

Use these links to rapidly review the document

[TABLE OF CONTENTS](#)

[Table of Contents](#)

---

# UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

## Form 10-K

(Mark One)

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

For the fiscal year ended March 31, 2013

OR

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

For the transition period from \_\_\_\_\_ to \_\_\_\_\_

Commission file number: 1-14131

### ALKERMES PUBLIC LIMITED COMPANY

(Exact name of registrant as specified in its charter)

**Ireland** **98-1007018**  
(State or other jurisdiction of (I.R.S. Employer  
incorporation or organization) Identification No.)

**Connaught House**  
**1 Burlington Road**  
**Dublin 4, Ireland**  
(Address of principal executive (Zip code)  
offices)

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

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

<u>Ordinary shares, \$0.01 par value</u>	<u>NASDAQ Global Select Stock Market</u>
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   
(Do not check if a  
smaller reporting company)

Smaller Reporting company

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

The aggregate market value of the registrant's ordinary shares held by non-affiliates of the registrant (without admitting that any person whose shares are not included in such calculation is an affiliate) computed by reference to the price at which the ordinary shares was last sold as of the last business day of the registrant's most recently completed second fiscal quarter was \$2,712,520,116.

As of May 08, 2013, 134,380,999 shares of ordinary shares were issued and outstanding.

#### **DOCUMENTS INCORPORATED BY REFERENCE**

Portions of the definitive proxy statement for our Annual General Meeting of Shareholders' for the fiscal year ended March 31, 2013 are incorporated by reference into Part III of this report.

---

---

**ALKERMES PLC AND SUBSIDIARIES**  
**ANNUAL REPORT ON FORM 10-K**  
**FOR THE FISCAL YEAR ENDED MARCH 31, 2013**  
**INDEX**

<u>PART I</u>		
<u>Item 1.</u>	<u>Business</u>	<u>5</u>
<u>Item 1A.</u>	<u>Risk Factors</u>	<u>32</u>
<u>Item 1B.</u>	<u>Unresolved Staff Comments</u>	<u>52</u>
<u>Item 2.</u>	<u>Properties</u>	<u>52</u>
<u>Item 3.</u>	<u>Legal Proceedings</u>	<u>52</u>
<u>Item 4.</u>	<u>Mine Safety Disclosures</u>	<u>52</u>
<u>PART II</u>		
<u>Item 5.</u>	<u>Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities</u>	<u>53</u>
<u>Item 6.</u>	<u>Selected Financial Data</u>	<u>57</u>
<u>Item 7.</u>	<u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	<u>59</u>
<u>Item 7A.</u>	<u>Quantitative and Qualitative Disclosures about Market Risk</u>	<u>79</u>
<u>Item 8.</u>	<u>Financial Statements and Supplementary Data</u>	<u>82</u>
<u>Item 9.</u>	<u>Changes in and Disagreements With Accountants on Accounting and Financial Disclosures</u>	<u>83</u>
<u>Item 9A.</u>	<u>Controls and Procedures</u>	<u>83</u>
<u>Item 9B.</u>	<u>Other Information</u>	<u>84</u>
<u>PART III</u>		
<u>Item 10.</u>	<u>Directors, Executive Officers and Corporate Governance</u>	<u>85</u>
<u>Item 11.</u>	<u>Executive Compensation</u>	<u>85</u>
<u>Item 12.</u>	<u>Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters</u>	<u>85</u>
<u>Item 13.</u>	<u>Certain Relationships and Related Transactions, and Director Independence</u>	<u>85</u>
<u>Item 14.</u>	<u>Principal Accounting Fees and Services</u>	<u>85</u>
<u>PART IV</u>		
<u>Item 15.</u>	<u>Exhibits and Financial Statement Schedules</u>	<u>85</u>
<u>SIGNATURES</u>		<u>86</u>

## FORWARD-LOOKING STATEMENTS

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

- our expectations regarding our financial performance, including revenues, expenses, income taxes, liquidity and capital expenditures;
- our expectations regarding the commercialization of our products, including the sales and marketing efforts of our partners and, for VIVITROL® (naltrexone for extended-release injectable suspension), our ability to establish and maintain successful sales and marketing, reimbursement and distribution arrangements;
- our expectations regarding our products, including the development, regulatory review (including expectations about regulatory approval and regulatory timelines) and therapeutic and commercial potential of such products and the costs and expenses related thereto;
- our expectations regarding the initiation, timing and results of clinical trials of our products;
- our expectations regarding the successful manufacture of our products, by us or our partners, for clinical use or commercial sale;
- the continuation of our collaborations and other significant agreements and our ability to establish and maintain successful development collaborations;
- our expectations regarding the financial impact of currency exchange rate fluctuations and valuations;
- the impact of new accounting pronouncements;
- our ability to protect our intellectual property rights, not infringe third-party intellectual property rights and the impact of recent patent legislation;
- our expectations regarding near-term changes in the nature of our market risk exposures or in management's objectives and strategies with respect to managing such exposures;
- our ability to comply with restrictive covenants of our indebtedness and our ability to fund our debt service obligations;
- our expectations concerning the status, intended use and financial impact of, and arrangements involving, our properties, including manufacturing facilities;
- our future capital requirements and capital expenditures and our ability to finance our operations and capital requirements; and
- other risk factors described in "*Item 1A—Risk Factors*" in this Annual Report.

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

section. Except as required by applicable law or regulation, we do not undertake any obligation to update publicly or revise any forward-looking statements, whether as a result of new information, future events or otherwise. In light of these risks, uncertainties and assumptions, the forward-looking events discussed in this Annual Report might not occur. For more information regarding the risks and uncertainties of our business, see "Item 1A—Risk Factors."

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

## PART I

### Item 1. Business

*The following discussion contains forward-looking statements. Actual results may differ significantly from those projected in the forward-looking statements. See "Forward-Looking Statements" on page 3 of this Annual Report. Factors that might cause future results to differ materially from those projected in the forward-looking statements also include, but are not limited to, those discussed in "Item 1A—Risk Factors" and elsewhere in this Annual Report.*

*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"). Use of the terms such as "us," "we," "our," "Alkermes" or the "Company" in this Annual Report is meant to refer to Alkermes plc and its consolidated subsidiaries, except where the context makes clear that the time period being referenced is prior to September 16, 2011, in which case such terms shall refer to Alkermes, Inc. and its consolidated subsidiaries. Prior to September 16, 2011, Alkermes, Inc. was an independent pharmaceutical company incorporated in the Commonwealth of Pennsylvania and traded on the NASDAQ Global Select Stock Market (the "NASDAQ") under the symbol "ALKS." For a more detailed discussion of the Business Combination, please refer to the notes to our consolidated financial statements, including Note 1, The Company, and Note 3, Acquisitions, in the accompanying consolidated financial statements.*

#### Overview

Alkermes plc is a fully integrated, global biopharmaceutical company that applies its scientific expertise and proprietary technologies to develop innovative medicines that improve patient outcomes. 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. Headquartered in Dublin, 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.

We leverage our formulation expertise and proprietary product platforms to develop, both with partners and on our own, innovative and competitively advantaged medications that can enhance patient outcomes in major therapeutic areas. We enter into select collaborations with pharmaceutical and biotechnology companies to develop significant new product candidates, based on existing drugs and incorporating our proprietary product platforms. In addition, we apply our innovative formulation expertise and drug development capabilities to create our own new, proprietary pharmaceutical products.

#### Our Strengths and Strategy

The products that we develop leverage multiple proprietary technologies to create new medicines that are designed to address therapeutic areas of significant unmet medical need and improve patient outcomes. As of March 31, 2013, we and our pharmaceutical and biotechnology partners had more than 20 commercialized products sold worldwide, including the United States ("U.S."). We earn manufacturing and/or royalty revenues on net sales of products commercialized by our partners and earn revenue on net sales of VIVITROL, which is a proprietary product that we manufacture, market and sell in the U.S. Our five key products are expected to generate significant revenues for us in the near- and medium-term, as they possess long patent lives, are singular or competitively advantaged products in their class and are generally in the launch phases of their commercial lives. These five key products are: RISPERDAL® CONSTA® and INVEGA® SUSTENNA®/XEPLION®, both antipsychotics marketed by Ortho-McNeil-Janssen Pharmaceuticals, Inc. and Janssen Pharmaceutica International, a division of Cilag International AG ("Janssen"); AMPYRA®/FAMPYRA® for the improvement of

walking in patients with multiple sclerosis and marketed by Acorda Therapeutics, Inc. ("Acorda") in the U.S. and by Biogen Idec International GmbH ("Biogen Idec") outside the U.S.; BYDUREON®, the only once-weekly treatment for type 2 diabetes, which is co-developed and marketed by Bristol-Myers Squibb Company ("Bristol-Myers") and AstraZeneca PLC ("Astra Zeneca"); and VIVITROL, the only once-monthly, injectable, non-addictive treatment for the prevention of relapse to opioid dependence following detoxification and for alcohol dependence, which is marketed by us.

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

#### Our Competitive Strengths

We believe our principal competitive strengths include:

- our broad and diverse product portfolio and pipeline, which, as of March 31, 2013, included more than 20 marketed products and numerous proprietary and partnered pipeline candidates;
- our five key commercial products that are expected to generate significant revenues for the company in the near- and medium-term;
- our focused R&D approach that leverages proprietary technologies and our extensive experience in developing CNS treatments, with the proven ability to advance candidates from well-informed preclinical testing to cost-effective proof-of-concept studies;
- our intellectual property portfolio covering composition of matter, process, formulation and/or methods-of-use for our currently marketed five key commercial products and for our product candidates in development;
- our three established manufacturing facilities that are compliant with current Good Manufacturing Practices ("cGMP"), can produce multiple dosage forms and are fully scaled to meet the manufacturing needs of ourselves and our collaborative partners; and
- our experienced management team and personnel who have grown our business to be an established biopharmaceutical company with a track record of more than 40 years of development, regulatory, manufacturing and partnering expertise.

#### Our Strategy

**Capitalize on growth from our five key commercial products.** Our key commercial products are generally in their launch stages for large and growing disease areas, with significant opportunities for growth. We expect that the revenues that we earn from the portfolio—RISPERDAL CONSTA and INVEGA SUSTENNA/XEPLION, AMPYRA/FAMPYRA, BYDUREON and VIVITROL—will continue to increase in the near- and medium-term, as they address large and growing markets and are competitively advantaged. We expect that revenues generated from these products will enable us to meet our near- and medium-term financial goals and position the company for sustainable profitability.

**Continue to advance our pipeline.** Our R&D approach is based on return on investment and, between us and our partners, we have a diverse pipeline of new drug candidates. We currently have one proprietary product candidate in phase 3, one proprietary candidate in phase 2 and one proprietary candidate in phase 1. We also have one partnered product candidate that is under review by the

U.S. Food and Drug Administration ("FDA") and other proprietary candidates in preclinical testing. In addition, we and our collaborators are in the process of developing line extensions and new formulations for some of our existing commercial products. Our proprietary product candidates have undergone extensive preclinical testing prior to reaching the clinical development stage, which we believe improves these candidates' probability of success in later-stage drug development (See "Key Development Programs" on page 10 in this Annual Report).

**Grow revenues and strategically invest in our late-stage pipeline.** Our five key commercial products are expected to grow our revenues in the near- and medium-term, and we will seek to invest in our late-stage pipeline to drive long-term value for the Company.

**Products and Development Programs**

Commercial Products

Our commercial 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:

<b>Product</b>	<b>Indication</b>	<b>Technology</b>	<b>Territory</b>	<b>Revenue Source</b>	<b>Marketer</b>
<i>RISPERDAL</i> <i>CONSTA</i>	Schizophrenia Bipolar I Disorder	Extended-release microsphere	Worldwide	Manufacturing and Royalty	Janssen
<i>INVEGA</i> <i>SUSTENNA</i>	Schizophrenia	NanoCrystal®	U.S.	Royalty	Janssen
<i>XEPLION</i>			Worldwide		
<i>AMPYRA</i>	Treatment to improve walking in patients with multiple sclerosis ("MS"), as demonstrated by an increase in walking speed	Oral Controlled Release ("OCR") (MXDAS®)	U.S.	Manufacturing and Royalty	Acorda in U.S. Biogen Idec (ex-U.S. under sublicense from Acorda)
<i>FAMPYRA</i>			Worldwide		
<i>BYDUREON</i>	Type 2 diabetes	Extended-release microsphere	Worldwide	Royalty	Bristol-Myers and Astra Zeneca
<i>VIVITROL</i>	Alcohol dependence Opioid dependence	Extended-release microsphere	U.S. Russia and Commonwealth of Independent States ("CIS")	Product sales Manufacturing and Royalty	Alkermes plc Janssen
<i>TRICOR</i> ® <i>LIPANTHYL</i> ® <i>LIPIDIL</i> <i>SUPRALIP</i>	Cholesterol lowering	NanoCrystal	Worldwide	Royalty	AbbVie Inc. Abbott Laboratories
<i>ZANAFLEX</i> ® <i>CAPSULES</i> ® <i>ZANAFLEX</i> ® <i>TABLETS</i> <i>TIZANIDINE</i> <i>HYDROCHLORIDE (AB Rated to ZANAFLEX CAPSULES)</i>	Muscle spasticity	OCR (SODAS®)	U.S.	Manufacturing (capsules only) and Royalty	Acorda; Actavis, Inc. (formerly Watson Pharmaceutical)
<i>AVINZA</i> ®	Chronic moderate to severe pain	OCR (SODAS)	U.S.	Manufacturing and Royalty	Pfizer, Inc. ("Pfizer")
<i>EMEND</i> ®	Nausea associated with chemotherapy and surgery	NanoCrystal	Worldwide	Manufacturing and Royalty	Merck & Co. Inc. ("Merck")



<b>Product</b>	<b>Indication</b>	<b>Technology</b>	<b>Territory</b>	<b>Revenue Source</b>	<b>Marketer</b>
<i>FOCALIN® XR</i> <i>RITALIN LA®</i>	Attention Deficit Hyperactivity Disorder	OCR (SODAS)	Worldwide	Manufacturing and Royalty	Novartis AG ("Novartis")
<i>MEGACE® ES</i>	Anorexia, Cachexia associated with AIDS	NanoCrystal	U.S.	Royalty	Strativa Pharmaceuticals (a business division of Par Pharmaceutical Companies, Inc.)
<i>LUVOX CR®</i>	Obsessive-compulsive disorder	OCR (SODAS)	U.S.	Manufacturing and 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 (IPDAS®)	U.S. Canada	Manufacturing	Shionogi Sunovion Pharmaceuticals Canada, Inc.
<i>VERAPAMIL SR</i> <i>VERELAN®</i> <i>VERELAN® PM</i> <i>VERAPAMIL PM</i> <i>VERECAPS®</i> <i>UNIVER</i>	Hypertension	OCR (SODAS)	Licensed on country/region basis throughout the world	Manufacturing and Royalty (on select formulations)	UCB Kremers-Urban; Cephalon; Aspen Pharma; Orient Europharma; Actavis, Inc.
<i>DILZEM</i> <i>DILZEM SR</i> <i>DILZEM XL</i> <i>DILTELAN</i> <i>ACALIX CD</i> <i>DINISOR</i> <i>TILAZEM CR</i> <i>CARDIZEM® CD</i>	Hypertension and/or Angina	OCR (SODAS)	Licensed on country/region basis throughout the world	Manufacturing and Royalty (for CARDIZEM CD only)	Cephalon; Pfizer; Roemmers; Kun Wha; Orient Europharma; Sanofi-Aventis; Valeant Pharmaceuticals International Inc.
<i>AFEDitab® CR</i> ( <i>AB Rated to Adalat CC®</i> )	Hypertension	OCR (MXDAS®)	U.S.	Manufacturing	Actavis, Inc.
<i>LYXUMIA®</i>	Type 2 diabetes in adults	—	United Kingdom	Royalty	Sanofi-Aventis
<i>ZONEGRAN®</i>	Hypertension	—	EU	Royalty	Eisai Pharmaceuticals

We have five principal commercial products which either currently, or in the future, are expected to contribute meaningfully to our revenues. These five 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 FDA approved RISPERDAL CONSTA as both monotherapy and adjunctive therapy to lithium or valproate in the maintenance treatment of bipolar I disorder in May 2009. RISPERDAL CONSTA is also approved for the maintenance treatment of bipolar I disorder in Canada, Australia and Saudi Arabia.

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 35%, 48% and 83% of our consolidated revenues for the fiscal years ended March 31, 2013, 2012 and 2011, 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 have schizophrenia, with men and women affected equally. Worldwide, it is estimated that one person in every 100 develops schizophrenia. Studies have demonstrated that as many as 75% of patients with schizophrenia have difficulty taking their oral medication on a regular basis, which can lead to worsening of symptoms.

*What is bipolar I disorder?*

Bipolar disorder is a brain disorder that causes unusual shifts in a person's mood, energy and ability to function. It is often characterized by debilitating mood swings, from extreme highs (mania) to extreme lows (depression). Bipolar I disorder is characterized based on the occurrence of at least one manic episode, with or without the occurrence of a major depressive episode. Bipolar disorder is believed to affect approximately 5.7 million American adults, or about 2.6% of the U.S. population aged 18 and older in a given year. The median age of onset for bipolar disorder is 25 years.

**AMPYRA/FAMPYRA**

Dalfampridine extended-release tablets are marketed and sold in the U.S. under the trade name AMPYRA by Acorda. Prolonged-release fampridine tablets received conditional approval in the EU in July 2011 and are marketed and sold outside the U.S. under the trade name FAMPYRA by Biogen Idec. The FDA approved AMPYRA as a treatment to improve walking in patients with MS as demonstrated by an increase in walking speed in January 2010. Efficacy was shown in people with all four major types of MS (relapsing remitting, secondary progressive, progressive relapsing and primary progressive). It is the first and, currently, only product to be approved for this indication. 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**

We collaborated with Amylin Pharmaceuticals, Inc., now a wholly-owned subsidiary of Bristol-Myers, on the development of a once-weekly formulation of exenatide, BYDUREON, which 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. Through their diabetes collaboration, Bristol-Myers and AstraZeneca co-develop and market Amylin's portfolio of products, including 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 347 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 the first and only once-monthly injectable medication approved by the FDA for the treatment of alcohol dependence in April 2006 and 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 where it was approved for the treatment of alcohol dependence in 2008 and for 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 2011 U.S. National Survey on Drug Use and Health, an estimated 1.6 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. Approximately 16 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 Commercial Products**

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

On April 4, 2013, we announced the approval of a restructuring plan pursuant to which we will terminate manufacturing services for certain older products becoming uneconomic to produce due to decreasing demand from our customers resulting from generic competition, and we will implement a

corresponding reduction in headcount of up to 130 employees at our Athlone, Ireland manufacturing facility.

### Key Development Programs

We leverage our formulation expertise and proprietary product platforms to develop, both with partners and on our own, innovative and competitively advantaged medications that can 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. 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."

#### ***Aripiprazole Lauroxil***

We are studying aripiprazole lauroxil, which we formerly referred to as ALKS 9070, 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™ product platform. A phase 3 trial to assess the efficacy, safety and tolerability of aripiprazole lauroxil in approximately 690 patients experiencing acute exacerbation of schizophrenia is currently ongoing, and the clinical data from this study, expected in the first half of calendar-year 2014, is expected to form the basis of a New Drug Application ("NDA") to the FDA for aripiprazole lauroxil for the treatment of schizophrenia.

In April 2013, U.S. Patent 8,431,576, titled "Heterocyclic Compounds for the Treatment of Neurological and Psychological Disorders" issued. The allowed claims of such patent will cover a class of compounds that includes aripiprazole lauroxil. The patent will expire in the U.S. in 2030.

#### ***ALKS 33***

ALKS 33 is an 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 investigational medicine with a novel mechanism for the treatment of major depressive disorder ("MDD"). The mechanism of action for ALKS 5461 in the treatment of depressive symptoms is based on modulation of the opioid system in the brain, employing a balanced combination of agonism and antagonism of opioid receptors. ALKS 5461 consists of buprenorphine, a partial agonist, and ALKS 33, a potent mu-opioid antagonist, and is designed to be a once-daily, non-addictive medicine. A phase 2 study evaluating the efficacy and safety of ALKS 5461 when administered once daily for four weeks in 142 patients with MDD who had an inadequate response to standard antidepressant therapies was completed in April 2013. Preliminary topline results from the study showed that ALKS 5461 significantly reduced depressive symptoms across a range of standard measures including the study's primary outcome measure, the Hamilton Depression Rating Scale (HAM-D17), the Montgomery—Åsberg Depression Rating Scale (MADRS) and the Clinical Global Impression—Severity Scale (CGI-S). ALKS 5461 was generally well tolerated. Based on these results, as well as the positive phase 1/2 results previously reported, Alkermes plans to request a meeting with the FDA and to advance ALKS 5461 into a pivotal development program. Data from this phase 2 study will be presented at a scientific meeting in May 2013.

## **ZOHYDRO ER™**

ZOHYDRO ER (hydrocodone bitartrate extended-release capsules) is a novel, oral, single-entity (without acetaminophen), controlled-release formulation of hydrocodone in development by Zogenix, Inc. ("Zogenix") for the U.S. market. ZOHYDRO ER utilizes our oral controlled-release technology, which potentially enables longer-lasting and more consistent pain relief with fewer daily doses than the commercially available formulations of hydrocodone. In December 2012, the FDA Anesthetic and Analgesic Drug Products Advisory Committee ("AADPAC") voted 2-11 (with 1 abstention) against the approval of ZOHYDRO ER. In February 2013, in advance of the March 1, 2013 FDA PDUFA date, Zogenix announced that it was informed by the FDA that it was unlikely to receive an action letter with respect to its ZOHYDRO ER NDA by March 1, 2013. In May 2013, Zogenix reported that it had been notified by the FDA and told that the FDA was preparing to take action on the ZOHYDRO ER NDA in the summer of 2013. In addition, Zogenix announced that it had not been provided a reason for the delay and had not been informed of any deficiencies in the NDA for ZOHYDRO ER during the review process. We have also entered into a license and distribution agreement with Paladin Labs Inc. in respect of ZOHYDRO ER in Canada. We will earn manufacturing revenues and a royalty on U.S. and Canadian sales of ZOHYDRO ER, if approved and when commercialized. We have maintained all rights to the product in territories outside the U.S. and Canada and expect to seek to develop and license the product through commercial partnerships in those territories.

