . . .	—	—	1,205
Total . . . . .	<u>1,404</u>	<u>4,497</u>	<u>9,504</u>

**14. 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, 2013, 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 nine months ended December 31, 2013 and the twelve months ended March 31, 2013, the Company did not acquire any shares of outstanding ordinary shares under the repurchase program.

**ALKERMES PLC AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**15. 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 income (loss):

(In thousands)	Nine Months Ended December 31, 2013	Twelve Months Ended March 31,	
		2013	2012
Cost of goods manufactured and sold . . . . .	\$ 3,308	\$ 4,375	\$ 2,962
Research and development . . . . .	7,799	9,078	8,784
Selling, general and administrative . . . . .	22,302	21,263	17,080
Total share-based compensation expense . . . . .	\$33,409	\$34,716	\$28,826

At December 31, 2013 and March 31, 2013 and 2012, \$0.4 million, \$0.6 million and \$0.4 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, the 2011 Stock Option and Incentive Plan (the "2011 Plan"); (ii) and the 2008 Stock Option and Incentive Plan (the "2008 Plan"). The Company has five share-based compensation plans pursuant to which outstanding awards have been made, but from which no further awards can or will be made: (i) the 1996 Stock Option Plan for Non-Employee Directors (the "1996 Plan"); (ii) the 1998 Equity Incentive Plan (the "1998 Plan"); (iii) the 1999 Stock Option Plan (the "1999 Plan"); (iv) the 2002 Restricted Stock Award Plan (the "2002 Plan"); and (v) the 2006 Stock Option Plan for Non-Employee Directors (the "2006 Plan"). The 2011 Plan and the 2008 Plan provides for issuance of non-qualified and incentive stock options, restricted stock, restricted stock units, cash-based awards and performance shares to employees, officers and directors of, and consultants to, the Company in such amounts and with such terms and conditions as may be determined by the compensation committee of the Company's board of directors, subject to provisions of the 2011 Plan and the 2008 Plan.

At December 31, 2013, there were 10.4 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 Plan provides that awards other than stock options will be counted against the total number of shares available under the plan in a 2-to-1 ratio.

**ALKERMES PLC AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

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

*Stock Options*

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

	<u>Number of Shares</u>	<u>Weighted Average Exercise Price</u>
Outstanding, April 1, 2013 . . . . .	16,451,104	\$14.57
Granted . . . . .	2,047,250	\$33.52
Exercised . . . . .	(3,497,443)	\$14.26
Forfeited . . . . .	(312,750)	\$19.29
Expired . . . . .	(1)	\$14.62
Outstanding, December 31, 2013 . . . . .	<u>14,688,160</u>	\$17.18
Exercisable, December 31, 2013 . . . . .	<u>9,372,735</u>	\$14.54

The weighted average grant date fair value of stock options granted during the nine months ended December 31, 2013 and the twelve months ended March 31, 2013 and 2012 was \$16.27, \$8.11 and \$8.00, respectively. The aggregate intrinsic value of stock options exercised during the nine months ended December 31, 2013 and the twelve months ended March 31, 2013 and 2012 was \$65.6 million, \$28.1 million and \$11.1 million, respectively.

At December 31, 2013, there were 5.2 million stock options expected to vest with a weighted average exercise price of \$21.73 per share, a weighted average contractual remaining life of 8.3 years and an aggregate intrinsic value of \$98.3 million. At December 31, 2013, the aggregate intrinsic value of stock options exercisable was \$244.8 million with a weighted average remaining contractual term of 4.9 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, 2013, there was \$30.7 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 nine months ended December 31, 2013 and the twelve months ended March 31, 2013 and 2012 was \$49.1 million, \$34.4 million and \$20.9 million, respectively.



**ALKERMES PLC AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

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

*Time-Vested Restricted Stock Units*

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

	<b>Number of Shares</b>	<b>Weighted Average Grant Date Fair Value</b>
Unvested, April 1, 2013 . . . . .	2,226,771	\$15.14
Granted . . . . .	770,150	\$33.72
Vested . . . . .	(920,021)	\$13.56
Forfeited . . . . .	(89,013)	\$20.37
Unvested, December 31, 2013 . . . . .	<u>1,987,887</u>	<u>\$22.83</u>

The weighted average grant date fair value of time-vested RSUs granted during the nine months ended December 31, 2013 and the twelve months ended March 31, 2013 and 2012 was \$33.72, \$16.55 and \$17.91, respectively. The total fair value of time-vested RSUs that vested during the nine months ended December 31, 2013 and the twelve months ended March 31, 2013, and 2012 was \$12.5 million, \$9.9 million and \$6.1 million, respectively.