## **ALKS 3831**

ALKS 3831 is a proprietary investigational medicine designed as a broad spectrum treatment for schizophrenia. ALKS 3831 is comprised of ALKS 33, a novel opioid modulator that acts as a potent mu-opioid antagonist, in combination with the established antipsychotic drug olanzapine. ALKS 3831 is designed to attenuate olanzapine-induced metabolic side effects, including weight gain, and offer the therapeutic benefits of olanzapine to a wider range of patients with schizophrenia. ALKS 3831 will also be studied to evaluate its utility in patients with schizophrenia and comorbid substance abuse. In January 2013, we announced positive topline results from a phase 1 study of ALKS 3831. The multicenter, randomized, double-blind, placebo- and active-controlled study was designed to compare the mean change from baseline in body weight in 106 healthy volunteers following three weeks of once-daily, oral administration of ALKS 3831, compared to olanzapine alone or placebo. Data from the study showed that healthy volunteers administered ALKS 3831 demonstrated significantly less weight gain compared to healthy volunteers taking olanzapine. Weight gain is a common and clinically relevant side effect of atypical antipsychotic medications, and olanzapine has one of the highest incidences and greatest amounts of weight gain among the widely prescribed products in this class of drugs. Based on the positive results of the phase 1 study, we plan to initiate a phase 2 study of ALKS 3831 in mid calendar-year 2013 and meet with the FDA.

## **Other**

A three-month formulation of INVEGA SUSTENNA is in development by Janssen Research & Development, LLC. Two phase 3 studies are expected to enroll approximately 1,800 patients with schizophrenia and will assess the efficacy, safety and tolerability of the three-month injectable formulation. These clinical studies are expected to be completed in the second half of calendar 2014. The investigational product is being developed by Janssen Pharmaceutica, NV, licensee of our proprietary technology for nanoparticles.

Line extensions for BYDUREON are in development by Bristol-Myers. These line extensions include a dual-chamber pen device and weekly and monthly suspension formulations using our proprietary technology for extended-release microspheres. Bristol-Myers is expected to submit data for the dual-chamber pen device for FDA review in the third quarter of calendar-year 2013.

In April 2013, Acorda reported positive results from an 83-subject proof-of-concept study of dalfampridine-ER 10 mg in the treatment of post-stroke deficits, as demonstrated by improvement in walking measured by the Timed 25-Foot Walk. Acorda plans to proceed with a clinical development program for this indication. A separate proof-of-concept trial including 24 participants explored the use of dalfampridine-ER 10 mg dosed twice daily in adults with cerebral palsy ("CP"). Efficacy data from the study in adults with CP suggested potential treatment activity on measures of walking and hand strength; however, these data are being analyzed by Acorda to determine if they are sufficiently robust to warrant further clinical studies. Acorda plans to present data from the post-stroke deficits and CP trials in appropriate medical forums following additional analysis of the data.

### ***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 our prior three fiscal years.

### **Collaborative Arrangements**

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

#### ***Janssen***

##### **RISPERDAL CONSTA**

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

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

The manufacturing and supply agreement terminates on expiration of the license agreements. In addition, either party may terminate the manufacturing and supply agreement upon a material breach by the other party, which is not resolved within 60 days after receipt of a written notice specifying the material breach or upon written notice in the event of the other party's insolvency or bankruptcy. Janssen may terminate the agreement upon six months' written notice to us. In the event that Janssen

terminates the manufacturing and supply agreement without terminating the license agreements, the royalty rate payable to us on Janssen's net sales of RISPEDAL 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 lack of patent coverage or patent litigation, or where competing products achieve 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 United States (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 and receipt of positive data from all preclinical and clinical studies required for filing a marketing authorization application. If we terminate Acorda's license in any country, we are entitled to a license from Acorda of its patent rights and know-how

relating to the product as well as the related data, information and regulatory files, and to market the product in the applicable country, subject to an initial payment equal to Acorda's cost of developing such data, information and regulatory files and to ongoing royalty payments to Acorda. Subject to the termination of the license agreement, licenses granted under the license agreement terminate on a country-by-country basis on the later of (i) September 2018 or (ii) the expiration of the last to expire of our patents or the existence of a threshold level of competition in the marketplace.

Under our commercial manufacturing supply agreement with Acorda, we manufacture and supply AMPYRA/FAMPYRA for Acorda (and its sub-licensees). Under the terms of the agreement, Acorda may obtain up to 25% of its total annual requirements of product from a second-source manufacturer. We receive 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 of the other party. In addition, subject to early termination of the supply agreement noted above, the supply agreement terminates upon the expiry or termination of the license agreement.

In January 2011, we entered into a development and supplemental agreement to our amended and restated license agreement with Acorda. Under the terms of this agreement, we granted Acorda the right, either with us or with a third party, in each case in accordance with certain terms and conditions, to develop new formulations of dalfampridine or other aminopyridines. Under the terms of the agreement, Acorda has the right to select either a formulation developed by us or by a third party for commercialization. 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.

### ***Bristol-Myers***

In May 2000, we entered into a development and license agreement with Amylin, now a wholly-owned subsidiary of Bristol-Myers, for the development of exendin products falling within the scope of our patents, which include the once-weekly formulation of exenatide, BYDUREON. Pursuant to the development and license agreement, Bristol-Myers 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 Bristol-Myers.

Under our agreement, Bristol-Myers is responsible for commercializing exenatide products, including BYDUREON, in the U.S. and for U.S. regulatory matters relating to exenatide products, including conducting clinical trials and securing regulatory approvals. In April 2013, Bristol-Myers and AstraZeneca announced that the companies had completed their assumption of all rights related to BYETTA and BYDUREON from Eli Lilly & Company ("Lilly"), Amylin's former worldwide collaboration partner with respect to exenatide products. Through their diabetes collaboration, Bristol-Myers and AstraZeneca co-develop and market Amylin's portfolio of products, including BYDUREON.

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. BYDUREON was launched in the U.S. in February 2012.

The development and license agreement terminates on the later of (i) 10 years from the first commercial sale of the last of the products covered by the development and license agreement, or (ii) the expiration or invalidation of all of our patents covering such product. Upon termination, all licenses become non-exclusive and royalty-free. Bristol-Myers 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.

### **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.

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

## **Proprietary Product Platforms**

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

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

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

### ***LinkeRx Technology***

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

### ***NanoCrystal Technology***

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

### ***Oral Controlled Release Technology***

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

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

- **SODAS Technology:** SODAS (Spheroidal Oral Drug Absorption System) technology involves producing uniform spherical beads of 1 mm to 2 mm in diameter containing drug plus excipients and coated with product-specific modified-release polymers. Varying the nature and combination of polymers within a selectively permeable membrane enables varying degrees of modified release depending upon the required product profile.
- **CODAS Technology:** CODAS (Chronotherapeutic Oral Drug Absorption System) enables the delayed onset of drug release incorporating the use of specific polymers, resulting in a drug release profile that more accurately complements circadian patterns.

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

## **Manufacturing and Product Supply**

We own and occupy manufacturing, office and laboratory facilities in: Wilmington, Ohio; Athlone, Ireland; and Gainesville, Georgia. We either purchase active drug product from third parties or receive it from our third-party collaborators to formulate product using our technologies. The manufacture of our products for clinical trials and commercial use is subject to cGMP and other regulatory agency regulations. Our manufacturing and development capabilities include formulation through process development, scale-up and full-scale commercial manufacturing and specialized capabilities for the development and manufacturing of controlled substances.

Although some materials for our drug products are currently available from a single source or a limited number of qualified sources, we attempt to acquire an adequate inventory of such materials, establish alternative sources and/or negotiate long-term supply arrangements. We believe we do not have any significant issues 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 are subject to risks related to the manufacture of our products," "—We rely on third parties to provide services in connection with the manufacture and distribution of our products," "—If we or our third-party providers fail to meet the stringent requirements of governmental regulation in the manufacture of our products, we could incur substantial remedial costs and a reduction in sales and/or revenues" and "—We rely heavily on collaborative partners in the commercialization and continued development of our products."

### ***Commercial Products***

We manufacture RISPERDAL CONSTA, VIVITROL and polymer for BYDUREON in our Wilmington, Ohio facility. We are currently operating two RISPERDAL CONSTA lines and one VIVITROL line at commercial scale. Janssen has granted us an option, exercisable upon 30 days' advance written notice, to purchase the most recently constructed and validated RISPERDAL CONSTA manufacturing line at its then-current net book value. We source our packaging operations for VIVITROL to a third-party contractor. Janssen is responsible for packaging operations for RISPERDAL CONSTA. The facility has been inspected by U.S., European (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. During fiscal year 2013, this facility was inspected by U.S., Irish, Brazilian 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 our prior three fiscal years.

### **Permits and Regulatory Approvals**

We hold various licenses in respect of our manufacturing activities conducted in Wilmington, Ohio; Athlone, Ireland; and Gainesville, Georgia. The primary licenses held in this regard are FDA Registrations of Drug Establishment and Drug Enforcement Administration ("DEA"), Controlled Substance Registration 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 would hold the relevant authorization from the FDA or other national regulator, and we would support this authorization by furnishing a copy of the Drug Master File ("DMF"), or the chemistry, manufacturing and controls data to the relevant regulator to prove adequate manufacturing data in respect of the product. We would generally update this information annually with the relevant regulator. In other cases where we are developing proprietary product candidates, such as VIVITROL, we may hold the appropriate regulatory documentation ourselves.

## **Marketing, Sales and Distribution**

We 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 fiscal year ended March 31, 2013, to McKesson Corporation, CVS Caremark Corporation, AmerisourceBergen Drug Corporation, and Cardinal Health ("Cardinal"), represented approximately 17%, 12%, 11% and 11%, respectively, of total VIVITROL sales.

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

Under our collaboration agreements with Janssen, Bristol-Myers, 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™; and other products currently in development. RISPERDAL CONSTA and INVEGA SUSTENNA may also compete with new oral compounds currently on the market or being developed for the treatment of schizophrenia.

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

In the treatment of opioid dependence, VIVITROL competes with methadone, oral naltrexone, and SUBOXONE® (buprenorphine HCl/naloxone HCl dehydrate sublingual tablets), SUBOXONE® (buprenorphine/naloxone) Sublingual Film, and SUBUTEX® (buprenorphine HCl sublingual tablets), each of which is marketed and sold by Reckitt Benckiser Pharmaceuticals, Inc. in the U.S. It also competes with 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, could compete with BYDUREON.

AMPYRA/FAMPYRA is, to our knowledge, the first product that is approved as a treatment to improve walking in patients with MS. However, there are a number of FDA-approved therapies for MS disease management that seek to reduce the frequency and severity of exacerbations or slow the accumulation of physical disability for people with certain types of MS. These products include AVONEX® from Biogen Idec, BETASERON® from Bayer HealthCare Pharmaceuticals, COPAXONE® from Teva Pharmaceutical Industries Ltd., REBIF® from Merck Serono, TYSABRI® and TECFIDERA™ from Biogen Idec, 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 product candidates and those of our collaborators, to maintain trade secret protection and to operate without infringing upon the proprietary rights of others. We have a proprietary portfolio of

patent rights and exclusive licenses to patents and patent applications. We have filed numerous patent applications in the U.S. and in other countries directed to compositions of matter as well as processes of preparation and methods of use, including applications relating to each of our delivery technologies. We own more than 200 issued U.S. patents. In the future, we plan to file additional patent applications in the U.S. and in other countries directed to new or improved products and processes. We intend to file additional patent applications when appropriate and defend our patent position aggressively.

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

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

We have filed 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 in the U.S. 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 in the U.S.

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

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

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

We try to protect our proprietary position by filing patent applications in the U.S. and in other countries related to our proprietary technology, inventions and improvements that are important to the

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

We are involved as a plaintiff in various Paragraph IV litigations in the U.S. and a similar suit in France in respect of three different products: TRICOR 145; FOCALIN XR; and MEGACE ES.

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

Our trademarks, including VIVITROL, are important to us and are generally covered by trademark applications or registrations in the U.S. Patent and Trademark Office and the patent or trademark offices of other countries. Our partnered products also use trademarks that are owned by our partners, such as the marks RISPERDAL CONSTA and INVEGA SUSTENNA, which are 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 fiscal years 2013, 2012 and 2011, our revenue and assets are presented below by geographical area.

(In thousands)	Year Ended March 31,		
	2013	2012	2011
<b>Revenue by region:</b>			
U.S.	\$ 380,565	\$ 212,859	\$ 76,700
Ireland	14,455	12,695	805
Rest of world	180,528	164,423	109,135
<b>Assets by region:</b>			
Current assets:			
U.S.	\$ 248,441	\$ 209,683	\$ 252,960
Ireland	159,544	122,077	—
Rest of world	603	7,393	—
Long-term assets:			
U.S.	\$ 233,369	\$ 217,406	\$ 199,488
Ireland	828,334	878,658	—
Rest of world	—	—	—

**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 efficacy, determine an appropriate dose and regimen, and define the conditions for safe use. This is a high-risk process that requires stepwise clinical studies in which the candidate product must successfully meet predetermined endpoints. In the U.S., the results of the preclinical and clinical testing of a product are then submitted to the FDA in the form of a Biologics License Application ("BLA"), or an NDA. In response to a BLA or NDA, the FDA may grant marketing approval, request additional information or deny the application if it determines the application does not provide an adequate basis for approval. The 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. The FDA may require larger or additional studies or request other scientific or technical information about the product, and these additional requirements may lead to unanticipated delay or expense. Even if a product is approved, the approval may be subject to limitations (discussed below) based on the FDA's interpretation of the data.

The FDA has developed four distinct approaches intended to make therapeutically important drugs available as rapidly as possible, especially when the drugs are the first available treatment or have advantages over existing treatments: accelerated approval; fast track; breakthrough therapy; and priority review.

In the U.S., the FDA may grant "accelerated approval" status to products that treat serious or life-threatening illnesses and that provide meaningful therapeutic benefits to patients over existing

treatments. Under this pathway, the FDA may approve a product based on surrogate endpoints, or clinical endpoints other than survival or irreversible morbidity. When approval is based on surrogate endpoints or clinical endpoints other than survival or morbidity, the sponsor will be required to conduct additional post-approval clinical studies to verify and describe clinical benefit. Under the accelerated approval regulations, if the FDA concludes that a drug that has been shown to be effective can be safely used only if distribution or use is restricted, it may require certain post-marketing restrictions as necessary to assure safe use. In addition, for all products approved under accelerated approval, sponsors may be required to submit all copies of their promotional materials, including advertisements, to the FDA at least 30 days prior to initial dissemination. The FDA may withdraw approval under accelerated approval after a hearing if, for instance, post-marketing studies fail to verify any clinical benefit or it becomes clear that restrictions on the distribution of the product are inadequate to ensure its safe use.

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

The FDA may also grant "breakthrough therapy" status to drugs designed to treat, alone or in combination with another drug or drugs, a serious or life-threatening disease or condition and for which preliminary evidence suggests a substantial improvement over existing therapies. Such drugs need not address an unmet need, but are nevertheless eligible for expedited review if they offer the potential for an improvement. Breakthrough therapy status entitles the sponsor to earlier and more frequent meetings with the FDA regarding the development of nonclinical and clinical data and permits the FDA to offer product development or regulatory advice for the purpose of shortening the time to product approval. Breakthrough therapy status does not guarantee that a product will be developed or reviewed more quickly and does not ensure FDA approval.

Finally, the FDA may grant "priority review" status to products that offer major advances in treatment or provide a treatment where no adequate therapy exists. Priority review is intended to reduce the time it takes for the FDA to review a NDA or BLA, with the goal for completing a priority review being six months (compared to ten months under standard review).

Regardless of the approval pathway employed, the FDA may require a sponsor to conduct additional post-marketing studies as a condition of approval to provide data on safety and effectiveness. If a sponsor fails to conduct the required studies, the agency may withdraw its approval. In addition, regardless of the approval pathway, if the FDA concludes that a drug that has been shown to be effective can be safely used only if distribution or use is restricted, it can mandate post-marketing restrictions as necessary to assure safe use. In such a case, the sponsor may be required to establish rigorous systems to assure use of the product under safe conditions. These systems are usually referred to as Risk Evaluation and Mitigation Strategies ("REMS"). The FDA can impose financial penalties for failing to comply with certain post-marketing commitments, including REMS. In addition, any changes to an approved REMS must be reviewed and approved by the FDA prior to implementation. 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 reported 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.

#### *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 European Medicines Agency ("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 payors (including Medicare and Medicaid) claims for reimbursed drugs or services that are false or fraudulent, claims for items or services not provided as claimed, or claims for medically unnecessary items or services. 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 payors, and a reduction in payment rate or reimbursement or an increase in our financial obligation to governmental payors could result in decreased sales of our products and revenue" and "—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 health care 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 health care reform legislation. 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 physicians and certain other healthcare practitioners or to teaching hospitals. State laws may 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***

In the U.S. and internationally, sales of our products, including those sold by our collaborators, and our ability to generate revenues on such sales are dependent, in significant part, on the availability and level of reimbursement from third-party payors such as state and federal governments, including Medicare and Medicaid, managed care providers and private insurance plans. Private insurers may also seek to manage cost and utilization by implementing coverage and reimbursement limitations. These include establishing formularies that govern the products that will be offered and the out-of-pocket obligations for such products.

The U.S. government and governments outside the U.S. regularly consider reforming healthcare coverage and costs. Such reform may include changes to the coverage and reimbursement of our products, which may have a significant impact on our business. 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 the upward adjustment equal to the excess amount. The rebate amount is required to be recomputed each quarter based on our report of current AMP and best price for each of our products to the Centers for Medicare and Medicaid Services ("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. The current payment rate for Medicare Part B drugs is ASP plus 6% outside the hospital outpatient setting and ASP plus 4% for most drugs in the hospital outpatient setting. 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.

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

Within the EU, products are paid for by a variety of payors, 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 we regularly interact with may meet the FCPA's definition of a foreign government official. The FCPA also requires public companies to make and keep books and records that accurately and fairly reflect their transactions and to devise and maintain an adequate system of internal accounting controls.

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 May 8, 2013, we had approximately 1,230 full-time employees. A significant number of our management and professional employees have prior experience with pharmaceutical, biotechnology or medical product companies. We believe that we have been successful in attracting skilled and experienced scientific and senior management personnel; however, competition for such personnel is intense. None of our employees is covered by a collective bargaining agreement. We consider our relations with our employees to be good.

## **Available Information**

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

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



**Item 1A. Risk Factors**

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

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

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

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

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

Pursuant to our arrangements with Bristol-Myers and Janssen, we are not responsible for the clinical development, manufacture or commercialization efforts for BYDUREON or INVEGA SUSTENNA/XEPLION, respectively.

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

*VIVITROL*

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

*REMAINING COMMERCIAL PORTFOLIO*

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

***We 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 a collaborative partner's performance, or factors that may affect a partner's sales, may materially adversely affect our business, financial condition, cash flows and results of operations.

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

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

- perception of physicians and other members of the healthcare community as to our products' safety and efficacy relative to that of competing products;
- the cost-effectiveness of our products;
- patient and physician satisfaction with our products;
- the successful manufacture of our commercial products on a timely basis;
- the cost and availability of raw materials necessary for the manufacture of our products;
- the size of the markets for our products;
- reimbursement policies of government and third-party payors;
- unfavorable publicity concerning our products, similar classes of drugs or the industry generally;
- the introduction, availability and acceptance of competing treatments, including treatments marketed and sold by our collaborators;
- the reaction of companies that market competitive products;
- adverse event information relating to our products or to similar classes of drugs;
- changes to the product labels of our products, or of products within the same drug classes, to add significant warnings or restrictions on use;
- our continued ability to access third parties to vial, label and distribute our products on acceptable terms;
- the unfavorable outcome of patent litigation, including so-called "Paragraph IV" litigation, related to any of our products;
- regulatory developments related to the manufacture or continued use of our products, including the issuance of a REMS by the FDA;

- the extent and effectiveness of the sales and marketing and distribution support our products receive;
- our collaborators' decisions as to the timing of product launches, pricing and discounting;
- disputes with our collaborators relating to the marketing and sale of partnered products;
- exchange rate valuations and fluctuations; and
- any other material adverse developments with respect to the commercialization of our products.

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

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

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

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

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

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

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

We rely on third parties for the timely supply of specified raw materials, equipment, contract manufacturing, formulation or packaging services, product distribution services, customer service activities and product returns processing. Although we actively manage these third-party relationships to

ensure continuity and quality, some events beyond our control could result in the complete or partial failure of these goods and services. Any such failure could materially adversely affect our business, financial condition, cash flows and results of operations.

The manufacture of products and product components, including the procurement of bulk drug product, packaging, storage and distribution of our products, 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 new vendors and to develop contingency plans so that production is not impacted by issues associated with single-source providers. Nonetheless, our business could be materially and adversely affected by issues associated with single-source providers.

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

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

We and our third-party providers are generally required to comply with cGMP and are subject to inspections by the FDA or comparable agencies in other jurisdictions to confirm such compliance. Any changes of suppliers or modifications of methods of manufacturing require amending our application to the FDA 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 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 regulations. Any third party we use to manufacture bulk drug product, or package, store or distribute our products to be sold in the U.S., must be licensed by the FDA. Failure to gain or maintain regulatory compliance with the FDA or regulatory agencies outside the U.S. could materially adversely affect our business, financial condition, cash flows and results of operations.

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

In both U.S. and non-U.S. markets, sales of our products depend, in part, on the availability of reimbursement from third-party payors such as state and federal governments, including Medicare and Medicaid in the U.S. and similar programs in other countries, managed care providers and private insurance plans. Deterioration in the timeliness, certainty and amount of reimbursement for our products, including the existence of barriers to coverage of our products (such as prior authorization, criteria for use or other requirements), limitations by healthcare providers on how much, or under what circumstances, they will prescribe or administer our products or unwillingness by patients to pay any required co-payments could reduce the use of, and revenues generated from, our products and could have a material adverse effect on our business, financial condition, cash flows and results of operations. In addition, when a new medical 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 payors continue to focus on containing the cost of health care. 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 payors 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 U.S. patents issued in the U.S. to third parties that may relate to our product candidates. We also know of patent applications filed by other parties in the U.S. and various countries outside the U.S. that may relate to some of our product candidates if such patents are issued in their present form. If patents are issued that cover our product candidates, we may not be able to manufacture, use, offer for sale, import or sell such product candidates without first getting a license from the patent holder. The patent holder may not grant us a license on reasonable terms or it may refuse to grant us a license at all. This could delay or prevent us from developing, manufacturing or selling those of our product candidates that would require the license. A patent holder might also file an infringement action against us claiming that the manufacture, use, offer for sale, import or sale of our product candidates infringed one or more of its patents. Even if we believe that such claims are without merit, our cost of defending such an action is likely to be high and we might not receive a favorable ruling, and the action could be time-consuming and distract management's attention and resources. Claims of intellectual property infringement also might require us to redesign affected products, enter into costly settlement or license agreements or pay costly damage awards, or face a temporary or permanent injunction prohibiting us from marketing or selling certain of our products. Even if we have an agreement to indemnify us against such costs, the indemnifying party may be unable to uphold its contractual obligations. If we cannot or do not license the infringed technology at all, license the technology on reasonable terms or substitute similar technology from another source, our revenue and earnings could be adversely impacted.

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

of the U.S. Thus, any patents that we own or license from others may not provide any protection against competitors. Furthermore, others may independently develop similar technologies outside the scope of our patent coverage.

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

***Uncertainty over intellectual property in the 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 involved in a number of Paragraph IV litigations in the U.S. and a similar suit in France in respect of some of our products. These litigations could result in new or additional generic competition to our marketed products and a potential reduction in product revenue.

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

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

On September 25, 2012, we entered into an amendment to our \$310.0 million First Lien Credit Agreement pursuant to which the First Lien Credit Agreement was amended and restated to, among other things, provide for a new tranche of term loans in an amount equal to \$375.0 million, the proceeds of which, together with cash-on hand of approximately \$75.0 million, were used to repay in full all monies due pursuant to our \$140.0 million Second Lien Credit Agreement. The new term loans consisted of a \$300.0 million, seven-year term loan at LIBOR plus 3.50% ("Term Loan B-1"), and a \$75.0 million, four-year term loan at LIBOR plus 3.00% ("Term Loan B-2" and together with Term Loan B-1, the "2013 Term Loans"), with, for each term loan, a LIBOR floor of 1.00%.

On February 14, 2013, we further amended our amended and restated credit agreement to secure: (i) a reduction in interest payable under Term Loan B-1 to LIBOR plus 2.75% and a decrease in the LIBOR floor to 0.75%; (ii) a reduction in interest payable under Term Loan B-2 to LIBOR plus 2.75% and a decrease in the LIBOR floor to 0%; and (iii) a shortened time period, from one year to six months, during which a refinancing of our term loans, as described in the amended and restated credit agreement, would trigger a 1% prepayment premium.

Our existing indebtedness is guaranteed by certain of our subsidiaries. Our level of indebtedness and the terms of these financing arrangements could adversely affect our business by, among other things:

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

Our term loan 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, results of operations, cash flows and financial condition.



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

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

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

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

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 preclinical 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 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, results of operations, cash flows and financial condition.

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

We must obtain government approvals before marketing or selling our drug candidates in the U.S. and in jurisdictions outside the U.S. The FDA and comparable regulatory agencies in other countries impose substantial and rigorous requirements for the development, production and commercial introduction of drug products. These include preclinical, laboratory and clinical testing procedures, sampling activities, clinical trials and other costly and time-consuming procedures. In addition, regulation is not static, and regulatory agencies, including the FDA, evolve in their staff, interpretations

and practices and may impose more stringent requirements than currently in effect, which may adversely affect our planned drug development and/or our commercialization efforts. Satisfaction of the requirements of the FDA and of other regulatory agencies typically takes a significant number of years and can vary substantially based upon the type, complexity and novelty of the drug candidate. The approval procedure and the time required to obtain approval also varies among countries. Regulatory agencies may have varying interpretations of the same data, and approval by one regulatory agency does not ensure approval by regulatory agencies in other jurisdictions. In addition, the FDA or regulatory agencies outside the U.S. may choose not to communicate with or update us during clinical testing and regulatory review periods. The ultimate decision by the FDA or other regulatory agencies regarding drug approval may not be consistent with prior communications. See "—Our revenues may be lower than expected as a result of failure by the marketplace to accept our products or for other factors."

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

- a product candidate may not demonstrate safety and efficacy for each target indication in accordance with FDA standards or standards of other regulatory agencies;
- poor rate of patient enrollment, including limited availability of patients who meet the criteria for certain clinical trials;
- data from preclinical testing and clinical trials may be interpreted by the FDA or other regulatory agencies in different ways than we or our partners interpret it;
- the FDA or other regulatory agencies might not approve our or our partners' manufacturing processes or facilities;
- the FDA or other regulatory agencies may not approve accelerated development timelines for our product candidates;
- the failure of third-party clinical research organizations and other third-party service providers and independent clinical investigators to manage and conduct the trials, to perform their oversight of the trials or to meet expected deadlines;
- the failure of our clinical investigational sites and the records kept at such sites, including the clinical trial data, to be in compliance with the FDA's 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 drug candidates that we submit for regulatory review. Our ability to generate revenues from the commercialization and sale of additional drug products will be limited by any failure to obtain these approvals. In addition, stock prices have declined significantly in certain instances where companies have failed to obtain FDA approval of a drug candidate or if the timing of FDA approval is delayed. If the FDA's or any other

regulatory agency's response to any application for approval is delayed or not favorable for any of our product candidates, our stock price could decline significantly.

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

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

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

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

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

In addition, we 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 underway in many countries around the world, including in Eastern Europe and Asia. We depend on independent clinical investigators, contract research organizations and other third-party service providers and our collaborators in the conduct of clinical trials for our product candidates 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 preclinical testing and early clinical trials often have not predicted results of later clinical trials. A number of new drugs have shown promising results in early clinical trials, but subsequently failed to establish sufficient safety and efficacy data to obtain necessary regulatory approvals. Clinical trials conducted by us, by our collaborative partners or by third parties on our

behalf may not demonstrate sufficient safety and efficacy to obtain the requisite regulatory approvals for our product candidates.

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

***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, results of operations, cash flows and financial condition. In addition, the reporting of adverse safety events involving our products and public rumors about such events could cause our 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 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 regulatory agencies outside of the U.S., including new or different approval requirements, timelines and processes, may also delay or prevent the approval of new products, require additional safety monitoring, labeling changes, restrictions on product distribution or other measures that could increase our costs of doing business and adversely affect the market for our products. The enactment in the U.S. of healthcare reform, new legislation or implementation of existing statutory provisions on importation of lower-cost competing drugs from other jurisdictions and legislation on comparative effectiveness research are examples of previously enacted and possible future changes in laws that could adversely affect our business.

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

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

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

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

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

With respect to our proprietary injectable product platform, we are aware that there are other companies developing extended-release delivery systems for pharmaceutical products. RISPERDAL CONSTA and INVEGA SUSTENNA may compete with a number of other injectable products including ZYPREXA RELPREVV (olanzapine) For Extended Release Injectable Suspension, which is marketed and sold by Lilly; 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; and other products currently in development. RISPERDAL CONSTA and INVEGA SUSTENNA may also compete with new oral compounds currently on the market or being developed for the treatment of schizophrenia.

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

In the treatment of opioid dependence, VIVITROL competes with methadone, oral naltrexone, and SUBOXONE (buprenorphine HCl/naloxone HCl dehydrate sublingual tablets), SUBOXONE (buprenorphine/naloxone) Sublingual Film, and SUBUTEX (buprenorphine HCl sublingual tablets), each of which is marketed and sold by Reckitt Benckiser Pharmaceuticals, Inc. in the U.S. It also competes with 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® from Biogen Idec, BETASERON® from Bayer HealthCare Pharmaceuticals, COPAXONE® from Teva Pharmaceutical Industries Ltd., REBIF® from Merck Serono, TYSABRI® and TECFIDERA™ from Biogen Idec, 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 March 31, 2013, our accumulated deficit was \$499.9 million, which was primarily the result of net losses incurred from 1987, the year Alkermes, Inc., was founded, through March 31, 2013, partially offset by net income over previous fiscal years. There can be no assurance we will achieve sustained profitability.

A major component of our revenue is dependent on our partners' and our ability to commercialize, and our 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 payors;
- obtain additional research and development funding from collaborative partners or funding for our proprietary product candidates; and
- achieve certain product development milestones.

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

- the progress of our research and development programs for our product candidates and for our partnered product candidates, including clinical trials;
- the time and expense that will be required to pursue FDA and/or non-U.S. regulatory approvals for our products and whether such approvals are obtained;
- the time and expense required to prosecute, enforce and/or challenge patent and other intellectual property rights;
- the cost of building, operating and maintaining manufacturing and research facilities;
- the cost of third-party manufacture;
- the number of product candidates we pursue, particularly proprietary product candidates;
- how competing technological and market developments affect our product candidates;
- the cost of possible acquisitions of technologies, compounds, product rights or companies;
- the cost of obtaining licenses to use technology owned by others for proprietary products and otherwise;
- the costs of potential litigation; and
- the costs associated with recruiting and compensating a highly skilled workforce in an environment where competition for such employees may be intense.

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

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

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

***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, results of operations, cash flows and financial condition or reputation.

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

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



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

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

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

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

As a result of the Business Combination, we incur substantial operating costs in Ireland. We face exposure to changes in the exchange ratio of the USD and the Euro arising from expenses and payables at our Irish operations that are settled in Euro. The impact of changes in the exchange ratio of the USD and the Euro on our USD-denominated manufacturing and royalty revenues earned in countries other than the U.S. is partially offset by the opposite impact of changes in the exchange ratio of the USD and the Euro on operating expenses and payables incurred at our Irish operations that are settled in Euro. For the fiscal year ended March 31, 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 \$7.5 million.

***We may not be able to retain our key personnel.***

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

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

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

- mergers;

- acquisitions;
- strategic alliances;
- licensing agreements; and
- co-promotion agreements.

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

If we are unable to successfully integrate the companies, businesses or properties that we acquire, such events could materially adversely affect our business, results of operations, cash flows and financial condition. 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 Annual Report.***

The pro forma financial data contained in this Annual Report are presented for illustrative purposes only and may not be an indication of what our financial condition or results of operations would have been had the Business Combination been completed on the dates indicated. The pro forma financial data have been derived from the audited and unaudited historical financial statements of 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 March 31, 2013, a significant amount of our investments were invested in U.S. government treasury and agency securities. Our investment objectives are, first, to preserve liquidity and conserve capital and, second, to generate investment income. Should our investments cease paying or reduce the amount of interest paid to us, our interest income would suffer. In addition, general credit, liquidity, market and interest risks associated with our investment portfolio may have an adverse effect on our financial condition.

***Our effective tax rate may increase.***

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

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

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

Proxy contests have been waged against many companies in the biopharmaceutical industry over the last few years. If faced with a proxy contest, we may not be able to respond successfully to the

contest, which would be disruptive to our business. Even if we are successful, our business could be adversely affected by a proxy contest involving us because:

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

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

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

None.

**Item 2. *Properties***

We lease approximately 8,500 square feet of corporate office space in Dublin, Ireland, which houses our corporate headquarters. This lease expires in 2022 and includes a tenant option to terminate in 2017. We lease approximately 115,000 square feet of space in Waltham, Massachusetts, which houses corporate offices, administrative areas and laboratories. This lease expires in 2020 and 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).

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 fifteen 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, we are currently involved in various sets of Paragraph IV litigations in the U.S. and a similar suit in France in respect of certain of three different products: TRICOR 145, FOCALIN XR, 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, results of operations, cash flows and financial condition.

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

Not Applicable.

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

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

	Fiscal 2013		Fiscal 2012	
	High	Low	High	Low
1st Quarter	\$ 18.64	\$ 15.12	\$ 18.60	\$ 13.06
2nd Quarter	20.87	17.22	19.52	13.91
3rd Quarter	20.88	18.08	18.03	13.88
4th Quarter	23.81	19.28	19.50	16.14

There were 256 shareholders of record for our ordinary shares on May 8, 2013. In addition, the last reported sale price of our ordinary shares as reported on the NASDAQ Global Select Stock Market on May 8, 2013 was \$29.85.

**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 fiscal year ended March 31, 2013. As of March 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 April 30, 2013, 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 or Exchange Act, except to the extent that Alkermes specifically incorporates it by reference into such filing.

The following graph compares the yearly percentage change in the cumulative total shareholder return on our ordinary shares for the last five fiscal years, with the cumulative total return on the Nasdaq Stock Market (U.S. and Foreign) Index and the Nasdaq Biotechnology Index. It is important to note that information set forth in the graph below with respect to the time period prior to September 16, 2011 refers to the common stock performance of 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, 2008 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**

	2008	2009	2010	2011	2012	2013
Alkermes	100	102	109	109	156	199
NASDAQ Stock Market (U.S.) Index	100	68	107	126	141	151
NASDAQ Biotechnology Index	100	87	120	133	164	214

**Item 6. Selected Financial Data**

The selected historical financial data set forth below at March 31, 2013 and 2012 and for the years ended March 31, 2013, 2012 and 2011 are derived from our audited consolidated financial statements, which are included elsewhere in this Annual Report. The selected historical financial data set forth below at March 31, 2011, 2010 and 2009 and for the years ended March 31, 2010 and 2009 are derived from audited consolidated financial statements, which are not included in this Annual Report. The selected historical financial data for the period prior to September 16, 2011 is that of Alkermes, Inc., while the selected historical financial data for the period after September 16, 2011 is that of Alkermes plc.

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

	Year Ended March 31,				
	2013	2012(1)	2011	2010	2009
(In thousands, except per share data)					
<b>Consolidated Statements of Operations Data:</b>					
<b>REVENUES:</b>					
Manufacturing and royalty revenues	\$ 510,900	\$ 326,444	\$ 156,840	\$ 149,917	\$ 150,091
Product sales, net	58,107	41,184	28,920	20,245	4,467
Research and development revenue	6,541	22,349	880	3,117	42,087
Net collaborative profit(2)	—	—	—	5,002	130,194
<b>Total revenues</b>	<b>575,548</b>	<b>389,977</b>	<b>186,640</b>	<b>178,281</b>	<b>326,839</b>
<b>EXPENSES:</b>					
Cost of goods manufactured and sold	170,466	127,578	52,185	49,438	43,396
Research and development	140,013	141,893	97,239	95,363	89,478
Selling, general and administrative(3)	125,758	137,632	82,847	76,514	59,008
Amortization of acquired intangible assets	41,852	25,355	—	—	—
Restructuring(4)	12,300	—	—	—	—
Impairment of long-lived assets(5)	3,346	45,800	—	—	—
<b>Total expenses</b>	<b>493,735</b>	<b>478,258</b>	<b>232,271</b>	<b>221,315</b>	<b>191,882</b>
<b>OPERATING INCOME (LOSS)</b>	<b>81,813</b>	<b>(88,281)</b>	<b>(45,631)</b>	<b>(43,034)</b>	<b>134,957</b>
<b>OTHER EXPENSE, NET</b>	<b>(46,372)</b>	<b>(26,111)</b>	<b>(860)</b>	<b>(1,667)</b>	<b>(3,945)</b>
<b>INCOME (LOSS) BEFORE INCOME TAXES</b>	<b>35,441</b>	<b>(114,392)</b>	<b>(46,491)</b>	<b>(44,701)</b>	<b>131,012</b>
<b>PROVISION (BENEFIT) FOR INCOME TAXES</b>	<b>10,458</b>	<b>(714)</b>	<b>(951)</b>	<b>(5,075)</b>	<b>507</b>
<b>NET INCOME (LOSS)</b>	<b>\$ 24,983</b>	<b>\$ (113,678)</b>	<b>\$ (45,540)</b>	<b>\$ (39,626)</b>	<b>\$ 130,505</b>
<b>EARNINGS (LOSS) PER COMMON SHARE:</b>					
BASIC	\$ 0.19	\$ (0.99)	\$ (0.48)	\$ (0.42)	\$ 1.37
DILUTED	\$ 0.18	\$ (0.99)	\$ (0.48)	\$ (0.42)	\$ 1.36
<b>WEIGHTED AVERAGE NUMBER OF COMMON SHARES OUTSTANDING:</b>					
BASIC	131,713	114,702	95,610	94,839	95,161
DILUTED	137,100	114,702	95,610	94,839	96,252

	Year Ended March 31,				
	2013	2012(1)	2011	2010	2009
(In thousands, except per share data)					
<b>Consolidated Balance Sheet Data:</b>					
Cash, cash equivalents and investments	\$ 304,179	\$ 246,138	\$ 294,730	\$ 350,193	\$ 404,482
Total assets	1,470,291	1,435,217	452,448	515,600	566,486
Long-term debt(6)	369,008	444,460	—	—	75,888
Shareholders' equity	952,374	853,852	392,018	412,616	434,888

- (1) On September 16, 2011, the business 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 the Company, 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 \$120.7 million recognized as revenue upon the termination of the VIVITROL collaboration with Cephalon, Inc. during the year ended March 31, 2009.
- (3) Includes \$29.1 million and \$1.1 million of expenses in the years ended March 31, 2012 and 2011, respectively, related to the acquisition of EDT, which consists primarily of banking, legal and accounting expenses.
- (4) Represents a one-time charge in connection with the restructuring plan related to our Athlone, Ireland manufacturing facility recorded in the year ended March 31, 2013. The charge consists of severance payments and other employee-related expenses.
- (5) Includes an impairment charge of \$3.3 million related to the impairment of certain of our equipment located at our Wilmington, Ohio manufacturing facility in the year ended March 31, 2013, and an impairment charge of \$45.8 million related to the impairment of certain of our IPR&D in the year ended March 31, 2012.
- (6) At March 31, 2013, long-term debt includes both the current and long-term portion of the 2013 Term Loans. The 2013 Term Loans were entered into to refinance our \$310.0 million first lien term loan (the "First Lien Term Loan") and the \$140.0 million second lien term loan (the "Second Lien Term Loan" and, together with the First Lien Term Loan, the "2012 Term Loans"), which were originally entered into in September 2011. At March 31, 2012, long-term debt includes both the current and long-term portion of the 2012 Term Loans. At March 31, 2009, long-term debt included both the current and long-term portion of the Non-Recourse RISPERDAL CONSTA secured 7% Notes (the "non-recourse 7% Notes"). The non-recourse 7% Notes were issued by RC Royalty Sub LLC, a wholly-owned subsidiary of Alkermes, Inc. ("Royalty Sub") on February 1, 2005 and were non-recourse to Alkermes, Inc. These notes were fully redeemed on July 1, 2010 in advance of the previously scheduled maturity date of January 1, 2012. Royalty Sub was dissolved during the year ended March 31, 2012.

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

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

### 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 business 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, *The Company*, and Note 3, *Acquisitions*, in the accompanying Notes to Consolidated Financial Statements for the year ended March 31, 2013.

### Executive Summary

We and our pharmaceutical and biotechnology partners have more than 20 commercialized products sold worldwide, including in the U.S. We earn manufacturing and/or royalty revenues on net sales of products commercialized by our partners and earn revenue on net sales of VIVITROL, which is a proprietary product that we manufacture, market and sell in the U.S. Our five key products are expected to generate significant revenues for us in the near- and medium-term, as they possess long patent lives, are singular or competitively advantaged products in their class and are generally in the launch phases of their commercial lives. These five key products are: RISPERDAL CONSTA and INVEGA SUSTENNA/XEPLION; AMPYRA/FAMPYRA; BYDUREON; and VIVITROL.

For the year ended March 31, 2013, we reported \$575.5 million in revenues which represented an increase of 48% over the year ended March 31, 2012. Revenues from our five key products accounted for 59% of our total consolidated revenues for the year ended March 31, 2013. For the year ended March 31, 2013, total operating expenses increased by \$15.5 million, as compared to the year ended March 31, 2012, due primarily to the addition of a full twelve months of activity from the former EDT business.

In September 2012, we entered into an amendment (the "Refinancing") to the First Lien Term Loan pursuant to which the First Lien Term Loan was amended and restated to, among other things, provide for a new tranche of term loans in an amount equal to \$375.0 million, the proceeds of which, together with cash-on hand of approximately \$75.0 million, were used to repay in full all monies due pursuant to the Second Lien Term Loan. The new term loan facility includes the 2013 Term Loans and each of the 2013 Term Loans included a LIBOR floor of 1.0%.

In February 2013, we further amended the 2013 Term Loans (the "Repricing") to secure: (i) a reduction in interest payable under Term Loan B-1 to LIBOR plus 2.75% and a decrease in the

LIBOR floor to 0.75%; (ii) a reduction in interest payable under Term Loan B-2 to LIBOR plus 2.75% and a decrease in the LIBOR floor to 0%; and (c) a shortened time period, from one year to six months, during which a refinancing of our term loans, as described in the amended and restated credit agreement, would trigger a 1% prepayment premium. In connection with the Refinancing and Repricing, we incurred a charge of \$19.7 million, which was recorded within "Interest Expense," and we expect to save approximately \$91.4 million in contractual cash interest expense through the remaining life of the 2013 Term Loans.

## Results of Operations

### 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 earned on our collaborators' sales of products that incorporate our technologies. Royalties are generally recognized in the period the products are sold by our collaborators. The following table compares manufacturing and royalty revenues earned in the years ended March 31, 2013, 2012 and 2011:

(In millions)	Years Ended March 31,			Change Favorable/(Unfavorable)	
	2013	2012	2011	2013 - 2012	2012 - 2011
Manufacturing and royalty revenues:					
RISPERDAL CONSTA	\$ 133.6	\$ 168.3	\$ 154.3	\$ (34.7)	\$ 14.0
INVEGA SUSTENNA/XEPLION	63.5	18.0	—	45.5	18.0
AMPYRA/FAMPYRA	65.0	24.6	—	40.4	24.6
RITALIN LA & FOCALIN XR	40.3	23.1	—	17.2	23.1
TRICOR 145	37.5	27.8	—	9.7	27.8
VERELAN	23.8	14.2	—	9.6	14.2
BYDUREON	16.4	1.5	—	14.9	1.5
Other	130.8	48.9	2.5	81.9	46.4
Manufacturing and royalty revenues	<u>\$ 510.9</u>	<u>\$ 326.4</u>	<u>\$ 156.8</u>	<u>\$ 184.5</u>	<u>\$ 169.6</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%. 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 decrease in RISPERDAL CONSTA manufacturing and royalty revenues for the year ended March 31, 2013, as compared to the year ended March 31, 2012, was primarily due to a 24% decrease in the number of units shipped to Janssen and a 9% decrease in royalties. The decrease in royalties was due to a decrease in Janssen's end-market sales of RISPERDAL CONSTA from \$1,540.3 million during the year ended March 31, 2012 to \$1,399.1 million during the year ended March 31, 2013. The increase in RISPERDAL CONSTA manufacturing and royalty revenues for the year ended March 31, 2012, as compared to the year ended March 31, 2011, was primarily due to an 8% increase in the number of units shipped to Janssen and a 1% increase in royalties. The increase in royalties was due to an increase in Janssen's end-market sales of RISPERDAL CONSTA from \$1,525.6 million during the year ended March 31, 2011 to \$1,540.3 million during the year ended March 31, 2012.

The increase in royalty revenues from INVEGA SUSTENNA/XEPLION in the year ended March 31, 2013, as compared to the year ended March 31, 2012, was due to having a full twelve months of INVEGA SUSTENNA/XEPLION royalties in the year ended March 31, 2013 and an increase in end-market sales of the product. Janssen's end-market sales of INVEGA SUSTENNA/XEPLION in the years ended March 31, 2013 and 2012 were \$920.0 million and \$473.6 million, respectively. In the year ended March 31, 2012, we earned a royalty from Janssen for sales made during the period of September 16, 2011, the closing date of the Business Combination, through March 31, 2012.

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 2018 in the EU and 2019 in the U.S., and as such, we do not anticipate any generic versions in the near-term for either of these products.