At December 31, 2013, there was \$24.7 million of total unrecognized compensation cost related to unvested time-vested RSUs, which will be recognized over a weighted average remaining contractual term of 2.0 years.

**16. COLLABORATIVE ARRANGEMENTS**

The Company's business strategy includes forming collaborations to develop and commercialize its products, and to access technological, financial, marketing, manufacturing and other resources. The Company'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.

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

**ALKERMES PLC AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**16. COLLABORATIVE ARRANGEMENTS (Continued)**

(ii) fifteen years after the date of the first commercial sale of the product in such country, provided that in no event will the license granted to Janssen expire later than the twentieth anniversary of the first commercial sale of the product in such country, with the exception of certain countries where the fifteen-year limitation shall pertain regardless. After expiration, Janssen retains a non-exclusive, royalty-free license to manufacture, use and sell RISPERDAL CONSTA. 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 \$82.5 million, \$98.6 million and \$129.8 million during the nine months ended December 31, 2013 and the twelve months ended March 31, 2013 and 2012, respectively. Under its agreements with Janssen, the Company recognized royalty revenues related to RISPERDAL CONSTA of \$24.7 million, \$35.0 million and \$38.5 million during the nine months ended December 31, 2013 and the twelve months ended March 31, 2013 and 2012, 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.

The Company receives certain development milestone payments from Janssen and aggregate 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 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 \$250.0 million, between \$250.0 million and \$500.0 million, and greater than \$500.0 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 lack of patent coverage or patent litigation, 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.

**ALKERMES PLC AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**16. COLLABORATIVE ARRANGEMENTS (Continued)**

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

Under its agreements with Janssen, the Company recognized royalty revenues from the sale of INVEGA SUSTENNA/XEPLION of \$82.9 million, \$63.5 million and \$18.0 million during the nine months ended December 31, 2013 and the twelve months ended March 31, 2013 and 2012, 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 license agreement upon 90 days' written notice. The Company has the right to terminate the license agreement for countries in which Acorda fails to launch a product within a specified time after obtaining the necessary regulatory approval or fails to file regulatory approvals within a commercially reasonable time after completion 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 license agreement by written notice following a 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, the Company is entitled to a license from Acorda of its patent rights and know-how relating to the product as well as the related data, information and regulatory files, and to market the product in the applicable country, subject to an initial payment equal to Acorda's cost of developing such data, information and regulatory files and to ongoing royalty payments to Acorda. Subject to the termination of the license agreement, licenses granted under the license agreement terminate on a country-by-country basis on the later of: (i) September 2018; or (ii) the expiration of the last to expire of our patents or the existence of a threshold level of competition in the marketplace.

Under its commercial manufacturing supply agreement with Acorda, the Company manufactures and supplies AMPYRA/FAMPYRA for Acorda (and its sub-licensees). Under the terms of the agreement, Acorda may obtain up to 25% of its total annual requirements of product from a second-source manufacturer. The Company receives royalties equal to 8% of net selling price for all product manufactured by it and a compensating payment for product manufactured and supplied by a third

**ALKERMES PLC AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**16. COLLABORATIVE ARRANGEMENTS (Continued)**

party. The Company may terminate the supply agreement upon 12 months' prior written notice to Acorda and either party may terminate the supply agreement following a material and uncured breach of the supply or license agreement or the entry into bankruptcy or dissolution proceedings by the other party. In addition, subject to early termination of the supply agreement noted above, the supply agreement terminates upon the expiry or termination of the license agreement.

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 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.

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 nine months ended December 31, 2013 and the twelve months ended March 31, 2013 and 2012, the Company recognized \$51.6 million, \$65.0 million and \$25.8 million, respectively, of revenues from its arrangements with Acorda.

**ALKERMES PLC AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**16. COLLABORATIVE ARRANGEMENTS (Continued)**

*AstraZeneca*

In May 2000, we entered into a development and license agreement with Amylin for the development of exendin products falling within the scope of our patents, 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 our 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. 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 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, 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 received a \$7.0 million milestone payment in July 2011 upon the first commercial sale of BYDUREON in the EU, and the Company received a \$7.0 million milestone payment upon the first commercial sale of BYDUREON in the U.S. BYDUREON was launched in the U.S. in February 2012.