The increase in royalty revenues from AMPYRA/FAMPYRA was due to having a full twelve months of AMPYRA/FAMPYRA royalties in the year ended March 31, 2013, an increase in demand for AMPYRA in the U.S. and an increase in the number of countries in which FAMPYRA is sold. Acorda's end-market sales of AMPYRA/FAMPYRA in the year ended March 31, 2013 and 2012 were \$329.4 million and \$249.7 million, respectively. In the year ended March 31, 2012, we earned a royalty from Acorda for sales made during the period of September 16, 2011, the closing date of the Business Combination, through March 31, 2012. We expect AMPYRA/FAMPYRA sales to continue to grow as Acorda continues to penetrate the U.S. market with AMPYRA and Biogen Idec continues to launch FAMPYRA in the rest of the world. AMPYRA is covered by a patent until 2027 in the U.S. and FAMPYRA is covered by a patent until 2025 in the EU, and as such, we do not anticipate any generic versions of these products in the near-term. A number of companies are working to develop products to treat multiple sclerosis that may compete with AMPYRA/FAMPYRA, which may negatively impact future sales of the products.

The increase in royalty revenues from RITALIN LA & FOCALIN XR, TRICOR 145, and VERELAN and the other manufacturing and royalty revenues were primarily due to the addition of the portfolio of commercialized products from the former EDT business. Included in other manufacturing and royalty revenues is \$50.0 million related to the exercise of an option to license certain of our intellectual property that is not used in our key clinical development programs or commercial products. A number of our mature products, including RITALIN LA and VERELAN currently face generic competition. In November 2012, a generic version of TRICOR 145 was introduced to the market, and as a result, we have seen a reduction in the sales of TRICOR 145. A generic version of certain doses of FOCALIN XR is expected to occur at any time. 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 years ended March 31, 2013, 2012 and 2011:

(In millions)	Year Ended March 31, 2013		Year Ended March 31, 2012		Year Ended March 31, 2011	
	Amount	% of Sales	Amount	% of Sales	Amount	% of Sales
Product sales, gross	\$ 78.5	100.0%	\$ 57.6	100.0%	\$ 39.3	100.0%
Adjustments to product sales, gross:						
Medicaid rebates	(5.9)	(7.5)%	(4.6)	(8.0)%	(3.1)	(8.0)%
Chargebacks	(5.4)	(6.9)%	(4.1)	(7.1)%	(2.4)	(6.1)%
Product returns(1)	0.2	0.3%	(1.3)	(2.3)%	(0.8)	(2.0)%
Co-pay assistance	(3.2)	(4.1)%	(1.6)	(2.8)%	(0.6)	(1.5)%
Other	(6.1)	(7.8)%	(4.8)	(8.3)%	(3.5)	(8.9)%
Total adjustments	(20.4)	(26.0)%	(16.4)	(28.5)%	(10.4)	(26.5)%
Product sales, net	\$ 58.1	74.0%	\$ 41.2	71.5%	\$ 28.9	73.5%

- (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 for the year ended March 31, 2013, as compared to the year ended March 31, 2012, was due to a 36% increase in the number of units sold. The increase in product sales, gross for the year ended March 31, 2012, as compared to the year ended March 31, 2011, was primarily due to a 34% increase in the number of units sold into the distribution channel and a 9% increase in price. The increases in Medicaid rebates and chargebacks during the year ended March 31, 2013, as compared to the year ended March 31, 2012, was primarily due to the increase in VIVITROL sales during the period. The increases in chargebacks during the year ended March 31, 2012, as compared to the year ended March 31, 2011, was primarily due to the increase in the price of VIVITROL and increased 340B/PHS pricing discounts.

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

#### Research and Development Revenue

(In millions)	Years Ended March 31,			Change Favorable/(Unfavorable)	
	2013	2012	2011	2013 - 2012	2012 - 2011
Research and development revenue	\$ 6.5	\$ 22.3	\$ 0.9	\$ (15.8)	\$ 21.4

Research and development ("R&D") revenue is generally earned for services performed and milestones achieved under arrangements with our collaborators. The decrease in R&D revenue for the year ended March 31, 2013, as compared to the year ended March 31, 2012, was primarily due to \$14.0 million in BYDUREON milestone payments we received during the year ended March 31, 2012. Under our agreement with Amylin, we received a \$7.0 million milestone payment related to the first commercial sale of BYDUREON in the EU in July 2011 and a \$7.0 million milestone payment related to the first commercial sale of BYDUREON in the U.S. in February 2012. During the year ended March 31, 2012, we also received a \$3.0 million milestone payment upon receipt of regulatory approval for VIVITROL in Russia for the opioid dependence indication.

## Costs and Expenses

### Cost of Goods Manufactured and Sold

(In millions)	Years Ended March 31,			Change	
	2013	2012	2011	Favorable/(Unfavorable) 2013 - 2012	2012 - 2011
Cost of goods manufactured and sold	\$ 170.5	\$ 127.6	\$ 52.2	\$ (42.9)	\$ (75.4)

The increase in cost of goods manufactured and sold in the year ended March 31, 2013, as compared to the year ended March 31, 2012, 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 is primarily due to having a full twelve months of cost of goods manufactured expense in the year ended March 31, 2013. The increase in VIVITROL cost of goods manufactured and sold is 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 is due to a 24% decrease in the amount of RISPERDAL CONSTA shipped to Janssen.

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

### 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 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. 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)	Years Ended March 31,			Change	
	2013	2012	2011	Favorable/(Unfavorable) 2013 - 2012	2012 - 2011
<b>External R&amp;D Expenses:</b>					
Key development programs:					
Aripiprazole lauroxil	\$ 40.2	\$ 21.8	\$ 6.5	\$ (18.4)	\$ (15.3)
ALKS 5461	8.3	—	—	(8.3)	—
ALKS 37	3.4	23.5	11.1	20.1	(12.4)
ALKS 3831	2.9	—	—	(2.9)	—
Other development programs	12.7	26.6	30.2	13.9	3.6
Total external expenses	67.5	71.9	47.8	4.4	(24.1)
<b>Internal R&amp;D expenses:</b>					
Employee-related	52.9	48.3	33.1	(4.6)	(15.2)
Occupancy	5.0	5.1	6.0	0.1	0.9
Depreciation	5.8	4.7	2.7	(1.1)	(2.0)
Other	8.8	11.9	7.6	3.1	(4.3)
Total internal R&D expenses	72.5	70.0	49.4	(2.5)	(20.6)
Research and development expenses	\$ 140.0	\$ 141.9	\$ 97.2	\$ 1.9	\$ (44.7)

These amounts are not necessarily predictive of future R&D expenditures. In an effort to allocate our spending most effectively, we continually evaluate the products under development, based on the performance of such products in preclinical 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 in the year ended March 31, 2013, as compared to the year ended March 31, 2012, 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 approximately 690 patients experiencing acute exacerbation of schizophrenia. The increase in R&D expenses related to the ALKS 5461 program in the year ended March 31, 2013, as compared to the year ended March 31, 2012, 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 approximately 130 patients with MDD. The results of this phase 2 study were announced in April 2013. The decrease in R&D expenses related to the ALKS 37 program in the year ended March 31, 2013, as compared to the year ended March 31, 2012, 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 R&D expenses related to the aripiprazole lauroxil program in the year ended March 31, 2012, as compared to the year ended March 31, 2011, was primarily due to increased work leading up to and the initiation of the phase 3 study in December 2011. The increase in R&D expenses related to the ALKS 37 program in the year ended March 31, 2012, as compared to the year ended March 31, 2011, was primarily due to increased work leading up to and the initiation of two phase 2b studies of ALKS 37, which began in July 2011 and October 2011.

The increase in total internal R&D expenses in the year ended March 31, 2013, as compared to the year ended March 31, 2012, and for the year ended March 31, 2012, as compared to the year ended March 31, 2011, are primarily due to the addition of the former EDT business in September 2011.

We expect an increase in R&D expenses in the year ended March 31, 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)	Years Ended March 31,			Change	
	2013	2012	2011	Favorable/(Unfavorable)	
				2013 - 2012	2012 - 2011
Selling, general and administrative	\$ 125.8	\$ 137.6	\$ 82.8	\$ 11.8	\$ (54.8)

The decrease in selling, general and administrative ("SG&A") expenses for the year ended March 31, 2013, as compared to the year ended March 31, 2012, was primarily due to a \$26.0 million decrease in professional service expense, partially offset by an \$11.4 million increase in employee-related expenses. The decrease in professional service expense was primarily due to \$29.1 million of costs incurred in connection with the Business Combination during the year ended March 31, 2012. The increase in employee-related expense 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 recent equity grants have been awarded with higher grant-date fair values than older grants due to the increase in our stock price.

The increase in SG&A costs for the year ended March 31, 2012, as compared to the year ended March 31, 2011, was primarily due to an increase of \$24.7 million in professional service expenses, \$8.0 million in employee-related expenses and \$3.0 million in marketing expense from the Alkermes, Inc., business, as well as the addition of \$18.3 million of SG&A expense for the former EDT business. The increase in professional services was primarily due to costs incurred in connection with the Business Combination. The increase in employee-related expenses was primarily due to an increase in headcount and share-based compensation expense as recent equity grants have been awarded with higher grant-date fair values than older grants, and the increase in marketing expenses was due to an analysis we performed to determine the marketability of our existing products and product candidates.

### ***Amortization of Acquired Intangible Assets***

(In millions)	Years Ended March 31,			Change	
	2013	2012	2011	Favorable/(Unfavorable)	
				2013 - 2012	2012 - 2011
Amortization of acquired intangible assets	\$ 41.9	\$ 25.4	\$ —	\$ (16.5)	\$ (25.4)

The intangible assets being amortized in the year ended March 31, 2013 and 2012 were acquired as part of the Business Combination. In connection with the Business Combination, we acquired certain amortizable intangible assets with a fair value of \$643.2 million, which are expected to be amortized over 12 to 13 years. We amortize our amortizable intangible assets using the economic use method, which reflects the pattern that the economic benefits of the intangible assets are consumed as revenue is generated from the underlying patent or contract. Based on our most recent analysis, amortization of intangible assets included within our consolidated balance sheet at March 31, 2013 is expected to be approximately \$50.0 million, \$60.0 million, \$65.0 million, \$70.0 million and \$70.0 million in the fiscal years ending March 31, 2014 through 2018, respectively.

We also acquired \$92.7 million of goodwill in connection with the Business Combination, which is considered an indefinite-lived asset and is not amortized, but is subject to an annual review for

impairment or when circumstances indicate the fair value may be below its carrying value. Our goodwill solely relates to, and has been assigned to, a reporting unit which consists of the former EDT business. We performed our annual goodwill impairment test during the three months ended December 31, 2012 and determined that the fair value of the former EDT business reporting unit was substantially in excess of its respective carrying value and there was no impairment in the value of this asset.

### Restructuring

(In millions)	Years Ended March 31,			Change	
	2013	2012	2011	Favorable/(Unfavorable)	
				2013 - 2012	2012 - 2011
Restructuring	\$ 12.3	\$ —	\$ —	\$ (12.3)	\$ —

On April 4, 2013, we approved a restructuring plan related to our Athlone, Ireland manufacturing facility consistent with the evolution of our product portfolio and designed to improve operational performance in the future. Under the restructuring plan, we will terminate manufacturing services for certain older products becoming uneconomic to produce due to decreasing demand from its customers resulting from generic competition. We expect to continue to generate revenues from the manufacturing of these products during fiscal year 2014 and, for certain of these products, into fiscal year 2015.

As a result of the termination of these services, we expect to implement a corresponding reduction in headcount of up to 130 employees. The restructuring plan commenced immediately and will be implemented over a period of approximately two years. This restructuring plan is expected to result in estimated annual cost savings of between \$15.0 million to \$20.0 million by fiscal year 2016 and beyond.

In conjunction with the restructuring plan, we recorded a one-time restructuring charge, expected to be settled in cash payments, related to severance and other employee-related expenses of \$12.3 million in the year ended March 31, 2013, as we determined that an obligation had been incurred, it was probable that the obligation would be paid and the amount of the obligation could be reasonably estimated. The total amount of the restructuring charges is accrued at March 31, 2013.

As part of the restructuring plan, we also expect to incur non-cash charges resulting from the accelerated depreciation of certain manufacturing assets, currently estimated to be approximately \$10.0 million and \$7.0 million in the years ended March 31, 2014 and 2015, respectively.

### Impairment of Long-Lived Assets

(In millions)	Years Ended March 31,			Change	
	2013	2012	2011	Favorable/(Unfavorable)	
				2013 - 2012	2012 - 2011
Impairment of long-lived assets	\$ 3.3	\$ 45.8	\$ —	\$ 42.5	\$ (45.8)

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. We determined that the manufacturing space previously assigned to VIVITROL will be used for the scale-up of the aripiprazole lauroxil manufacturing line. As such, certain equipment, originally purchased by Cephalon in connection with our VIVITROL collaboration and later acquired by us upon the termination of the VIVITROL collaboration, was determined to have no future use.

We recorded an impairment charge of \$3.3 million which represents the net carrying value of the equipment less the proceeds received upon the sale of certain of this equipment.

During the year ended March 31, 2012, and after finalization of the purchase accounting for the Business Combination, we identified events and changes in circumstances, such as correspondence from regulatory authorities and further clinical trial results related to three product candidates, including Megestrol for use in Europe, acquired as part of the Business Combination which indicated that the assets may be impaired. Accordingly, we performed an analysis to measure the amount of the impairment loss, if any. We performed the valuation of the IPR&D from the viewpoint of a market participant through the use of a discounted cash flow model. The model contained certain key assumptions including: the cost to bring the products through the clinical trial and regulatory approval process; the gross margin a market participant would likely earn if the product were approved for sale; the cost to sell the approved product; and a discount factor based on an industry average weighted average cost of capital. Based on the analysis performed, we determined that the IPR&D was impaired and recorded an impairment charge of \$45.8 million.

#### Other Expense, Net

(In millions)	Years Ended March 31,			Change	
	2013	2012	2011	Favorable/(Unfavorable) 2013 - 2012	2012 - 2011
Interest income	\$ 0.8	\$ 1.5	\$ 2.7	\$ (0.7)	\$ (1.2)
Interest expense	(49.0)	(28.1)	(3.3)	(20.9)	(24.8)
Other income (expense), net	1.8	0.5	(0.3)	1.3	0.8
Total other expense, net	\$ (46.4)	\$ (26.1)	\$ (0.9)	\$ (20.3)	\$ (25.2)

The increase in interest expense for the year ended March 31, 2013, as compared to the year ended March 31, 2012, is primarily due to the Refinancing and Repricing transactions. The Refinancing and Repricing transactions were considered a restructuring of our 2012 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 the 2012 Term Loans. The treatment of the debt restructuring and the \$19.7 million charge to interest expense in connection with the Refinancing and Repricing is as follows:

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

The increase in interest expense for the year ended March 31, 2012, as compared to the year ended March 31, 2011, was primarily due to our entry into \$450.0 million of term loan financing in July 2011. The 2012 Term Loans became effective upon the closing of the Business Combination in September 2011. Included in interest expense during the year ended March 31, 2012 are commitment fees of \$5.9 million which were incurred during the period from when we priced the 2012 Term Loans, effective July 1, 2011, to when the 2012 Term Loans were funded in September 2011.

**Provision for Income Taxes**

(In millions)	Years Ended March 31,			Change	
	2013	2012	2011	Favorable/(Unfavorable) 2013 - 2012	2012 - 2011
Income tax expense (benefit)	\$ 10.5	\$ (0.7)	\$ (1.0)	\$ (11.2)	\$ (0.3)

Our income tax expense for the year ended March 31, 2013 consists 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 is 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 is 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 exceeds the tax basis. The intangible assets are being amortized for book purposes over the life of the assets.

Our effective tax rate is 29.5%, which is higher than the Irish statutory tax rate of 12.5% due to a number of factors, including income taxable at a rate higher than the Irish statutory rate, losses in certain tax jurisdictions for which no tax benefit is currently available and various expenses not deductible for income tax purposes.

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

As of March 31, 2013, we had \$438.3 million of Irish Net Operating Loss ("NOL") carryforwards, \$70.4 million of U.S. federal NOL carryforwards and \$8.7 million of state NOL carryforwards which either expire on various dates through 2032 or can be carried forward indefinitely. These loss carryforwards are available to reduce certain future Irish and 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 have experienced a change of ownership. As a consequence, our U.S. federal NOL carryforwards and tax credit carryforwards are subject to an annual limitation of \$127.0 million.

At March 31, 2013 we determined, based on the weight of all available positive and negative evidence, on a jurisdiction by jurisdiction basis, that it is more likely than not that a significant portion of our net deferred tax assets will not be realized, and a valuation allowance has been recorded. However, if we demonstrate consistent profitability in the future, the evaluation of the recoverability of the net deferred tax assets could change and the valuation allowance could be released in whole or in part.

**Liquidity and Capital Resources**

Our financial condition is summarized as follows:

(In millions)	March 31, 2013	March 31, 2012
Cash and cash equivalents	\$ 97.0	\$ 83.6
Investments—short-term	124.4	106.8
Investments—long-term	82.8	55.7
Total cash and investments	<u>\$ 304.2</u>	<u>\$ 246.1</u>
Working capital	<u>\$ 322.7</u>	<u>\$ 250.0</u>
Outstanding borrowings—current and long-term	\$ 369.0	\$ 444.5

*Sources and Uses of Cash*

We expect that funds generated from results of operations will be sufficient to finance our anticipated working capital and other cash requirements, such as capital expenditures and principal and interest payments for the foreseeable future. In the event business conditions were to deteriorate, we could rely on borrowings under the 2013 Term Loans, 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.

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 years ended March 31, 2013, 2012 and 2011:

(In millions)	Years Ended March 31,		
	2013	2012	2011
Cash and cash equivalents, beginning of period	\$ 83.6	\$ 38.4	\$ 79.3
Cash provided by (used in) operating activities	126.5	(2.5)	(5.9)
Cash (used in) provided by investing activities	(68.1)	(417.1)	5.6
Cash (used in) provided by financing activities	(45.0)	464.8	(40.6)
Cash and cash equivalents, end of period	<u>\$ 97.0</u>	<u>\$ 83.6</u>	<u>\$ 38.4</u>

*Operating Activities*

Cash provided by operating activities increased in the year ended March 31, 2013, as compared to the year ended March 31, 2012, which was primarily due to an increase in cash provided from net income of \$150.4 million. This was partially offset by a decrease in cash from working capital, 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.

Cash used by operating activities decreased in the year ended March 31, 2012, as compared to the year ended March 31, 2011, which was primarily due to a decrease in cash used in net income of \$8.6 million and \$6.6 million of payments made in connection with the early redemption of our non-recourse 7% Notes during the year ended March 31, 2011. This was partially offset by changes in working capital, most notably from a decrease in cash provided by receivables of \$16.4 million and an increase in cash used to purchase inventory, prepaid expenses and other assets of \$10.1 million. During the year ended March 31, 2011, we redeemed the balance of our non-recourse 7% Notes in full at 101.75% of the outstanding principal balance in accordance with the terms of the Indenture for the non-recourse 7% Notes. We allocated \$6.6 million of the principal payments made during the year ended March 31, 2011 to operating activities to account for the original issue discount on the non-recourse 7% Notes, and the remaining \$45.4 million of principal payments was allocated to financing activities in the consolidated statement of cash flows.

*Investing Activities*

The increase in cash flows provided by investing activities in the year ended March 31, 2013, as compared to the year 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 year ended March 31, 2013, we made net purchases of investments of \$45.0 million whereas in the year 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.

The increase in cash flows provided by investing activities in the year ended March 31, 2012, as compared to the year ended March 31, 2011, was primarily due to the \$500.0 million of cash we paid to acquire EDT and a \$7.6 million increase in cash used to acquire property, plant and equipment, partially offset by a \$79.7 million increase in the net sales of investments.

We expect to spend approximately \$20.0 million during the nine months ended December 31, 2013 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*

The increase in cash flows used in financing activities in the year ended March 31, 2013, as compared to the year ended March 31, 2012, was primarily due to the \$444.1 million of cash received upon the issuance of the 2012 Term Loans in September 2011. During the year 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.

The increase in cash provided by financing activities during the year ended March 31, 2012, as compared to the year ended March 31, 2011, was primarily due to our entry into the 2012 Term Loans and an increase of \$14.7 million of cash received from our employees upon the exercise of stock awards.

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

(In millions)	Amortized Cost	Gross Unrealized		Estimated Fair Value
		Gains	Losses	
Investments—short-term	\$ 124.3	\$ 0.1	\$ —	\$ 124.4
Investments—long-term available-for-sale	81.8	—	(0.2)	81.6
Investments—long-term held-to-maturity	1.2	—	—	1.2
Total	<u>\$ 207.3</u>	<u>\$ 0.1</u>	<u>\$ (0.2)</u>	<u>\$ 207.2</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, and corporate debt securities. 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 March 31, 2013, we performed an analysis of our investments with unrealized losses for impairment and determined that they are temporarily impaired.

At March 31, 2013 and 2012, none and 7%, respectively, of our investments are valued using unobservable, or Level 3 inputs, to determine fair value as they are not actively trading and fair values could not be derived from quoted market prices. During the year ended March 31, 2013, the two securities that were included in Level 3 at March 31, 2012 were transferred out of Level 3 as trading in these securities resumed during the period.

### **Borrowings**

At March 31, 2013, our borrowings consisted of \$371.6 million of term loan financing under the 2013 Term Loans. 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 March 31, 2013:

<u>Contractual Obligations</u>	<u>Total</u>	<u>Less Than One Year (Fiscal 2014)</u>	<u>One to Three Years (Fiscal 2015 - 2016) (In thousands)</u>	<u>Three to Five Years (Fiscal 2017 - 2018)</u>	<u>More than Five Years (After Fiscal 2019)</u>
2013 Term Loans—Principal	\$ 371,625	\$ 6,750	\$ 13,500	\$ 67,875	\$ 283,500
2013 Term Loans—Interest	72,697	12,524	24,401	20,987	14,785
Operating lease obligations	27,348	3,838	8,038	7,122	8,350
Purchase obligations	72,277	72,277	—	—	—
Capital expansion programs	3,722	3,722	—	—	—
Total contractual cash obligations	<u>\$ 547,669</u>	<u>\$ 99,111</u>	<u>\$ 45,939</u>	<u>\$ 95,984</u>	<u>\$ 306,635</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 one-month LIBOR rate at March 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 March 31, 2013, we have \$1.2 million of net liabilities associated with uncertain tax positions and we expect a net reduction in the amount of the \$1.2 million due to the expected resolution of certain matters over 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 maturities.

### **Off-Balance Sheet Arrangements**

At March 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, changes in financial condition, revenue or expenses, results of operations, liquidity, capital expenditures or capital resources.

### **Critical Accounting Estimates**

Our consolidated financial statements are prepared in accordance with GAAP. 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 Bristol-Myers 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 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.