The development and license agreement 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.

**ALKERMES PLC AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**16. COLLABORATIVE ARRANGEMENTS (Continued)**

During the nine months ended December 31, 2013 and the twelve months ended March 31, 2013 and 2012, the Company recognized \$20.0 million, \$23.8 million and \$18.8 million, respectively, of revenues from its arrangements with respect to BYDUREON.

**17. INCOME TAXES**

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

(In thousands)	Nine Months Ended December 31, 2013	Twelve Months Ended March 31,	
	2013	2013	2012
Current income tax provision (benefit):			
U.S. federal . . . . .	\$ 9,224	\$ 8,152	\$ 7,321
U.S. state . . . . .	2,119	2,588	6,649
Rest of world . . . . .	89	1,758	28
Deferred income tax (benefit) provision:			
Ireland . . . . .	(3,426)	(1,961)	(4,551)
U.S. federal . . . . .	(18,317)	—	(10,024)
U.S. state . . . . .	(1,941)	(79)	(137)
Total tax (benefit) provision . . . . .	\$(12,252)	\$10,458	\$ (714)

The current income tax provision for the nine months ended December 31, 2013 and twelve months ended March 31, 2013 was primarily due to U.S. federal and state taxes on income earned by the Company in the U.S. during the fiscal period. An \$11.4 million and an \$8.9 million benefit were recorded to additional paid-in capital in the nine months ended December 31, 2013 and twelve months 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 current income tax provision for the twelve months ended March 31, 2012 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, partially offset by a \$4.3 million benefit recorded to additional paid-in capital related to the utilization of certain NOL carryforwards resulting from the exercise of employee stock options.

The deferred income tax 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 twelve months ended March 31, 2013 was primarily due to the unwind 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. The deferred income tax benefit for the twelve months ended March 31, 2012 was primarily due to the partial release of an existing U.S. federal valuation allowance as a consequence of the Business Combination and a benefit from the partial release of an Irish deferred tax liability relating to acquired intellectual property that was established in connection with the Business Combination.

No provision for income tax has been provided on undistributed earnings of the Company's foreign subsidiaries because such earnings may be repatriated in a tax efficient manner. Cumulative unremitted earnings of overseas subsidiaries totaled approximately \$53.7 million at December 31, 2013.



**ALKERMES PLC AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**17. INCOME TAXES (Continued)**

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

(In thousands)	Nine Months Ended December 31,	Twelve Months Ended March 31,	
	2013	2013	2012
Ireland . . . . .	\$(63,975)	\$(14,722)	\$ (36,711)
U.S. . . . .	49,338	23,503	(84,858)
Rest of world . . . . .	20,034	26,660	7,177
Income (loss) before provision for income taxes . . . . .	<u>\$ 5,397</u>	<u>\$ 35,441</u>	<u>\$(114,392)</u>

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

(In thousands)	December 31, 2013	March 31, 2013
Deferred tax assets:		
Irish NOL carryforwards . . . . .	\$ 68,459	\$ 55,842
Tax benefit from the exercise of stock options . . . . .	9,122	8,437
Share-based compensation . . . . .	24,353	23,468
Tax credit carryforwards . . . . .	6,247	10,543
Property, plant and equipment . . . . .	1,912	653
Bonus accrual . . . . .	4,585	7,034
Other . . . . .	10,538	11,605
Less: valuation allowance . . . . .	<u>(69,659)</u>	<u>(86,714)</u>
Total deferred tax assets . . . . .	<u>55,557</u>	<u>30,868</u>
Deferred tax liabilities:		
Intangible assets . . . . .	(38,238)	(40,968)
Property, plant and equipment . . . . .	(21,571)	(19,607)
Unrealized gains on investments . . . . .	(7,719)	—
Other . . . . .	<u>(4,421)</u>	<u>(2,072)</u>
Total deferred tax liabilities . . . . .	<u>(71,949)</u>	<u>(62,647)</u>
Net deferred tax liabilities . . . . .	<u>\$(16,392)</u>	<u>\$(31,779)</u>

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

(In thousands)	December 31, 2013	March 31, 2013
Current deferred tax assets . . . . .	\$ 12,777	\$ 5,824
Non-current deferred tax liabilities . . . . .	<u>(29,169)</u>	<u>(37,603)</u>
Net deferred tax liabilities . . . . .	<u>\$(16,392)</u>	<u>\$(31,779)</u>

**ALKERMES PLC AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**17. INCOME TAXES (Continued)**

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. At December 31, 2013, the Company maintained a valuation allowance of \$10.7 million against certain U.S. federal and state deferred tax assets and \$58.9 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. \$9.1 million of the \$10.7 million valuation allowance held against certain U.S. tax assets, when recognized, will be accounted for as a credit to additional paid-in capital rather than a reduction of income tax expense.