### **Product Sales, Net**

We recognize revenue from product sales of VIVITROL when persuasive evidence of an arrangement exists, and title to the product and associated risk of loss has passed to the customer, the sales price is fixed or determinable and collectability is reasonably assured. We sell VIVITROL to pharmaceutical wholesalers, specialty distributors and specialty pharmacies.

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

- **Medicaid Rebates**—we record accruals for rebates to states under the Medicaid Drug Rebate Program as a reduction of sales when the product is shipped into the distribution channel. We rebate individual states for all eligible units purchased under the Medicaid program based on a rebate per unit calculation, which is based on our Average Manufacturer Price ("AMP"). We estimate expected unit sales and rebates per unit under the Medicaid program and adjust our rebate estimates based on actual unit sales and rebates per unit. To date, actual Medicaid rebates have not differed materially from our estimates;
- **Chargebacks**—wholesaler and specialty pharmacy chargebacks are discounts that occur when contracted customers purchase directly from an intermediary wholesale purchaser. Contracted customers, which consist primarily of federal government agencies purchasing under the 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 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 March 31, 2013, our product return reserve rate 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;

- Co-pay assistance—we have a program whereby a patient can receive up to \$500 per month towards their co-payment, co-insurance or deductible, provided the patient meets certain eligibility criteria. Reserves are recorded upon the sale of VIVITROL.

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

(In millions)	Medicaid Rebates	Chargebacks	Product Returns	Co-Pay Assistance	Other	Total
<b>Balance, April 1, 2011</b>	\$ 1.3	\$ 0.1	\$ 2.5	\$ —	\$ 1.2	\$ 5.1
Provision:						
Current period	4.6	4.2	3.8	2.3	4.9	19.8
Prior period	—	—	—	—	—	—
Total	4.6	4.2	3.8	2.3	4.9	19.8
Actual:						
Current period	(3.3)	(4.1)	—	(2.2)	(4.2)	(13.8)
Prior period	(1.1)	(0.1)	(2.5)	—	(1.1)	(4.8)
Total	(4.4)	(4.2)	(2.5)	(2.2)	(5.3)	(18.6)
<b>Balance, March 31, 2012</b>	\$ 1.5	\$ 0.1	\$ 3.8	\$ 0.1	\$ 0.8	\$ 6.3
Provision:						
Current period	6.0	5.4	3.7	3.2	6.1	24.4
Prior period	(0.1)	—	(3.9)	—	—	(4.0)
Total	5.9	5.4	(0.2)	3.2	6.1	20.4
Actual:						
Current period	(4.2)	(5.4)	(0.5)	(3.3)	(5.6)	(19.0)
Prior period	(1.3)	(0.1)	—	—	(0.3)	(1.7)
Total	(5.5)	(5.5)	(0.5)	(3.3)	(5.9)	(20.7)
<b>Balance, March 31, 2013</b>	\$ 1.9	\$ —	\$ 3.1	\$ —	\$ 1.0	\$ 6.0

## Investments

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

The earnings on our investment portfolio may be adversely affected by changes in interest rates, credit ratings, collateral value, the overall strength of credit markets and other factors that may result in other-than-temporary declines in the value of the securities. On a quarterly basis, we review the fair market value of our investments in comparison to amortized cost. If the fair market value of a security is less than its carrying value, we perform an analysis to assess whether we intend to sell or whether we would more likely than not be required to sell the security before the expected recovery of the

amortized cost basis. Where we intend to sell a security, or may be required to do so, the security's decline in fair value is deemed to be other-than-temporary, and the full amount of the unrealized loss is recorded within earnings as an impairment loss. Regardless of our intent to sell a security, we perform additional analysis on all securities with unrealized losses to evaluate losses associated with the creditworthiness of the security. Credit losses are identified where we do not expect to receive cash flows sufficient to recover the amortized cost basis of a security.

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

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

### **Share-Based Compensation**

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

The fair value of restricted stock units is equal to the closing price of our stock on the date of grant. The fair value of stock option awards is determined through the use of a Black-Scholes option-pricing model. The Black-Scholes model requires us to estimate certain subjective assumptions. These assumptions include the expected option term, which takes into account both the contractual term of the option and the effect of our employees' expected exercise and post-vesting termination behavior, expected volatility of our ordinary shares over the option's expected term, which is developed using both the historical volatility of our ordinary shares and implied volatility from our publicly traded options, the risk-free interest rate over the option's expected term, and an expected annual dividend yield. Due to the differing exercise and post-vesting termination behavior of our employees and non-employee directors, we establish separate Black-Scholes input assumptions for three distinct employee populations: our senior management; our non-employee directors; and all other employees.

For the year ended March 31, 2013, 2012 and 2011, the ranges in weighted-average assumptions were as follows:

	Year Ended March 31,		
	2013	2012	2011
Expected option term	5 - 7 years	5 - 7 years	5 - 7 years
Expected stock volatility	47% - 49%	47% - 51%	46% - 51%
Risk-free interest rate	0.61% - 1.18%	0.82% - 2.5%	1.11% - 3.42%
Expected annual dividend yield	—	—	—

In addition to the above, we apply judgment in developing estimates of award forfeitures. For the year ended March 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. An analysis of the anticipated product sales generated from our amortizable intangible assets is performed at least annually during our planning cycle, and this analysis serves as the basis for the calculation of our economic benefit amortization model.

We amortize our amortizable intangible assets using the economic use method, which reflects the pattern in which the economic benefits of the intangible assets are consumed. 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 include: (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.

We allocate the value of our intangible assets to match the expected revenue pattern. Based on our most recent analysis, amortization of intangible assets included within our consolidated balance sheet at March 31, 2013, is expected to be approximately \$50.0 million, \$60.0 million, \$65.0 million, \$70.0 million and \$70.0 million in the fiscal years ending March 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 their 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, 2012, we have one operating segment and two reporting units. Our goodwill, which solely relates to the EDT acquisition in the fiscal year 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: (1) assumptions that market

participants would use in their estimates of fair value; (ii) current period actual results; and (iii) budgeted 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 respective carrying value and there was no impairment in the value of this asset as of December 31, 2012. 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 47% 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, the sales and profitability of the company may be adversely affected in future periods. Additionally, the value of the acquired intangible assets may become impaired. No assurance can be given, however, that the underlying assumptions used to estimate expected product sales, development costs or profitability, or the events associated with such products, will transpire as estimated.

## Income Taxes

We use the asset and liability method of accounting for deferred income taxes. Our most significant tax jurisdictions are the Irish and U.S. federal governments and states. Significant estimates are required in determining our provision for income taxes. Some of these estimates are based on management's interpretations of jurisdiction-specific tax laws or regulations and the likelihood of settlement related to tax audit issues. Various internal and external factors may have favorable or unfavorable effects on our future effective income tax rate. These factors include, but are not limited to, changes in tax laws, regulations and/or rates, changing interpretations of existing tax laws or regulations, changes in estimates of prior years' items, likelihood of settlement, and changes in overall levels of income before taxes. In evaluating our ability to recover our deferred tax assets, we consider all available positive and negative evidence including our past operating results, the existence of cumulative income in the most recent fiscal years, changes in the business in which we operate and our forecast of future taxable income. In determining future taxable income, we are responsible for assumptions utilized including the amount of state, federal and international pre-tax operating income, the reversal of temporary differences and the implementation of feasible and prudent tax planning strategies. These assumptions require significant judgment about the forecasts of future taxable income and are consistent with the plans and estimates that we are using to manage the underlying businesses. At March 31, 2013, we determined, based on the weight of all available positive and negative evidence, on a jurisdiction by jurisdiction basis, that it is more likely than not that a significant portion of the net deferred tax assets will not be realized, and a valuation allowance has been recorded. However, if we demonstrate consistent profitability in the future, the evaluation of the recoverability of the deferred tax asset could change and the valuation allowance could be released in part or in whole.

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

## Recent Accounting Pronouncements

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

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

We hold securities in our investment portfolio that are sensitive to market risks. Our securities with fixed interest rates may have their market value adversely impacted by a rise in interest rates, while floating rate securities may produce less income than expected if interest rates fall. Due in part to these factors, our future investment income may fall short of expectation due to a fall in interest rates or we may suffer losses in principal if we are forced to sell securities that decline in market value



due to changes in interest rates. However, because we classify our investments in debt securities as available-for-sale, no gains or losses are recognized due to changes in interest rates unless such securities are sold prior to maturity or declines in fair value are determined to be other-than-temporary. Should interest rates fluctuate by 10%, our interest income would change by 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 78% of our investments are in debt securities issued by the U.S. government, our exposure to liquidity and credit risk is not believed to be significant.

In accordance with the terms of the 2012 Term Loans, we entered into two interest rate cap agreements and an interest rate swap agreement to mitigate the interest rate risk on \$225.0 million principal amount of the 2012 Term Loans, however, in connection with the Refinancing, there is no longer a requirement that we enter into such instruments to mitigate our interest rate risk. At March 31, 2013, an interest rate cap and an interest rate swap agreement have yet to mature and remain outstanding. The interest rate cap, with a notional amount of \$160.0 million, protects us if three-month LIBOR were to reach 3% from the date of issuance through December 13, 2013. The interest rate swap protects us if three-month LIBOR were to reach 2.057% from December 3, 2012 through September 3, 2014.

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 0.28% at March 31, 2013, and the LIBOR floor under Term Loan B-1 is 0.75%; and as our interest rate cap and swap fixes our interest rate at 3% for \$160.0 million principal amount and 2.057% for \$65.0 million principal amount, respectively, we do not expect changes in the three-month LIBOR to have a material effect on our financial statements through March 31, 2014.

Term Loan B-2 bears interest at one-month LIBOR plus 2.75% with no LIBOR floor. At March 31, 2013, the one-month LIBOR rate was 0.20%. A 10% increase in the one-month LIBOR rate would increase our interest expense in the year ended March 31, 2014 by an immaterial amount.

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

### **Currency Exchange Rate Risk**

Manufacturing and royalty revenues we receive on certain of our significant products, including RISPERDAL CONSTA, XEPLION, FAMPYRA, TRICOR 145, BYDUREON, FOCALIN XR and RITALIN LA are a percentage of the net sales made by our collaborative partners. A significant portion of these sales are made in countries outside the U.S. and are denominated in currencies in which the product is sold, which is predominantly the Euro. The manufacturing and royalty payments on these non-U.S. sales are calculated initially in the currency in which the sale is made and are then converted into USD to determine the amount that our partners pay us for manufacturing and royalty revenues. Fluctuations in the exchange ratio of the USD and these non-U.S. currencies will have the effect of increasing or decreasing our manufacturing and royalty revenues even if there is a constant amount of sales in non-U.S. currencies. For example, if the USD weakens against a non-U.S. currency, then our manufacturing and royalty revenues will increase given a constant amount of sales in such non-U.S. currency. For the year ended March 31, 2013, an average 10% strengthening of the USD relative to the currencies in which these products are sold would have resulted in our manufacturing and royalty revenues being reduced by approximately \$14.9 million.

As a result of the Business Combination, we incur substantial operating costs in Ireland. We face exposure to changes in the exchange ratio of the USD and the Euro arising from expenses and payables at our Irish operations that are settled in Euro. The impact of changes in the exchange ratio of the USD and the Euro on our USD denominated manufacturing and royalty revenues earned in countries other than the U.S. is partially offset by the opposite impact of changes in the exchange ratio of the USD and the Euro on operating expenses and payables incurred at our Irish operations that are settled in Euro. For the fiscal year ended March 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 \$7.5 million.

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

(In thousands, except per share data)	First Quarter	Second Quarter	Third Quarter	Fourth Quarter	Total
<b>Year Ended March 31, 2013</b>					
REVENUES:					
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>
EXPENSES:					
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	(8,948)	(21,709)	(4,597)	(11,118)	(46,372)
INCOME (LOSS) BEFORE INCOME TAXES	<u>23,197</u>	<u>(16,285)</u>	<u>20,663</u>	<u>7,866</u>	<u>35,441</u>
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>
EARNINGS (LOSS) PER SHARE—DILUTED	<u>\$ 0.17</u>	<u>\$ (0.13)</u>	<u>\$ 0.12</u>	<u>\$ 0.02</u>	<u>\$ 0.18</u>
<b>Year Ended March 31, 2012</b>					
REVENUES:					
Manufacturing and royalty revenues	\$ 48,940	\$ 54,039	\$ 112,780	\$ 110,685	\$ 326,444
Product sales, net	9,686	9,887	10,597	11,014	41,184
Research and development revenue	3,257	8,052	2,266	8,774	22,349
Total revenues	<u>61,883</u>	<u>71,978</u>	<u>125,643</u>	<u>130,473</u>	<u>389,977</u>
EXPENSES:					
Cost of goods manufactured and sold	16,219	17,530	42,752	51,077	127,578
Research and development	28,050	28,160	40,493	45,190	141,893
Selling, general and administrative	31,497	36,234	35,469	34,432	137,632
Amortization of acquired intangible assets	—	1,817	11,896	11,642	25,355
Impairment of long-lived assets	—	—	—	45,800	45,800
Total expenses	<u>75,766</u>	<u>83,741</u>	<u>130,610</u>	<u>188,141</u>	<u>478,258</u>
OPERATING INCOME (LOSS)	(13,883)	(11,763)	(4,967)	(57,668)	(88,281)
OTHER INCOME (EXPENSE), NET	591	(6,842)	(9,763)	(10,097)	(26,111)
INCOME (LOSS) BEFORE INCOME TAXES	<u>(13,292)</u>	<u>(18,605)</u>	<u>(14,730)</u>	<u>(67,765)</u>	<u>(114,392)</u>
INCOME TAX (BENEFIT) PROVISION	(54)	3,650	98	(4,408)	(714)
NET INCOME (LOSS)	<u>\$ (13,238)</u>	<u>\$ (22,255)</u>	<u>\$ (14,828)</u>	<u>\$ (63,357)</u>	<u>\$ (113,678)</u>
BASIC AND DILUTED (LOSS) PER SHARE	<u>\$ (0.14)</u>	<u>\$ (0.22)</u>	<u>\$ (0.11)</u>	<u>\$ (0.49)</u>	<u>\$ (0.99)</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 Securities Exchange Act of 1934, as amended), as of March 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 Securities Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms, and (b) such information is accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate to allow timely decisions regarding required disclosure. In designing and evaluating our disclosure controls and procedures, our management recognized that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives, and our management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

**Changes in Internal Control over Financial Reporting**

There were no changes in our internal control over financial reporting during the quarter ended March 31, 2013 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

**Management's Annual Report on Internal Control over Financial Reporting**

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

- pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect our transactions and dispositions of the assets of the issuer;
- provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with GAAP, and that receipts and expenditures of the issuer are being made only in accordance with authorizations of management and directors of the issuer; and
- provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of the issuer's assets that could have a material effect on the financial statements.

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

Our management assessed the effectiveness of our internal control over financial reporting as of March 31, 2013. In making this assessment, management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission ("COSO") in Internal Control—Integrated Framework.

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

The effectiveness of our internal control over financial reporting as of March 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***

On May 21, 2013, with such authority delegated to it by our Board of Directors, the Audit and Risk Committee of our Board approved a change to our fiscal year-end from March 31 to December 31. We will file the report for the transition period ending December 31, 2013 in our Annual Report on Form 10-K.

**PART III**

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

The information required by this item is incorporated herein by reference to the 2013 Proxy Statement.

**Item 11. *Executive Compensation***

The information required by this item is incorporated herein by reference to the 2013 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 2013 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 2013 Proxy Statement.

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

The information required by this item is incorporated herein by reference to the 2013 Proxy Statement.

**PART IV**

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

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



<u>Signature</u>	<u>Title</u>	<u>Date</u>
<u>/s/ WENDY L. DIXON</u>		
Wendy L. Dixon	Director	May 23, 2013
<u>/s/ GERALDINE HENWOOD</u>		
Geraldine Henwood	Director	May 23, 2013
<u>/s/ PAUL J. MITCHELL</u>		
Paul J. Mitchell	Director	May 23, 2013
<u>/s/ MARK B. SKALETSKY</u>		
Mark B. Skaletsky	Director	May 23, 2013
<u>/s/ NANCY J. WYSENSKI</u>		
Nancy J. Wysenski	Director	May 23, 2013



**EXHIBIT INDEX**

<u>Exhibit No.</u>	<u>Description of Exhibit</u>
2.1 <sup>++</sup>	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 <sup>++</sup>	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 <sup>++</sup>	Lease Agreement, dated as of April 22, 2009 between PDM Unit 850, LLC, and Alkermes, Inc. (Incorporated by reference to Exhibit 10.5 to the Alkermes, Inc. Annual Report on Form 10-K for the fiscal year ended March 31, 2009 (File No. 001-14131).)
10.4 <sup>++</sup>	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 <sup>++*</sup>	License Agreement, dated as of February 13, 1996, between Medisorb Technologies International L.P. and Janssen Pharmaceutica Inc. (U.S.) (assigned to Alkermes, Inc. in July 2006). (Incorporated by reference to Exhibit 10.19 to the Alkermes, Inc. Annual Report on Form 10-K for the fiscal year ended March 31, 1996 (File No. 000-19267).)
10.6 <sup>++*</sup>	License Agreement, dated as of February 21, 1996, between Medisorb Technologies International L.P. and Janssen Pharmaceutica International (worldwide except United States) (assigned to Alkermes, Inc. in July 2006). (Incorporated by reference to Exhibit 10.20 to the Alkermes, Inc. Annual Report on Form 10-K for the fiscal year ended March 31, 1996 (File No. 000-19267).)
10.7 <sup>++**</sup>	Manufacturing and Supply Agreement, dated August 6, 1997, by and among Alkermes Controlled Therapeutics Inc. II, Janssen Pharmaceutica International and Janssen Pharmaceutica, Inc. (assigned to Alkermes, Inc. in July 2006). (Incorporated by reference to Exhibit 10.19 to the Alkermes, Inc. Annual Report on Form 10-K for the fiscal year ended March 31, 2002 (File No. 001-14131).)
10.8 <sup>++***</sup>	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).)

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

<u>Exhibit No.</u>	<u>Description of Exhibit</u>
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. (Incorporated herein by reference to Exhibit 10.3 of the Alkermes plc Quarterly Report on Form 10-Q for the quarter ended September 30, 2012).
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 herein 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.
10.22#*****	Supply Agreement, dated September 26, 2003, by and between Acorda Therapeutics, Inc. and Elan Corporation, plc.
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.
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.
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.

<u>Exhibit No.</u>	<u>Description of Exhibit</u>
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).)
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 year 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 year 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 fiscal year 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).)

<u>Exhibit No.</u>	<u>Description of Exhibit</u>
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 fiscal year 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 fiscal year 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 fiscal 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 fiscal quarter ended September 30, 2006 (File No. 001-14131).)
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 fiscal year 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 fiscal year 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).)

<u>Exhibit No.</u>	<u>Description of Exhibit</u>
10.49 <sup>++****</sup>	Development and License Agreement, dated as of May 15, 2000, by and between Alkermes Controlled Therapeutics Inc. II and Amylin Pharmaceuticals, Inc., as amended on October 24, 2005 and July 17, 2006 (assigned, as amended, to Alkermes, Inc. in July 2006). (Incorporated by reference to Exhibit 10.28 to the Alkermes, Inc. Annual Report on Form 10-K for the fiscal year ended March 31, 2010 (File No. 001-14131).)
10.50 <sup>++</sup>	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 herein by reference to Exhibit 10.1 of the Alkermes plc Current Report on Form 8-K filed on September 25, 2012).
10.51 <sup>++</sup>	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 herein by reference to Exhibit 10.1 of the Alkermes plc Current Report on Form 8-K filed on February 19, 2013).
10.52 <sup>#</sup>	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.
10.53 <sup>++</sup>	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 <sup>++</sup>	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 <sup>++</sup>	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 <sup>++</sup>	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 <sup>++</sup>	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 <sup>++</sup>	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.)

<u>Exhibit No.</u>	<u>Description of Exhibit</u>
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 (File No. 001-35299)).
10.62+ ++	Alkermes plc 2011 Stock Option and Incentive Plan, as amended (Incorporated herein 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), as amended.
10.64#+	Alkermes plc 2011 Stock Option and Incentive Plan, Stock Option Award Certificate (Non-Qualified Option), as amended.
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 (File No. 001-35299)).
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 (File No. 001-35299)).
10.67+ ++	Employment agreement, dated as of July 30, 2012, by and between Rebecca J. Peterson and Alkermes, Inc. (Incorporated herein 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 (File No. 001-35299)).
10.69+ ++	Amended and Restated Fiscal 2013 Alkermes plc Affiliated Company Reporting Officer Performance Pay Plan (Incorporated herein 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 herein 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).
21.1	List of subsidiaries
23.1	Consent of PricewaterhouseCoopers LLP

<u>Exhibit No.</u>	<u>Description of Exhibit</u>
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.

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

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

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

\*\*\*\* Confidential status has been granted for certain portions thereof pursuant to a Commission Order granted June 28, 2010. Such provisions have been filed separately with the Commission.

\*\*\*\*\* Confidential status 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.

\*\*\*\*\* Certain portions of this exhibit have been omitted pursuant to a request for confidentiality. Such omitted portions have been filed separately with the Commission.



## Report of Independent Registered Public Accounting Firm

To the Board of Directors and Shareholders of Alkermes plc:

In our opinion, the accompanying consolidated balance sheets and the related statements of operations and comprehensive income (loss), of shareholders' equity and of cash flows present fairly, in all material respects, the financial position of Alkermes plc and its subsidiaries at March 31, 2013 and 2012, and the results of their operations and their cash flows for each of the three 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 March 31, 2013 based on criteria established in *Internal Control—Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). The Company's management is responsible for these financial statements, for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting, included in Management's Annual Report on Internal Control over Financial Reporting under Item 9A. Our responsibility is to express opinions on these financial statements and on the Company's internal control over financial reporting based on our integrated audits. We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the financial statements are free of material misstatement and whether effective internal control over financial reporting was maintained in all material respects. Our audits of the financial statements included examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. Our audit of internal control over financial reporting included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audits also included performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

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/ PRICEWATERHOUSECOOPERS LLP  
Boston, Massachusetts  
May 23, 2013

**ALKERMES PLC AND SUBSIDIARIES**
**CONSOLIDATED BALANCE SHEETS**
**March 31, 2013 and 2012**

	<u>2013</u>	<u>2012</u>
	(In thousands, except share and per share amounts)	
<b>ASSETS</b>		
<b>CURRENT ASSETS:</b>		
Cash and cash equivalents	\$ 96,961	\$ 83,601
Investments—short-term	124,391	106,846
Receivables	124,620	96,381
Inventory	43,483	39,759
Prepaid expenses and other current assets	19,133	12,566
Total current assets	<u>408,588</u>	<u>339,153</u>
PROPERTY, PLANT AND EQUIPMENT, NET	288,435	302,995
INTANGIBLE ASSETS—NET	575,993	617,845
GOODWILL	92,740	92,740
INVESTMENTS—LONG-TERM	82,827	55,691
OTHER ASSETS	21,708	26,793
<b>TOTAL ASSETS</b>	<b><u>\$ 1,470,291</u></b>	<b><u>\$ 1,435,217</u></b>
<b>LIABILITIES AND SHAREHOLDERS' EQUITY</b>		
<b>CURRENT LIABILITIES:</b>		
Accounts payable and accrued expenses	\$ 76,910	\$ 79,154
Deferred revenue—current	2,270	6,910
Long-term debt—current	6,750	3,100
Total current liabilities	<u>85,930</u>	<u>89,164</u>
LONG-TERM DEBT	362,258	441,360
DEFERRED REVENUE—LONG-TERM	8,866	7,578
DEFERRED TAX LIABILITIES, NET—LONG-TERM	37,603	34,512
OTHER LONG-TERM LIABILITIES	23,260	8,751
Total liabilities	<u>517,917</u>	<u>581,365</u>
<b>COMMITMENTS AND CONTINGENCIES (Note 18)</b>		
<b>SHAREHOLDERS' EQUITY:</b>		
Preferred stock, par value, \$0.01 per share; 50,000,000 shares authorized; zero issued and outstanding at March 31, 2013 and 2012, respectively	—	—
Ordinary shares, par value, \$0.01 per share; 450,000,000 shares authorized; 134,065,107 and 130,212,530 shares issued; 133,751,610 and 130,177,452 shares outstanding at March 31, 2013 and 2012, respectively	1,338	1,300
Treasury stock, at cost (313,497 and 35,078 shares at March 31, 2013 and 2012, respectively)	(5,380)	(571)
Additional paid-in capital	1,458,857	1,380,742
Accumulated other comprehensive loss	(2,518)	(2,713)
Accumulated deficit	(499,923)	(524,906)
Total shareholders' equity	<u>952,374</u>	<u>853,852</u>
<b>TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY</b>	<b><u>\$ 1,470,291</u></b>	<b><u>\$ 1,435,217</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)**
**Years Ended March 31, 2013, 2012 and 2011**

	2013	2012	2011
	(In thousands, except per share amounts)		
<b>REVENUES:</b>			
Manufacturing and royalty revenues	\$ 510,900	\$ 326,444	\$ 156,840
Product sales, net	58,107	41,184	28,920
Research and development revenue	6,541	22,349	880
Total revenues	<u>575,548</u>	<u>389,977</u>	<u>186,640</u>
<b>EXPENSES:</b>			
Cost of goods manufactured and sold	170,466	127,578	52,185
Research and development	140,013	141,893	97,239
Selling, general and administrative	125,758	137,632	82,847
Amortization of acquired intangible assets	41,852	25,355	—
Restructuring	12,300	—	—
Impairment of long-lived assets	3,346	45,800	—
Total expenses	<u>493,735</u>	<u>478,258</u>	<u>232,271</u>
OPERATING INCOME (LOSS)	<u>81,813</u>	<u>(88,281)</u>	<u>(45,631)</u>
<b>OTHER EXPENSE, NET:</b>			
Interest income	841	1,516	2,728
Interest expense	(48,994)	(28,111)	(3,298)
Other income (expense), net	1,781	484	(290)
Total other expense, net	<u>(46,372)</u>	<u>(26,111)</u>	<u>(860)</u>
INCOME (LOSS) BEFORE INCOME TAXES	35,441	(114,392)	(46,491)
PROVISION (BENEFIT) FOR INCOME TAXES	10,458	(714)	(951)
NET INCOME (LOSS)	<u>\$ 24,983</u>	<u>\$ (113,678)</u>	<u>\$ (45,540)</u>
<b>EARNINGS (LOSS) PER COMMON SHARE:</b>			
Basic	\$ 0.19	\$ (0.99)	\$ (0.48)
Diluted	<u>\$ 0.18</u>	<u>\$ (0.99)</u>	<u>\$ (0.48)</u>
<b>WEIGHTED AVERAGE NUMBER OF COMMON SHARES OUTSTANDING:</b>			
Basic	131,713	114,702	95,610
Diluted	<u>137,100</u>	<u>114,702</u>	<u>95,610</u>
<b>COMPREHENSIVE INCOME (LOSS):</b>			
Net income (loss)	\$ 24,983	\$ (113,678)	\$ (45,540)
Unrealized gains (losses) on marketable securities, net of tax:			
Holding gains, net of tax	703	627	379
Less: Reclassification adjustment for gains included in net income (loss)	(1,030)	—	—
Unrealized (losses) gains on marketable securities	<u>(327)</u>	<u>627</u>	<u>379</u>
Unrealized (losses) gains on derivative contracts:			
Unrealized losses on derivative contracts, net of tax	(72)	(327)	—
Less: Reclassification adjustment for losses included in net income (loss)	594	—	—
Unrealized gains (losses) on derivative contracts	<u>522</u>	<u>(327)</u>	<u>—</u>
COMPREHENSIVE INCOME (LOSS)	<u>\$ 25,178</u>	<u>\$ (113,378)</u>	<u>\$ (45,161)</u>

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

**ALKERMES PLC AND SUBSIDIARIES**
**CONSOLIDATED STATEMENTS OF SHAREHOLDERS' EQUITY**
**Years Ended March 31, 2013, 2012 and 2011**

	Ordinary Shares		Non-voting Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Loss (Income)	Accumulated Deficit	Treasury Stock		Total
	Shares	Amount	Shares	Amount				Shares	Amount	
BALANCE—March 31, 2010	104,815,328	\$ 1,047	382,632	\$ 4	\$ 910,326	\$ (3,392)	\$ (365,688)	(9,945,265)	\$ (129,681)	\$ 412,616
Issuance of common stock under employee stock plans	956,179	8	—	—	6,150	—	—	—	—	6,158
Receipt of Alkermes' stock for the purchase of stock options or to satisfy minimum tax withholding obligations related to stock based awards	—	—	—	—	—	—	—	(123,943)	(1,414)	(1,414)
Share-based compensation expense	—	—	—	—	19,819	—	—	—	—	19,819
Unrealized gain on marketable securities, net of tax of \$225	—	—	—	—	—	379	—	—	—	379
Net loss	—	—	—	—	—	—	(45,540)	—	—	(45,540)
BALANCE—March 31, 2011	105,771,507	\$ 1,055	382,632	\$ 4	\$ 936,295	\$ (3,013)	\$ (411,228)	(10,069,208)	\$ (131,095)	\$ 392,018
Issuance of common stock to Elan Corporation, plc in connection with the purchase of Elan Drug Technologies	31,900,000	319	—	—	524,755	—	—	—	—	525,074
Issuance of ordinary shares under employee stock plans	2,398,422	24	—	—	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

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

**ALKERMES PLC AND SUBSIDIARIES**
**CONSOLIDATED STATEMENTS OF CASH FLOWS**
**Years Ended March 31, 2013, 2012 and 2011**

	<u>2013</u>	<u>2012</u>	<u>2011</u>
	(In thousands)		
<b>CASH FLOWS FROM OPERATING ACTIVITIES:</b>			
Net income (loss)	\$ 24,983	\$(113,678)	\$ (45,540)
Adjustments to reconcile net income (loss) to cash flows from operating activities:			
Depreciation and amortization	73,751	47,884	8,652
Share-based compensation expense	34,716	28,826	19,832
Loss on debt refinancing transactions	19,670	—	—
Prepayment penalties in connection with debt refinancing transactions	(6,533)	—	—
Excess tax benefit from share-based compensation	(8,867)	(4,335)	—
Impairment of long-lived assets	3,346	45,800	—
Deferred income taxes	(2,113)	(14,556)	—
Principal payments on long-term debt attributable to original issue discount	(2,657)	—	—
Loss on purchase of non-recourse RISPERDAL CONSTA secured 7% Notes	—	—	841
Payment or purchase of non-recourse RISPERDAL CONSTA secured 7% notes attributable to original issue discount	—	—	(6,611)
Other non-cash charges	5,698	4,342	1,861
Changes in assets and liabilities, excluding the effect of acquisitions:			
Receivables	(28,239)	(14,014)	2,347
Inventory, prepaid expenses and other assets	(6,577)	(4,879)	5,211
Accounts payable and accrued expenses	19,406	15,552	6,954
Deferred revenue	(3,351)	6,068	635
Other long-term liabilities	3,318	508	(88)
Cash flows provided by (used in) operating activities	<u>126,551</u>	<u>(2,482)</u>	<u>(5,906)</u>
<b>CASH FLOWS FROM INVESTING ACTIVITIES:</b>			
Additions to property, plant and equipment	(22,217)	(16,988)	(9,401)
Proceeds from the sale of equipment	193	35	395
Acquisition of Elan Drug Technologies, net of cash acquired	—	(494,774)	—
Investment in Acceleron Pharmaceuticals, Inc.	—	(231)	(501)
Promissory note issued to Civitas Therapeutics, Inc.	(1,116)	—	—
Purchases of investments	(303,945)	(228,229)	(370,375)
Sales and maturities of investments	258,937	323,028	385,511
Cash flows (used in) provided by investing activities	<u>(68,148)</u>	<u>(417,159)</u>	<u>5,629</u>
<b>CASH FLOWS FROM FINANCING ACTIVITIES:</b>			
Proceeds from the issuance of ordinary shares for share-based compensation arrangements	34,360	20,864	6,158
Excess tax benefit from share-based compensation	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	(4,809)	(3,676)	(1,414)
Principal payments of long-term debt	(449,944)	(775)	—
Payment or purchase of non-recourse RISPERDAL CONSTA secured 7% notes	—	—	(45,397)
Cash flows (used in) provided by financing activities	<u>(45,043)</u>	<u>464,848</u>	<u>(40,653)</u>
<b>NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS</b>	<b>13,360</b>	<b>45,207</b>	<b>(40,930)</b>
CASH AND CASH EQUIVALENTS—Beginning of period	83,601	38,394	79,324
CASH AND CASH EQUIVALENTS—End of period	<u>\$ 96,961</u>	<u>\$ 83,601</u>	<u>\$ 38,394</u>
<b>SUPPLEMENTAL CASH FLOW DISCLOSURE:</b>			
Cash paid for interest	\$ 7,656	\$ 21,658	\$ 1,684
Cash paid for taxes	\$ 5,921	\$ 10,068	\$ 60
Non-cash investing and financing activities:			
Purchased capital expenditures included in accounts payable and accrued expenses	\$ 2,450	\$ 3,416	\$ 424
Investment in Civitas Therapeutics, Inc.	\$ 1,116	\$ 1,547	\$ 1,320
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. THE COMPANY

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, Alkermes plc 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 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."

#### 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.

##### *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.

ALKERMES PLC AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

*Cash and Cash Equivalents*

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

*Investments*

The Company has investments in various types of securities including U.S. government and agency obligations, debt securities issued by foreign agencies and backed by foreign governments and corporate debt securities. The Company generally holds its interest-bearing investments with major financial institutions and in accordance with documented investment policies. The Company limits the amount of credit exposure to any one financial institution or corporate issuer. At March 31, 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 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

## ALKERMES PLC AND SUBSIDIARIES

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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

measurement. The Company's financial assets and liabilities consist of cash equivalents and investments and are classified within the fair value hierarchy as follows:

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

*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 and backed by foreign governments, investments in corporate debt securities that are trading in the credit markets and an interest rate cap and swap contract;

*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. At March 31, 2013, the Company did not have any assets or liabilities utilizing Level 3 inputs.

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.

**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



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

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

***Goodwill and Intangible Assets***

Goodwill represents the excess cost of the Company's investment in the net assets of acquired companies over the fair value of the underlying identifiable net assets at the date of acquisition. The Company's goodwill, which solely relates to the EDT acquisition in the fiscal year 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 reviewed for impairment 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 and are 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 life using the economic use method, which reflects the pattern that the economic benefits of the intangible assets are consumed as revenue is generated from the underlying patent or contract. The useful lives of the Company's intangible assets are primarily based on the legal or contractual life of the underlying patent or contract, which does not include additional years for the potential extension or renewal of the contract or patent. The Company's intangible assets were all acquired as part of the EDT acquisition in the fiscal year ended March 31, 2012, as described in Note 3, *Acquisitions*.

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

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

## 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 March 31, 2013 and 2012, was \$2.0 million and \$1.9 million, respectively, and is included within "Other Long-Term Liabilities" in the accompanying consolidated balance sheets.

The following table shows changes in the carrying amount of the Company's asset retirement obligation for the years ended March 31, 2013 and 2012:

<b>(In thousands)</b>	<b>Carrying Amount</b>
Balance, April 1, 2011	\$ 1,692
Accretion expense	170
Balance, March 31, 2012	\$ 1,862
Accretion expense	187
Balance, March 31, 2013	\$ 2,049

**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 Amylin Pharmaceuticals, Inc. ("Amylin"), now a wholly-owned subsidiary of Bristol-Myers Squibb Company ("Bristol-Myers") for BYDUREON®. These collaborative arrangements typically include upfront payments, funding of R&D, payments based upon achievement of pre-clinical and clinical development milestones, manufacturing services, sales milestones and royalties on product sales.

On April 1, 2011, the Company adopted new authoritative guidance on revenue recognition for multiple element arrangements. The guidance, which applies to multiple element arrangements entered into or materially modified on or after April 1, 2011, amends the criteria for separating and allocating consideration in a multiple element arrangement by modifying the fair value requirements for revenue recognition and eliminating the use of the residual method. The fair value of deliverables under the arrangement may be derived using a "best estimate of selling price" if vendor-specific objective

ALKERMES PLC AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

evidence and third-party evidence is not available. Deliverables under the arrangement will be separate units of accounting provided that (i) a delivered item has value to the customer on a stand-alone basis, and (ii) if the arrangement includes a general right of return relative to the delivered item, delivery or performance of the undelivered item is considered probable and substantially in the control of the vendor. The Company did not enter into any significant multiple element arrangements or materially modify any of its existing multiple element arrangements during the year ended March 31, 2013. The Company's existing collaboration agreements continue to be accounted for under previously issued revenue recognition guidance for multiple element arrangements, as described below.

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

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

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

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

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

Contingent consideration received from the achievement of a substantive milestone subsequent to April 1, 2011, is recognized in its entirety in the period in which the milestone is achieved, which the Company believes is more consistent with the substance of its performance under its various collaboration agreements. A milestone is defined as an event (i) that can only be achieved based in whole or in part on either the entity's performance or on the occurrence of a specific outcome resulting from the entity's performance, (ii) for which there is substantive uncertainty at the date the arrangement is entered into that the event will be achieved, and (iii) that would result in additional payments being due to the entity. A milestone is substantive if the consideration earned from the achievement of the milestone is consistent with the Company's performance required to achieve the milestone, or the increase in value to the collaboration resulting from the Company's performance, relates solely to the Company's past performance, and is reasonable relative to all of the other deliverables and payments within the arrangement. The Company's collaboration agreements with its partners provide for payments to the Company upon the achievement of development milestones, such as the completion of clinical trials or regulatory approval for drug candidates.

Milestone payments received prior to April 1, 2011 from arrangements where the Company has continuing performance obligations have been deferred and are recognized through the application of a proportional performance model where the milestone payment is recognized over the related performance period or, in full, when there are no remaining performance obligations. The Company makes its best estimate of the period of time for the performance period. The Company will continue to recognize milestone payments received prior to April 1, 2011 in this manner. As of March 31, 2013, the Company has deferred revenue of \$4.3 million from milestone payments received prior to April 1, 2011 that will be recognized through the use of a proportional performance model through 2018.

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

The estimate of deferred revenue also reflects management's estimate of the periods of the Company's involvement in certain of its collaborations. The Company's performance obligations under these collaborations consist of participation on steering committees and the performance of other research and development services. In certain instances, the timing of satisfying these obligations can be difficult to estimate. Accordingly, the Company's estimates may change in the future. Such changes to estimates would result in a change in revenue recognition amounts. If these estimates and judgments change over the course of these agreements, it may affect the timing and amount of revenue that the Company recognizes and records in future periods. At March 31, 2013, the Company had short-term and long-term deferred revenue of \$2.3 million and \$8.9 million, respectively, related to its collaborations.

## ALKERMES PLC AND SUBSIDIARIES

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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

*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 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.

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

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

Product Sales, Net

The Company's product sales consist of sales of VIVITROL in the U.S. to wholesalers, specialty distributors and specialty pharmacies. Product sales are recognized from the sale of VIVITROL when persuasive evidence of an arrangement exists, title to the product and associated risk of loss has passed to the customer, which is considered to occur when the product has been received by the customer, the sales price is fixed or determinable and collectability is reasonably assured.

The Company records its product sales net of the following significant categories of sales discounts and allowances as a reduction of product sales at the time VIVITROL is shipped:

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

## ALKERMES PLC AND SUBSIDIARIES

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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

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 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 March 31, 2013, the product return reserve was estimated to be approximately 2% of product sales and amounts to \$3.2 million.

- *Co-pay assistance*—the Company has a program whereby a patient can receive up to \$500 per month towards their co-payment, co-insurance or deductible, provided the patient meets certain eligibility criteria. Reserves are recorded upon the sale of VIVITROL.

***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 March 31, 2013, the Company's risk management instruments consisted of an interest rate swap agreement and an interest rate cap agreement. The objective of the interest rate cap and swap agreements are to limit the impact of fluctuations in interest rates in earnings related to the Company's long-term debt. The interest rate cap and swap agreements are not designated as hedging instruments and are recorded at fair value. The associated gains and losses related to the interest rate cap are recognized in "Other income (expense), net" and 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.

## ALKERMES PLC AND SUBSIDIARIES

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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

*Foreign Currency*

The Company's functional and reporting currency is the U.S. dollar. Transactions in foreign currencies are recorded at the exchange rate prevailing on the date of the transaction. The resulting monetary assets and liabilities are translated into U.S. dollars at exchange rates prevailing on the subsequent balance sheet date. Gains and losses as a result of translation adjustments are recorded within "Other income (expense), net" in the accompanying consolidated statement of operations and comprehensive income (loss). During the years ended March 31, 2013, 2012 and 2011, the Company recorded a gain on foreign currency translation of \$0.1 million, \$0.5 million and none, respectively.

*Concentrations*

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

Customer	2013		2012		2011	
	Receivables	Revenue	Receivables	Revenue	Receivables	Revenue
Janssen	32%	35%	30%	48%	75%	83%
Acorda	15%	11%	11%	—	—	—

The Company generally holds its interest-bearing investments with major financial institutions and in accordance with documented investment policies and 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)	Year Ended March 31,		
	2013	2012	2011
Revenue by region:			
U.S.	\$ 380,565	\$ 212,859	\$ 76,700
Ireland	14,455	12,695	805
Rest of world	180,528	164,423	109,135
Assets by region:			
Current assets:			
U.S.	\$ 248,441	\$ 209,683	\$ 252,960
Ireland	159,544	122,077	—
Rest of world	603	7,393	—
Long-term assets:			
U.S.	\$ 233,369	\$ 217,406	\$ 199,488
Ireland	828,334	878,658	—
Rest of world	—	—	—

*Research and Development Expenses*

For each of the 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. 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.

*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



## ALKERMES PLC AND SUBSIDIARIES

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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

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

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

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

	Year Ended March 31,		
	2013	2012	2011
Expected option term	5 - 7 years	5 - 7 years	5 - 7 years
Expected stock volatility	47% - 49%	47% - 51%	46% - 51%
Risk-free interest rate	0.61% - 1.18%	0.82% - 2.5%	1.11% - 3.42%
Expected annual dividend yield	—	—	—

*Time-Vested Restricted Stock Units*

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

**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. 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 common shares divided by the weighted average number of shares outstanding. For the calculation of diluted earnings per share, the Company uses the weighted average number of shares outstanding, as adjusted for the effect of potential dilutive securities, including stock options and RSUs.

***Segment Information***

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

***Employee Benefit Plans******401(K) Plan***

The Company maintains a 401(k) retirement savings plan (the "401(k) Plan"), which covers substantially all of its U.S.-based employees. Eligible employees may contribute up to 100% of their eligible compensation, subject to certain Internal Revenue Service ("IRS") limitations. Through March 31, 2012, the Company matched 50% of the first 6% of employee pay and beginning April 1, 2012, the Company matches 100% of employee contributions up to the first 5% of employee pay, up to IRS limits. Employee and Company contributions are fully vested when made. During the years ended March 31, 2013, 2012 and 2011, the Company contributed \$4.1 million, \$2.5 million and \$2.0 million, respectively, to match employee deferrals under the 401(k) Plan.

**ALKERMES PLC AND SUBSIDIARIES****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)****2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)***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 years ended March 31, 2013, 2012 and 2011, the Company contributed \$3.7 million, \$1.8 million and none, respectively, in contributions to the defined contribution plan.

*Reclassifications*

An amount equal to \$45.8 million that was previously classified as "Amortization of acquired intangibles" in the year ended March 31, 2012, has been reclassified to "Impairment of long-lived assets" in the accompanying consolidated statements of operations and comprehensive income (loss) and statement of cash flows to conform to current period presentation.

Similarly, \$3.7 million and \$1.4 million that were previously classified as "Proceeds from the issuance of ordinary shares under share-based compensation arrangements" in the years ended March 31, 2012 and 2011, respectively, have been reclassified to "Employee taxes paid related to net share settlement of equity awards" in the accompanying consolidated statements of cash flows to conform to current period presentation.

*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.

**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.

## ALKERMES PLC AND SUBSIDIARIES

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

## 3. ACQUISITIONS (Continued)

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>

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

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

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

**ALKERMES PLC AND SUBSIDIARIES**

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

**3. ACQUISITIONS (Continued)**

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 7 of this Annual 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 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

## ALKERMES PLC AND SUBSIDIARIES

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

## 3. ACQUISITIONS (Continued)

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

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

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

Investments consist of the following:

(In thousands)	Amortized Cost	Gross Unrealized		Estimated Fair Value	
		Gains	Losses		
		Less than One Year	Greater than One Year		
<b>March 31, 2013</b>					
<b>Short-term investments:</b>					
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
	<u>123,128</u>	<u>64</u>	<u>(2)</u>	<u>—</u>	<u>123,190</u>
Money market funds	1,201	—	—	—	1,201
	<u>124,329</u>	<u>64</u>	<u>(2)</u>	<u>—</u>	<u>124,391</u>
<b>Long-term investments:</b>					
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
	<u>81,832</u>	<u>—</u>	<u>(43)</u>	<u>(162)</u>	<u>81,627</u>
Held-to-maturity securities:					
Certificates of deposit	1,200	—	—	—	1,200
	<u>83,032</u>	<u>—</u>	<u>(43)</u>	<u>(162)</u>	<u>82,827</u>
<b>Total investments</b>	<u>\$ 207,361</u>	<u>\$ 64</u>	<u>\$ (45)</u>	<u>\$ (162)</u>	<u>\$ 207,218</u>

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

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

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

(In thousands)	Year Ended March 31,		
	2013	2012	2011
Proceeds from the sales and maturities of marketable securities	\$ 258,937	\$ 323,028	\$ 385,511
Realized gains	\$ 39	\$ 47	\$ 77
Realized losses	\$ 5	\$ 11	\$ 32



## ALKERMES PLC AND SUBSIDIARIES

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

## 4. INVESTMENTS (Continued)

In addition, during the year ended March 31, 2013, the Company sold \$4.7 million of its held-to-maturity securities. These securities were held as collateral for certain lease agreements that ended in June 2012. There were no gains or losses recognized on the sale of these investments. The Company's available-for-sale and held-to-maturity securities at March 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	\$ 80,388	\$ 80,399	\$ 1,200	\$ 1,200
After 1 year through 5 years	124,572	124,418	—	—
Total	\$ 204,960	\$ 204,817	\$ 1,200	\$ 1,200

At March 31, 2013, the Company believes that the unrealized losses on its available-for-sale investments are temporary. The investments with unrealized losses consist primarily of corporate debt securities. In making the determination that the decline in fair value of these securities was temporary, the Company considered various factors, including but not limited to: the length of time each security was in an unrealized loss position; the extent to which fair value was less than cost; financial condition and near-term prospects of the issuers; and the Company's intent not to sell these securities, and the assessment that it is more likely than not that the Company would not be required to sell these securities before the recovery of their amortized cost basis.