The decrease in the valuation allowance from the twelve months ended March 31, 2013 to the nine months ended December 31, 2013 was primarily related to the reversal of part of the valuation allowance held against the Company's U.S. federal and state deferred tax assets, partially offset by an increase in the valuation allowance held against its Irish deferred tax assets.

The tax benefit from stock option exercises included in the table above represents benefits accumulated prior to the adoption of Accounting Standards Codification ("ASC") Topic 718 ("ASC 718") that have not been realized. Subsequent to the adoption of ASC 718 on April 1, 2006, an additional \$41.1 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 once they are realized. In total, the Company has approximately \$50.2 million of tax benefits related to certain NOL carryforwards and tax credit carryforwards resulting from the exercise of employee stock options and the vesting of restricted stock units, which when recognized, will be accounted for as a credit to additional paid-in capital rather than a reduction of income tax expense.

As of December 31, 2013, the Company had \$494.6 million of Irish NOL carryforwards, \$77.1 million of U.S. federal NOL carryforwards, \$9.8 million of state NOL carryforwards, \$22.3 million of federal research and development credits, \$7.5 million of alternative minimum tax ("AMT") credits and \$0.6 million of state tax credits which will either expire on various dates through 2033 or can be carried forward indefinitely. These loss carryforwards and credits are available to reduce certain future Irish and foreign taxable income, 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.

**ALKERMES PLC AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**17. INCOME TAXES (Continued)**

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

	<b>Nine Months Ended December 31, 2013</b>	<b>Twelve Months Ended March 31,</b>	
		<b>2013</b>	<b>2012</b>
Statutory tax rate . . . . .	12.5%	12.5%	12.5%
U.S. state income taxes, net of U.S. federal benefit . . . . .	40.8%	4.7%	(6.8)%
R&D credit . . . . .	(29.6)%	(20.5)%	(8.4)%
Share-based compensation . . . . .	13.6%	3.3%	(0.7)%
Non-refundable withholding tax . . . . .	0.4%	4.7%	—%
Permanent items . . . . .	(83.6)%	(8.2)%	—%
State tax law change . . . . .	12.7%	—%	—%
Change in valuation allowance . . . . .	(321.4)%	(7.5)%	55.7%
Rate differential . . . . .	127.6%	40.5%	(51.7)%
Effective tax rate . . . . .	<u>(227.0)%</u>	<u>29.5%</u>	<u>0.6%</u>

The U.S. federal research and development credit has not yet been enacted for 2014 and, unless retroactively reinstated, will cause an increase to the Company's 2014 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, 2011 . . . . .	\$ 4,933
Additions based on tax positions related to prior periods . . . . .	1,741
Decreases due to lapse of statute of limitations . . . . .	<u>(68)</u>
Balance, March 31, 2012 . . . . .	6,606
Additions based on tax positions related to prior periods . . . . .	1,065
Decreases due to settlements with tax authorities . . . . .	<u>(413)</u>
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 . . . . .	<u>(7,258)</u>
Balance, December 31, 2013 . . . . .	<u>\$ 1,125</u>

\$1.1 million of the unrecognized tax benefits at December 31, 2013, 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 nine months ended December 31, 2013 and the twelve months ended March 31, 2013 and 2012, the Company's accrued interest and penalties related to uncertain tax positions were not material.

**ALKERMES PLC AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**17. INCOME TAXES (Continued)**

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 2011 through 2013 fiscal years remain subject to examination by the respective tax authorities. In Ireland, fiscal years 2009 to 2013 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 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 the examination have been reflected in the financial statements. Fiscal year 2012 for Alkermes, Inc. is currently under examination by the Commonwealth of Massachusetts.