The Company's investment in Acceleron Pharma, Inc. ("Acceleron") was \$8.7 million at March 31, 2013 and 2012, which is recorded within "Other assets" in the accompanying consolidated balance sheets. The Company accounts for its investment in Acceleron under the cost method as Acceleron is a privately-held company over which the Company does not exercise significant influence. The Company continues to monitor this investment to evaluate whether any decline in its value has occurred that would be other-than-temporary, based on the implied value from any recent rounds of financing completed by Acceleron, market prices of comparable public companies and general market conditions.

The Company's investment in Civitas Therapeutics, Inc. ("Civitas") was \$0.8 million and \$2.0 million at March 31, 2013 and 2012, respectively, which is recorded within "Other assets" in the accompanying consolidated balance sheets. The Company accounts for its investment in Civitas under the equity method as the Company has an approximately 11% ownership position in Civitas, has a seat on the board of directors and believes it may be able to exercise significant influence over the operating and financial policies of Civitas.

During the year ended March 31, 2012, Civitas issued 14.3 million shares of Series A preferred stock in exchange for \$12.5 million. The Company did not participate in the financing, however, it received 12.4% of these Series A preferred shares in accordance with the terms of its arrangement with Civitas and recorded an increase to its investment in Civitas of \$1.5 million. The Company has deferred the recognition of the gain on its investment in Civitas and will recognize it into "Other (expense) income, net", ratably over a period of approximately four years, in the Company's consolidated statement of operations and comprehensive income (loss). During the year ended March 31, 2013, the Company recorded a reduction in its investment in Civitas of \$1.2 million, which represented the Company's proportionate share of Civitas' net losses for this period.

## ALKERMES PLC AND SUBSIDIARIES

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

## 4. INVESTMENTS (Continued)

In December 2012, the Company and four other existing investors agreed to provide Civitas with a promissory note in the amount of \$9.0 million. The promissory note will pay 6% interest per year, is payable on demand at any time on or after December 18, 2013, and is convertible into either common or preferred shares of Civitas upon a majority vote of the promissory note holders on or after December 18, 2013, or in the event of a qualified financing as defined in the Note Purchase Agreement. The Company's share of the promissory note, \$1.1 million, was recorded within "Prepaid expenses and other current assets" in the accompanying consolidated balance sheets.

## 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)	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	—
International government agency debt securities	13,156	—	13,156	—
Corporate debt securities	29,510	—	29,510	—
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>

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

## ALKERMES PLC AND SUBSIDIARIES

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

## 5. FAIR VALUE (Continued)

The following table is a rollforward of the fair value of the Company's investments whose fair value was determined using Level 3 inputs at March 31, 2013:

(In thousands)	Fair Value
Balance, April 1, 2012	\$ 10,656
Investments transferred into Level 3	1,579
Investments transferred out of Level 3	(12,247)
Total unrealized gains included in comprehensive loss	12
Balance, March 31, 2013	\$ —

The Company transfers its financial assets and liabilities measured at fair value on a recurring basis between fair value hierarchies at the end of each reporting period. During the year ended March 31, 2013, the Company transferred \$87.1 million of its investments in U.S. government agency debt securities and \$3.1 million of its investments in international government agency debt securities from Level 1 to Level 2 as the Company had limited visibility into their trading volumes. There were no transfers of any securities from Level 2 to Level 1 during the year ended March 31, 2013. Also, during the year ended March 31, 2013, there were two securities transferred from Level 3 to Level 2 as trading resumed for these securities.

A third-party pricing service was used to determine the estimated fair value of the Company's securities. The third-party pricing service develops its estimate of fair value through a proprietary model using variables including reportable trades and last trade date, bids and offers, trading frequency, benchmark yields, credit spreads and other industry and economic events. The Company validates the prices provided by its third-party pricing service by reviewing their pricing methods and matrices, obtaining market values from other pricing sources, analyzing pricing data in certain instances and confirming the activity in the relevant markets. After completing its validation procedures, the Company did not adjust or override any fair value measurements provided by its pricing services at March 31, 2013.

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

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

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

## ALKERMES PLC AND SUBSIDIARIES

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

## 5. FAIR VALUE (Continued)

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 consist 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 "2013 Term Loans"). The estimated fair value of these term loans, which was based on quoted market price indications (Level 2 in the fair value hierarchy) and may not be representative of actual values that could have been or will be realized in the future at March 31, 2013, was as follows:

(In thousands)	Carrying Value	Estimated Fair Value
Term Loan B-1	\$ 296,029	\$ 298,375
Term Loan B-2	\$ 72,979	\$ 73,308

## 6. INVENTORY

Inventory consists of the following:

(In thousands)	March 31,	
	2013	2012
Raw materials	\$ 13,506	\$ 12,841
Work in process	13,842	9,569
Finished goods(1)	16,135	16,968
Consigned-out inventory(2)	—	381
Inventory	\$ 43,483	\$ 39,759

- (1) At March 31, 2013 and 2012, the Company had \$0.6 million and \$1.3 million, respectively, of finished goods inventory located at its third party warehouse and shipping service provider.
- (2) At March 31, 2012, consigned-out inventory related to VIVITROL inventory in the distribution channel for which the Company had not recognized revenue. As previously disclosed, in August 2012, the Company changed the way in which revenue is recognized on VIVITROL product sales, and, consequently, it no longer expects to have consigned-out inventory.

## ALKERMES PLC AND SUBSIDIARIES

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

## 7. PROPERTY, PLANT AND EQUIPMENT

Property, plant and equipment consist of the following:

(In thousands)	March 31,	
	2013	2012
Land	\$ 8,357	\$ 8,891
Building and improvements	141,092	127,583
Furniture, fixture and equipment	197,743	189,262
Leasehold improvements	24,137	45,798
Construction in progress	39,399	44,768
Subtotal	410,728	416,302
Less: accumulated depreciation	(122,293)	(113,307)
Total property, plant and equipment, net	\$ 288,435	\$ 302,995

The Company reclassified \$11.5 million of "Furniture, fixtures, and equipment" and \$0.7 million of "Land" at March 31, 2012 as "Buildings and improvements" to revise prior period presentation. Depreciation expense was \$31.9 million, \$22.5 million and \$8.7 million for the years ended March 31, 2013, 2012 and 2011, respectively.

During the year 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 determined using level 3 inputs including internally established estimates and the selling prices of similar assets. Also, during the years ended March 31, 2013 and 2012, the Company wrote off furniture, fixtures and equipment that had a carrying value of less than \$0.1 million at the time of disposition and received proceeds from the sales of furniture, fixtures and equipment of less than \$0.1 million.

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.

## ALKERMES PLC AND SUBSIDIARIES

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

## 8. GOODWILL AND INTANGIBLE ASSETS

Goodwill and intangible assets consists of the following:

(In thousands)	Weighted Amortizable Life	March 31, 2012			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	\$ (17,734)	\$ 481,966	\$ 499,700	\$ (50,143)	\$ 449,557
NanoCrystal technology	13	74,600	(1,839)	72,761	74,600	(5,373)	69,227
OCR technology	12	66,300	(3,182)	63,118	66,300	(9,091)	57,209
Trademark	—	2,600	(2,600)	—	—	—	—
Total finite-lived intangible assets		\$ 643,200	\$ (25,355)	\$ 617,845	\$ 640,600	\$ (64,607)	\$ 575,993
Indefinite-lived intangible assets							
IPR&D	—	45,800	(45,800)	—	—	—	—
Total		\$ 689,000	\$ (71,155)	\$ 617,845	\$ 640,600	\$ (64,607)	\$ 575,993

During the three months ended December 31, 2012, 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) budgeted 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.

The Company determined that the fair value of its reporting unit was substantially in excess of its respective carrying value and there was no impairment in the value of this asset as of October 31, 2012.

During the three months ended March 31, 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, and classified as IPR&D, which indicated that the assets may be impaired. As such, the Company performed an analysis to measure the amount of the impairment loss, if any. The Company performed the valuation of its IPR&D from the viewpoint of a market participant through the use of a discounted cash flow model. The model contained certain key assumptions, including the cost to bring the pre-clinical products through the clinical trial and regulatory approval process, the gross margin a market participant would expect to earn if the products were approved for sale, the cost to sell the approved product and a discount factor based on an industry average weighted average cost of capital. Based on the analysis performed, the Company

## ALKERMES PLC AND SUBSIDIARIES

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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

determined that the IPR&D was impaired and recorded an impairment charge of \$45.8 million within "Impairment of long-lived assets" in the accompanying statement of operations and comprehensive income (loss).

The Company recorded \$41.9 million and \$25.4 million of amortization expense related to its finite-lived intangible assets during the years ended March 31, 2013 and 2012, respectively. Based on the Company's most recent analysis, amortization of intangible assets included within its consolidated balance sheet at March 31, 2013, is expected to be approximately \$50.0 million, \$60.0 million, \$65.0 million, \$70.0 million and \$70.0 million in the fiscal years ending March 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 asset 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)	March 31,	
	2013	2012
Accounts payable	\$ 18,282	\$ 18,400
Accrued compensation	30,432	25,023
Accrued interest	970	2,472
Accrued other	27,226	33,259
Total accounts payable and accrued expenses	<u>\$ 76,910</u>	<u>\$ 79,154</u>

**10. RESTRUCTURING**

On April 4, 2013, the Company, approved a restructuring plan related to its Athlone, Ireland manufacturing facility consistent with the evolution of the Company's product portfolio and designed to improve operational performance for the future.

Under the restructuring plan, the Company will terminate manufacturing services for certain older products becoming uneconomic 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 during fiscal year 2014 and, for certain of these products, into fiscal year 2015.

As a result of the termination of these services, it is contemplated that the Company will also implement a corresponding reduction in headcount of up to 130 employees. In connection with the Plan, the Company recorded restructuring charges consisting of the following within "Restructuring" in

## ALKERMES PLC AND SUBSIDIARIES

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

## 10. RESTRUCTURING (Continued)

the accompanying consolidated statements of operations and comprehensive income (loss), (in thousands):

Severance	\$ 12,100
Outplacement services	200
<b>Total</b>	<b>\$ 12,300</b>

This Plan is expected to result in estimated annual cost savings of between \$15.0 million to \$20.0 million by fiscal year 2016 and beyond. The total amount of the restructuring charges is accrued at March 31, 2013. As part of the Plan, the Company also expects to incur non-cash charges resulting from the accelerated depreciation of certain manufacturing assets, which are currently estimated to be approximately \$10.0 million in fiscal year 2014 and \$7.0 million in fiscal year 2015.

## 11. LONG-TERM DEBT

Long-term debt consists of the following:

(In thousands)	March 31, 2013	March 31, 2012
Term Loan B-1, due September 25, 2019	\$ 296,029	\$ —
Term Loan B-2, due September 25, 2016	72,979	—
First Lien Term Loan, due September 16, 2017	—	306,822
Second Lien Term Loan, due September 16, 2018	—	137,638
<b>Total</b>	<b>369,008</b>	<b>444,460</b>
Less: current portion	(6,750)	(3,100)
<b>Long-term debt</b>	<b>\$ 362,258</b>	<b>\$ 441,360</b>

*Term Loans*

In September 2012, the Company entered into an amendment (the "Refinancing") to the first lien term loan facility (the "First Lien Term Loan") pursuant to which the First Lien Term Loan was amended and restated to, among other things, provide for a new tranche of term loans in an amount equal to \$375.0 million, the proceeds of which, together with cash-on hand of approximately \$75.0 million, were used to repay in full all monies due pursuant to the second lien term loan facility (the "Second Lien Term Loan" and together with the First Lien Term Loan, the "2012 Term Loans"). The new term loan facility includes the 2013 Term Loans and each of the 2013 Term Loans included a LIBOR floor of 1.0%.

In February 2013, the Company further amended the 2013 Term Loans (the "Repricing") to secure: (i) a reduction in interest payable under Term Loan B-1 to LIBOR plus 2.75% and a decrease in the LIBOR floor to 0.75%; (ii) a reduction in interest payable under Term Loan B-2 to LIBOR plus 2.75% and a decrease in the LIBOR floor to 0%; and (iii) a shortened time period, from one year to six months, during which a refinancing of the 2013 Term Loans, as described in the amended and restated credit agreement, would trigger a 1% prepayment premium.



## ALKERMES PLC AND SUBSIDIARIES

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

## 11. LONG-TERM DEBT (Continued)

Term Loan B-1 was issued with a principal balance of \$300.0 million, an original issue discount of \$3.0 million and 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, an original issue discount of \$0.4 million and 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 2013 Term Loans are guaranteed by certain subsidiaries of the Company (the "Guarantors") and is secured by a first priority lien on substantially all of the assets and properties of the Company and the Guarantors (subject to certain exceptions and limitations).

Scheduled maturities with respect to the 2013 Term Loans are as follows (in thousands):

<b>Fiscal Year:</b>	
2014	\$ 6,750
2015	6,750
2016	6,750
2017	64,875
2018	3,000
Thereafter	283,500
Total	<u>\$ 371,625</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. Commencing with the completion of the Company's fiscal year ended March 31, 2014, the Company is subject to mandatory prepayments of principal if certain excess cash flow thresholds, as defined in the 2013 Term Loans, are met. The Company may make prepayments of principal without premium or penalty, however, in the event that, prior to September 25, 2013, the Company prepays any of Term Loan B-1 or Term Loan B-2 pursuant to a repricing transaction or an amendment of the Term Loan Facility that results in a repricing transaction, the Company will be subject to a prepayment premium of 1% of the amount of the term loan being repaid or the aggregate amount of the applicable term loan outstanding immediately prior to such amendment.

The 2013 Term Loans have 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 2013 Term Loans include a number of restrictive covenants that, among other things and subject to certain exceptions and baskets, impose operating and financial restrictions on the Company and certain of its subsidiaries. The 2013 Term Loans also contain customary affirmative covenants and events of default. The Company was in compliance with its debt covenants at March 31, 2013.

The Refinancing was a restructuring of the 2012 Term Loans 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 2013 Term Loans were considered substantially different from the 2012 Term Loans if the present value of the cash flows under the 2013 Term Loans was at least 10% different from the present value of the remaining cash flows under the 2012 Term Loans (commonly referred to as the "10% Test"). The

## ALKERMES PLC AND SUBSIDIARIES

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

## 11. LONG-TERM DEBT (Continued)

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 2013 Term Loans were accounted for as a debt extinguishment.

The Repricing was a restructuring of the 2013 Term Loans 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 Debt 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 2013 Term Loans.

As the 2012 and 2013 Term Loans 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 2013 Term Loans 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 year 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
<b>Extinguished debt:</b>			
Unamortized deferred financing costs	\$ 4,600	\$ 1,566	\$ 6,166
Unamortized original issue discount	2,657	1,435	4,094
<b>Modified debt:</b>			
Debt financing costs	1,967	807	2,772
Original issue discount	105	—	105
Prepayment penalty	2,800	3,733	6,533
<b>Total</b>	<b>\$ 12,129</b>	<b>\$ 7,541</b>	<b>\$ 19,670</b>

## ALKERMES PLC AND SUBSIDIARIES

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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

At March 31, 2013, the Company's balance of unamortized deferred financing costs and unamortized original issue discount costs were \$3.3 million and \$2.6 million, respectively. These costs are being amortized to interest expense over the estimated repayment period of the 2013 Term Loans using the effective interest method. During the years ended March 31, 2013 and 2012, the Company had amortization expense of \$5.8 million and \$3.5 million, respectively, related to deferred financing costs and original issue discount.

**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 expires in December 2013, has a notional value of \$160.0 million and is 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 years ended March 31, 2013 and 2012. At March 31, 2013, this contract has an immaterial balance included within "Other assets" in the accompanying consolidated balance sheets.

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 bear 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 years 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 and, accordingly, the Company reclassified its unrealized losses of \$0.6 million to "Interest expense" in the accompanying consolidated statement of operations and comprehensive income (loss). The following table summarizes the beginning and ending accumulated derivative loss for the interest rate swap (in thousands):

Unrealized losses included in accumulated other comprehensive income at March 31, 2012	\$ (522)
Unrealized losses incurred during the year ended March 31, 2013	(72)
Reclassification of unrealized losses to realized losses during the year ended March 31, 2013	594
Unrealized losses included in accumulated other comprehensive income at March 31, 2013	<u>\$ —</u>

**ALKERMES PLC AND SUBSIDIARIES**
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**
**12. DERIVATIVE INSTRUMENTS (Continued)**

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

(In thousands)	Balance Sheet Location	Fair Value	
		March 31, 2013	March 31, 2012
<i>Interest rate swap</i>			
Liability derivative not designated as a cash flow hedge	Other long-term liabilities	\$ (541)	—
Liability derivative designated as a cash flow hedge	Other long-term liabilities	\$ —	(522)

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

(In thousands)	Year Ended March 31,		
	2013	2012	2011
<b>Numerator:</b>			
Net income (loss)	\$ 24,983	\$ (113,678)	\$ (45,540)
<b>Denominator:</b>			
Weighted average number of ordinary shares outstanding	131,713	114,702	95,610
<b>Effect of dilutive securities:</b>			
Stock options	4,025	—	—
Restricted stock units	1,362	—	—
Dilutive ordinary share equivalents	5,387	—	—
Shares used in calculating diluted earnings (loss) per share	137,100	114,702	95,610

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)	Year Ended March 31,		
	2013	2012	2011
Stock options	4,497	8,299	13,357
Restricted stock units	—	1,205	936
<b>Total</b>	<b>4,497</b>	<b>9,504</b>	<b>14,293</b>

## ALKERMES PLC AND SUBSIDIARIES

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

## 14. SHAREHOLDERS' EQUITY

*Share Repurchase Programs*

On September 16, 2011, the board of directors authorized the continuation of the Alkermes, Inc. share repurchase program to repurchase up to \$215.0 million of the Company's ordinary shares at the discretion of management from time to time in the open market or through privately negotiated transactions. At March 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 years ended March 31, 2013 and 2012, the Company did not acquire any shares of outstanding ordinary shares under the repurchase program.

## 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)	Year Ended March 31,		
	2013	2012	2011
Cost of goods manufactured and sold	\$ 4,375	\$ 2,962	\$ 1,725
Research and development	9,078	8,784	6,218
Selling, general and administrative	21,263	17,080	11,889
Total share-based compensation expense	<u>\$ 34,716</u>	<u>\$ 28,826</u>	<u>\$ 19,832</u>

At March 31, 2013, 2012 and 2011, \$0.6 million, \$0.4 million and \$0.6 million, respectively, of share-based compensation expense was capitalized and recorded as "Inventory" in the consolidated balance sheets.

*Share-based Compensation Plans*

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

At March 31, 2013, there were 9.8 million shares of ordinary shares available for issuance under the Company's stock plans. The 2011 Plan provides that awards other than stock options will be counted against the total number of shares available under the plan in a 1.8-to-1 ratio and the 2008

## ALKERMES PLC AND SUBSIDIARIES

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

## 15. SHARE-BASED COMPENSATION (Continued)

Plan provides that awards other than stock options will be counted against the total number of shares available under the plan in a 2-to-1 ratio.

*Stock Options*

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

	Number of Shares	Weighted Average Exercise Price
Outstanding, April 1, 2012	17,359,760	\$ 13.68
Granted	2,535,500	\$ 16.84
Exercised	(3,052,642)	\$ 11.26
Forfeited	(334,063)	\$ 14.98
Expired	(57,451)	\$ 20.12
Outstanding, March 31, 2013	16,451,104	\$ 14.57
Exercisable, March 31, 2013	10,321,840	\$ 14.13

The weighted average grant date fair value of stock options granted during the years ended March 31, 2013, 2012 and 2011 was \$8.11, \$8.00 and \$5.92, respectively. The aggregate intrinsic value of stock options exercised during the years ended March 31, 2013, 2012 and 2011 was \$28.1 million, \$11.1 million and \$2.0 million, respectively.

At March 31, 2013, there were 6.0 million stock options expected to vest with a weighted average exercise price of \$15.27 per share, a weighted average contractual remaining life of 8.3 years and an aggregate intrinsic value of \$50.5 million. At March 31, 2013, the aggregate intrinsic value of stock options exercisable was \$98.8 million with a weighted average remaining contractual term of 4.4 years. The number of stock options expected to vest is determined by applying the pre-vesting forfeiture rate to the total outstanding options. The intrinsic value of a stock option is the amount by which the market value of the underlying stock exceeds the exercise price of the stock option.

At March 31, 2013, there was \$20.3 million of unrecognized compensation cost related to unvested stock options, which is expected to be recognized over a weighted average period of approximately 1.9 years. Cash received from option exercises under the Company's award plans during the years ended March 31, 2013 and 2012 was \$34.4 million and \$20.9 million, respectively. The Company issued new shares upon option exercises during the years ended March 31, 2013 and 2012.

## 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:

	Number of Shares	Weighted Average Grant Date Fair Value
Unvested, April 1, 2012	2,114,176	\$ 13.45
Granted	1,032,530	\$ 16.55
Vested	(799,935)	\$ 12.41
Forfeited	(120,000)	\$ 15.70
Unvested, March 31, 2013	<u>2,226,771</u>	<u>\$ 15.14</u>

The weighted average grant date fair value of time-vested RSUs granted during the years ended March 31, 2013, 2012 and 2011 was \$16.55, \$17.91 and \$11.74, respectively. The total fair value of time-vested RSUs that vested during the years ended March 31, 2013, 2012 and 2011 was \$9.9 million, \$6.1 million and \$4.0 million, respectively.