**18. TRANSITION PERIOD COMPARATIVE DATA**

	Nine Months Ended	
(In thousands)	December 31, 2013	December 31, 2012 (unaudited)
Statement of Operations Data:		
Revenues . . . . .	\$432,911	\$412,126
Operating expenses . . . . .	<u>417,417</u>	<u>349,297</u>
Operating income . . . . .	15,494	62,829
Other expense (net) . . . . .	<u>(10,097)</u>	<u>(35,254)</u>
Income before income taxes . . . . .	5,397	27,575
Income tax (benefit) provision . . . . .	<u>(12,252)</u>	<u>5,591</u>
Net income . . . . .	<u>\$ 17,649</u>	<u>\$ 21,984</u>
Earnings per ordinary share—basic . . . . .	<u>\$ 0.13</u>	<u>\$ 0.17</u>
Earnings per ordinary share—diluted . . . . .	<u>\$ 0.12</u>	<u>\$ 0.16</u>
Weighted average ordinary shares outstanding—basic . . . . .	<u>135,960</u>	<u>131,202</u>
Weighted average ordinary shares outstanding—diluted . . . . .	<u>144,961</u>	<u>136,216</u>
Statement of Cash Flows Data:		
Cash flows provided by operations . . . . .	\$ 92,221	\$ 71,247
Cash flows (used in) provided by investing activities . . . . .	(65,366)	43,680
Cash flows provided by (used in) financing activities . . . . .	<u>43,746</u>	<u>(62,636)</u>
Increase in cash and cash equivalents . . . . .	<u>\$ 70,601</u>	<u>\$ 52,291</u>

**19. 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 2021. 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

**ALKERMES PLC AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**19. COMMITMENTS AND CONTINGENCIES (Continued)**

Massachusetts. As of December 31, 2013, the total future annual minimum lease payments under the Company's non-cancelable operating leases are as follows:

(In thousands)	<u>Payment Amount</u>
Year Ended:	
2014 .....	\$ 4,816
2015 .....	4,950
2016 .....	4,281
2017 .....	4,447
2018 .....	4,513
Thereafter .....	<u>7,409</u>
	30,416
Less: estimated sublease income .....	<u>(1,444)</u>
Total future minimum lease payments .....	<u>\$28,972</u>

Rent expense related to operating leases charged to operations was \$3.7 million, \$5.0 million and \$4.2 million for the nine months ended December 31, 2013 and twelve months ended March 31, 2013 and 2012, respectively. These amounts were net of sublease income of \$0.7 million, \$2.6 million and \$9.2 million, respectively. In addition to its lease commitments, the Company had open purchase orders totaling \$101.8 million at December 31, 2013.

***Litigation***

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

**20. SUBSEQUENT EVENTS**

In January 2014, the Company sold 5,917,160, \$0.01 par value, ordinary shares pursuant to its shelf registration statement on Form S-3 at a price of \$42.25 per share. The Company received total gross proceeds of \$250 million, before deducting expenses associated with the offering.

Also, in January 2014, the Company agreed to sell, subject to customary closing conditions, certain of its land, buildings and equipment at its Athlone, Ireland facility. The closing of the acquisition is expected to occur during the first quarter of 2014.

## CERTIFICATIONS

I, Richard F. Pops, certify that:

1. I have reviewed this transition report on Form 10-K of Alkermes plc;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared.
  - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, 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;
  - c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an transition report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

/s/ RICHARD F. POPS

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Richard F. Pops  
*Chairman and Chief Executive Officer*  
*(Principal Executive Officer)*

February 27, 2014



## CERTIFICATIONS

I, James M. Frates, certify that:

1. I have reviewed this transition report on Form 10-K of Alkermes plc;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared.
  - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, 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;
  - c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an transition report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

/s/ JAMES M. FRATES

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James M. Frates  
*Senior Vice President and Chief Financial Officer*  
*(Principal Financial and Accounting Officer)*

February 27, 2014

**CERTIFICATION PURSUANT TO  
18 U.S.C. SECTION 1350,  
AS ADOPTED PURSUANT TO  
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the Transition Report of Alkermes plc (the “Company”) on Form 10-K for the period ended December 31, 2013 as filed with the Securities and Exchange Commission on the date hereof (the “Report”), we, Richard F. Pops, Chairman and Chief Executive Officer of the Company, and James M. Frates, Senior Vice President and Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, to our knowledge that:

- (1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ RICHARD F. POPS

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Richard F. Pops  
*Chairman and Chief Executive Officer*  
*(Principal Executive Officer)*

/s/ JAMES M. FRATES

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James M. Frates  
*Senior Vice President and Chief Financial Officer*  
*(Principal Financial and Accounting Officer)*

February 27, 2014