At March 31, 2013, there was \$14.0 million of total unrecognized compensation cost related to unvested time-vested RSUs, which will be recognized over a weighted average remaining contractual term of 1.9 years.

*Performance-Based Restricted Stock Units*

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

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

ALKERMES PLC AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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. The licenses granted to Janssen expire on a country-by-country basis upon the later of (i) the expiration of the last patent claiming the product in such country or (ii) fifteen years after the date of the first commercial sale of the product in such country, provided that in no event will the license granted to Janssen expire later than the twentieth anniversary of the first commercial sale of the product in such country, with the exception of certain countries where the fifteen-year limitation shall pertain regardless. After expiration, Janssen retains a non-exclusive, royalty-free license to manufacture, use and sell RISPERDAL CONSTA. 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 \$98.6 million, \$129.8 million, and \$116.2 million during the years ended March 31, 2013, 2012 and 2011, respectively. Under its agreements with Janssen, the Company recognized royalty revenues related to RISPERDAL CONSTA of \$35.0 million, \$38.5 million and \$38.1 million during the years ended March 31, 2013, 2012 and 2011, respectively.



ALKERMES PLC AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

16. COLLABORATIVE ARRANGEMENTS (Continued)

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 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 royalty payments may be reduced in any country based on lack of patent coverage or patent litigation, or where competing products achieve certain minimum sales thresholds. The licenses granted to Janssen expire on a country-by-country basis upon the later of (i) March 31, 2019 or (ii) the expiration of the last of the patents claiming the product in such country. After expiration, Janssen retains a non-exclusive, royalty-free license to develop, manufacture and commercialize the product.

Under its license agreement with Janssen, there are no further development milestones to be earned by the Company related to INVEGA SUSTENNA/XEPLION.

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 \$63.5 million, \$18.0 million and none during the years ended March 31, 2013, 2012 and 2011, 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 sales of AMPYRA/FAMPYRA by Acorda or its sublicensee, Biogen Idec. This royalty payment may be reduced in any country based on lack of patent coverage, competing products achieving certain minimum sales thresholds, and whether Alkermes manufactures the product.

Acorda has the right to terminate the license agreement upon 90 days' written notice. The Company has the right to terminate the license agreement for countries in which Acorda fails to launch a product within a specified time after obtaining the necessary regulatory approval or fails to file regulatory approvals within a commercially reasonable time after completion and receipt of positive data from all preclinical and clinical studies required for filing a marketing authorization application. If the Company terminates Acorda's license in any country, the Company is entitled to a license from Acorda of its patent rights and know-how relating to the product as well as the related data, information and regulatory files, and to market the product in the applicable country, subject to an initial payment equal to Acorda's cost of developing such data, information and regulatory files and to ongoing royalty payments to Acorda. Subject to the termination of the license agreement, licenses granted under the license agreement terminate on a country-by-country basis on the later of

ALKERMES PLC AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

16. COLLABORATIVE ARRANGEMENTS (Continued)

(i) September 2018 or (ii) the expiration of the last to expire of our patents or the existence of a threshold level of competition in the marketplace.

Under its commercial manufacturing supply agreement with Acorda, the Company manufactures and supplies AMPYRA/FAMPYRA for Acorda (and its sub-licensees). Under the terms of the agreement, Acorda may obtain up to 25% of its total annual requirements of product from a second-source manufacturer. The Company receives royalties equal to 8% of net selling price for all product manufactured by it and a compensating payment for product manufactured and supplied by a third party. The Company may terminate the supply agreement upon 12 months' prior written notice to Acorda and either party may terminate the supply agreement following a material and uncured breach of the supply or license agreement or the entry into bankruptcy or dissolution proceedings of the other party. In addition, subject to early termination of the supply agreement noted above, the supply agreement terminates upon the expiry or termination of the license agreement.

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;
- Upon the acceptance of an NDA by the FDA: \$1.0 million;
- Upon the approval of the NDA by the FDA: \$1.5 million; and
- Upon 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,

ALKERMES PLC AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

16. COLLABORATIVE ARRANGEMENTS (Continued)

regulatory exclusivity and/or the absence of significant market competition. These financial obligations survive termination.

During the years ended March 31, 2013, 2012 and 2011, the Company recognized \$65.0 million, \$25.8 million and none respectively, of revenue from its arrangements with Acorda.

***Bristol-Myers***

In May 2000, the Company entered into a development and license agreement with Amylin, now a wholly-owned subsidiary of Bristol-Myers, for the development of exendin products falling within the scope of its patents, which includes the once-weekly formulation of exenatide, BYDUREON. Pursuant to the development and license agreement, Bristol-Myers 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. The Company received milestone payments upon the achievement of certain development and commercialization goals, and there are no further milestones to be earned under the agreements. In October 2005 and in July 2006, the Company amended the development and license agreement. Under the amended agreement, the Company is responsible for formulation and is principally responsible for non-clinical development of any products that may be developed pursuant to the agreement and for manufacturing these products for use in early-phase clinical trials.

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

In conjunction with the 2005 amendment of the development and license agreement with Bristol-Myers, the Company reached an agreement regarding Bristol-Myers' construction of a manufacturing facility for BYDUREON and certain technology transfer related thereto. The facility and technology transfer of the Company's manufacturing processes was completed in 2009. Bristol-Myers is responsible for the manufacture of BYDUREON and operates the facility.

Until December 31 of the tenth full calendar year following the year in which the first commercial sale of BYDUREON occurs, the Company will receive royalties equal to 8% of net sales from the first 40 million units of BYDUREON sold in any particular year and 5.5% of net sales from units sold beyond the first 40 million units for that year. Thereafter, during the term of the development and license agreement, the Company will receive royalties equal to 5.5% of net sales of products sold. The Company received milestone payments upon the achievement of certain development and commercialization goals, and there are no further milestones to be earned under the agreements.

## ALKERMES PLC AND SUBSIDIARIES

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

## 16. COLLABORATIVE ARRANGEMENTS (Continued)

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

During the years ended March 31, 2013, 2012 and 2011, the Company recognized \$23.8 million, \$18.8 million and \$2.9 million, respectively, of revenue from its arrangements with Bristol-Myers.

## 17. INCOME TAXES

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

(In thousands)	Year Ended March 31,		
	2013	2012	2011
Current income tax provision (benefit):			
U.S. federal	\$ 8,152	\$ 7,321	\$ (756)
U.S. state	2,588	6,649	30
Rest of world	1,758	28	—
Deferred income tax (benefit) provision:			
Ireland	(1,961)	(4,551)	—
U.S. federal	—	(10,024)	(206)
U.S. state	(79)	(137)	(19)
Total tax provision (benefit)	<u>\$ 10,458</u>	<u>\$ (714)</u>	<u>\$ (951)</u>

The current income tax provision for the year ended March 31, 2013 is primarily due to income earned by the Company during the fiscal year. An \$8.9 million benefit has been recorded to additional paid-in capital due to the utilization of NOL carryforwards that were created from the exercise of employee stock options. The current income tax provision for the year ended March 31, 2012 is primarily due to a provision of \$13.1 million on the taxable transfer of the BYDUREON intellectual property from the U.S. to Ireland, partially offset by a \$4.3 million benefit recorded to additional paid-in capital related to the utilization of certain NOL carryforwards resulting from the exercise of employee stock options. The current income tax benefit for the year ended March 31, 2011 is primarily related to a tax benefit for bonus depreciation pursuant to the *Small Business Jobs Act of 2010*.

The deferred income tax benefit for the year ended March 31, 2013 is primarily due to the reversals of deferred tax liabilities for intangible assets for which the book basis exceeds the tax basis. These intangible assets are being amortized for book purposes over the life of the intangible assets. The deferred income tax benefit in Ireland for the year ended March 31, 2012 is primarily due to a benefit from the partial release of the Irish deferred tax liability relating to acquired intellectual property that was established in connection with the Business Combination. The Company also recorded a benefit of \$9.9 million due to the partial release of an existing U.S. federal valuation allowance as a consequence of the Business Combination. The deferred income tax benefits for the year ended March 31, 2011 is primarily due to the recognition of \$0.2 million of income tax expense associated with the increase in the value of certain securities that it carried at fair market value.

## ALKERMES PLC AND SUBSIDIARIES

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

## 17. INCOME TAXES (Continued)

No provision for income tax has been provided on undistributed earnings of the Company's foreign subsidiaries because the Company considers such earnings to be indefinitely reinvested. Cumulative unremitted earnings of overseas subsidiaries totaled approximately \$39.0 million at March 31, 2013. In the event of distribution of those earnings in the form of dividends or otherwise, the Company would be subject to income taxes, subject to an adjustment, if any, for foreign tax credits, and foreign withholding taxes payable to certain foreign tax authorities. Determination of the amount of income tax liability that would be incurred is not practicable because of the complexities associated with this hypothetical calculation, however, unrecognized foreign tax credit carryforwards may be available to reduce some portion of the tax liability, if any.

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

(In thousands)	Year Ended March 31,		
	2013	2012	2011
Ireland	\$ (14,722)	\$ (36,711)	\$ —
U.S.	23,503	(84,858)	(46,491)
Rest of world	26,660	7,177	—
Income (loss) before provision for income taxes	<u>\$ 35,441</u>	<u>\$ (114,392)</u>	<u>\$ (46,491)</u>

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

(In thousands)	March 31,	
	2013	2012
Deferred tax assets:		
Irish NOL carryforwards	\$ 55,842	\$ 55,176
Tax benefit from the exercise of stock options	8,437	22,089
Share-based compensation	23,468	21,992
Tax credit carryforwards	10,543	12,294
U.S. federal and state NOL carryforwards	496	1,516
Alkermes Europe, Ltd. NOL carryforward	—	4,675
Deferred revenue	1,682	1,778
Intangible assets	277	748
Property, plant and equipment	653	—
Bonus accrual	7,034	5,849
Other	9,150	9,774
Less: valuation allowance	(86,714)	(107,128)
Total deferred tax assets	<u>30,868</u>	<u>28,763</u>
Deferred tax liabilities:		
Intangible assets	(40,968)	(43,606)
Property, plant and equipment	(19,607)	(19,049)
Other	(2,072)	—
Total deferred tax liabilities	<u>(62,647)</u>	<u>(62,655)</u>
Net deferred tax liabilities	<u>\$ (31,779)</u>	<u>\$ (33,892)</u>

## ALKERMES PLC AND SUBSIDIARIES

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

## 17. INCOME TAXES (Continued)

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

(In thousands)	Year Ended March 31,	
	2013	2012
Current deferred tax assets	\$ 5,824	\$ 656
Current deferred tax liabilities	—	(36)
Non-current deferred tax liabilities	(37,603)	(34,512)
Net deferred tax liabilities	<u>\$ (31,779)</u>	<u>\$ (33,892)</u>

In 2013, the Company identified an error in the prior year related to the separate identification and classification of accrued bonus in the net deferred tax disclosure of \$5.8 million. The impact of the accrued bonus was previously disclosed within the U.S. federal and state NOL carryforward line item in the prior year footnote. The Company believes that the accrued bonus deferred tax asset should have been disclosed as a separate line item within the footnote. There was no impact to the provision for income taxes for any period presented. The error had no effect on the Company's consolidated statements of operations and comprehensive income (loss), changes in shareholders' equity or cash flows for any period presented. The prior period amounts presented in the tax footnote herein have been revised to correct for this immaterial misstatement.

As of March 31, 2013, the Company had \$438.2 million of Irish NOL carryforwards, \$70.4 million of U.S. federal NOL carryforwards and \$8.7 million of state NOL carryforwards, which either expire on various dates through 2032 or can be carried forward indefinitely. These loss carryforwards are available to reduce certain future Irish and foreign taxable income, if any. These loss carryforwards are subject to review and possible adjustment by the appropriate taxing authorities. These loss carryforwards, which may be utilized in any future period, may be subject to limitations based upon changes in the ownership of the company's stock. The Company has performed a review of ownership changes in accordance with the U.S. Internal Revenue Code and the Company has determined that it is more likely than not that, as a result of the Business Combination, the Company has experienced a change of ownership. As a consequence, the Company's U.S. federal NOL carryforwards and tax credit carryforwards are subject to an annual limitation of \$127.0 million.

The Company records a deferred tax asset or liability based on the difference between the financial statement and tax basis of assets and liabilities, as measured by enacted tax rates assumed to be in effect when these differences reverse. In evaluating the Company's ability to recover its deferred tax assets, the Company considers all available positive and negative evidence including its past operating results, the existence of cumulative income in the most recent fiscal years, changes in the business in which the Company operates and its forecast of future taxable income. In determining future taxable income, the Company is responsible for assumptions utilized including the amount of Irish, U.S. and other foreign pre-tax operating income, the reversal of temporary differences and the implementation of feasible and prudent tax planning strategies. These assumptions require significant judgment about the forecasts of future taxable income and are consistent with the plans and estimates that the Company is using to manage the underlying businesses. As of March 31, 2013, the Company determined, based on the weight of all available positive and negative evidence, that it is more likely than not that a significant portion of the deferred tax assets will not be realized and a valuation allowance has been recorded. However, if the Company demonstrates consistent profitability in the

## ALKERMES PLC AND SUBSIDIARIES

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

## 17. INCOME TAXES (Continued)

future, the evaluation of the recoverability of the deferred tax asset could change and the valuation allowance could be released in part or in whole. The \$20.4 million decrease in the valuation allowance from the year ended March 31, 2012 to the year ended March 31, 2013 was primarily due to the utilization of NOLs. The Company has a \$31.8 million net deferred tax liability as of March 31, 2013 which is primarily related to book over tax basis differences in acquired intellectual property.

The tax benefit from stock option exercises included in the table above represents benefits accumulated prior to the adoption of Accounting Standards Codification ("ASC") Topic 718 ("ASC 718") that have not been realized. Subsequent to the adoption of ASC 718 on April 1, 2006, an additional \$34.5 million of tax benefits from stock option exercises, in the form of NOL carryforwards and tax credit carryforwards, have not been recognized in the financial statements and will be once they are realized. In total, the Company has approximately \$42.9 million related to certain NOL carryforwards and tax credit carryforwards resulting from the exercise of employee stock options, the tax benefit of which, when recognized, will be accounted for as a credit to additional paid-in capital rather than a reduction of income tax expense.

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

	Year Ended March 31,		
	2013	2012	2011
Statutory rate	12.5%	12.5%	34.0%
U.S. state income taxes, net of U.S. federal benefit	4.7%	(6.8)%	—%
R&D credit	—%	—%	1.4%
Share-based compensation	3.3%	(0.7)%	(2.6)%
Non-refundable withholding tax	4.7%	—%	—%
Permanent items	(8.2)%	—%	(0.6)%
Change in valuation allowance	(28.0)%	47.3%	(30.1)%
Rate differential	40.5%	(51.7)%	—%
Effective tax rate	29.5%	0.6%	2.1%

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

(In thousands)	Unrecognized Tax Benefits
Balance, April 1, 2010	\$ 3,373
Additions based on tax positions related to prior periods	1,560
Balance, March 31, 2011	4,933
Additions based on tax positions related to prior periods	1,741
Decreases due to lapse of statute of limitations	(68)
Balance, March 31, 2012	6,606
Additions based on tax positions related to prior periods	1,065
Decreases due to settlements with tax authorities	(413)
Balance, March 31, 2013	\$ 7,258

**ALKERMES PLC AND SUBSIDIARIES****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)****17. INCOME TAXES (Continued)**

In 2013, the Company identified errors related to uncertain tax positions driven by timing differences that were not identified and disclosed in the tabular rollforward in the prior years. The net impact of the error was \$1.5 million to the opening balance at April 1, 2010, \$1.5 million during 2011, \$3.0 million at March 31, 2011, \$1.2 million during 2012 and \$4.2 million at March 31, 2012. There was no impact to the net deferred tax assets or the provision for income taxes for any period presented. The error had no effect on the Company's consolidated balance sheets, statements of operations and comprehensive income (loss), changes in shareholders' equity or cash flows for any period presented. As a result, the Company believes the impact of this error is immaterial to previously issued financial statements. The prior period amounts presented in the tax footnote herein have been revised to correct for this immaterial misstatement.

\$0.2 million of the unrecognized tax benefits at March 31, 2013, if recognized, would affect the Company's effective tax rate before taking its' valuation allowance into consideration. The Company expects a net reduction in its unrecognized tax benefits in the amount of \$7.2 million due to the expected resolution of certain matters over the next twelve months. The Company has elected to include interest and penalties related to uncertain tax positions as a component of its provision for taxes. For the year ended March 31, 2013, the Company's accrued interest and penalties related to uncertain tax positions were not material.

Our major taxing jurisdictions include Ireland and the U.S. (federal and state). These jurisdictions have varying statutes of limitations. In the U.S., the 2007, 2008, and 2010 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 our Irish and U.S. loss carryforwards, certain tax returns from fiscal years 1993 onward may also be examined. These years generally remain open for three to four years after the loss carryforwards have been utilized. Fiscal years 2007, 2008 and 2010 for Alkermes, Inc., are currently under examination by the IRS. Fiscal year 2012 for Alkermes, Inc. is currently under examination by the state of Massachusetts. The Company does not believe there are any uncertain tax positions that have not been accounted for as a result of these examinations.

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

The Company leases certain of its offices, research laboratories and manufacturing facilities under operating leases with initial terms of one to twenty years, expiring through the year 2020. Certain of the leases contain provisions for extensions of up to ten years. These lease commitments are primarily related to the Company's corporate headquarters in Ireland and its corporate offices, R&D and



## ALKERMES PLC AND SUBSIDIARIES

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

## 18. COMMITMENTS AND CONTINGENCIES (Continued)

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

(In thousands)	Payment Amount
Fiscal Years:	
2014	\$ 3,838
2015	4,068
2016	3,970
2017	3,473
2018	3,650
Thereafter	8,350
	<u>27,349</u>
Less: estimated sublease income	(1,956)
Total future minimum lease payments	<u>\$ 25,393</u>

Rent expense related to operating leases charged to operations was \$5.0 million, \$4.2 million and \$5.4 million for the years ended March 31, 2013, 2012 and 2011, respectively. These amounts are net of sublease income of \$2.6 million, \$9.2 million and \$7.3 million earned in the years ended March 31, 2013, 2012 and 2011, respectively. In addition to its lease commitments, the Company has open purchase orders totaling \$76.0 million at March 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, results of operations, cash flows and financial condition.



Certain portions of this Exhibit have been omitted pursuant to a request for confidentiality. Such omitted portions, which are marked with brackets [ ] and an asterisk\*, have been separately filed with the Securities and Exchange Commission.

Execution Copy

ELAN PHARMA INTERNATIONAL LIMITED

AND

ACORDA THERAPEUTICS, INC.

---

DEVELOPMENT AND SUPPLEMENTAL AGREEMENT  
TO AMENDED AND RESTATED LICENSE  
AGREEMENT  
DATED 26 SEPTEMBER 2003 AS AMENDED AND  
SUPPLY AGREEMENT DATED 26 SEPTEMBER 2003

---

*Fampridine QD formulation*

---

Certain portions of this Exhibit have been omitted pursuant to a request for confidentiality. Such omitted portions, which are marked with brackets [ ] and an asterisk\*, have been separately filed with the Securities and Exchange Commission.

1.	Definitions and Interpretation	1
2.	Effect on Existing Agreements	3
3.	Development and Project Management (Development Product)	4
4.	Non-Elan Development Product	5
5.	Manufacture and Supply of Pre-Commercial Batches	6
6.	Registration	6
7.	Additional Financial Provisions	7
8.	Application of License Agreement	8
9.	Development Product Supply Agreement	9
10.	Non-Elan Development Product Supply Option	9
11.	Term and Termination	10
12.	Warranties	12
13.	Confidentiality	12
14.	Assignment	12
15.	General	13
Schedule 1	[*****]	17
Schedule 2	Work Plan Format	18
Schedule 3	Selection Criteria	19

---

Certain portions of this Exhibit have been omitted pursuant to a request for confidentiality. Such omitted portions, which are marked with brackets [ ] and an asterisk\*, have been separately filed with the Securities and Exchange Commission.

This Development and Supplemental Agreement (“Agreement”) is dated 14<sup>th</sup> day of January 2011 (the “Effective Date”).

PARTIES:

- (1) ELAN PHARMA INTERNATIONAL LIMITED, with an address at Monksland, Athlone, Co. Westmeath, Ireland (“Elan”) and
- (2) ACORDA THERAPEUTICS, INC., a Delaware corporation with an office at 15 Skyline Drive, Hawthorne, NY 10532, USA (“Acorda”)

BACKGROUND:

- (A) Elan Corporation, plc and Acorda are parties to (i) an Amended and Restated License Agreement dated 26 September 2003 pursuant to which, inter alia, Elan Corporation plc granted certain licenses under its intellectual property in respect of mono- and di- aminopyridines (as amended by Amendment No. 1 defined below, the “License Agreement”) and (ii) a Supply Agreement dated 26 September 2003 pursuant to which Elan Corporation agreed to supply Product to Acorda (as amended by Amendment No. 1 defined below, the “Supply Agreement”).
- (B) Elan is the successor in interest of Elan Corporation, plc.’s rights and obligations under the above described agreements.
- (C) By an Amendment No. 1 Agreement to the License Agreement and Supply Agreement and Consent to Sublicense dated 30 June 2009 (“Amendment No. 1”), Elan and Acorda made certain amendments to the said agreements. The License Agreement, Supply Agreement, and Amendment No. 1 are referred to herein as the “License and Supply Agreement.”
- (D) The Parties wish to pursue the development of one or more new formulations of the Compound and/or Alternate Compounds for existing and/or new indications and the commercialization of one of these additional formulations. The formulations will use Elan technologies upon the terms and conditions of the License and Supply Agreement and the terms and conditions set out below and/or third party technologies upon the terms and conditions set out below and specifically stated as applicable to a formulation developed using third party technologies. The Parties also wish to further to provide for certain clarifications in respect of the application of provisions of the license and Supply Agreement to formulations using Elan technologies.

TERMS:

The Parties agree as follows:

1. Definitions and Interpretation

1.1 Definitions:

In this Agreement the following expressions shall have the following meanings:

**“Agreement”** means this agreement, including its recitals, with the attached Schedules.

---

Certain portions of this Exhibit have been omitted pursuant to a request for confidentiality. Such omitted portions, which are marked with brackets [ ] and an asterisk\*, have been separately filed with the Securities and Exchange Commission.

**“Compound Know-How and First Product Know- How”** means the Elan Know-How that is or will be disclosed to Acorda in relation to the Compound or to the First Product under the License or Supply Agreement. For clarity and avoidance of doubt this term shall not include any knowledge, information, trade secrets, data or expertise which is generated or created by Elan in any Further Development Plan activities.

**“Compound and First Product Know-How License”** has the meaning set forth in Clause 4.7.

**“Development Product”** means the Product developed by Acorda and Elan pursuant to this Agreement, the Further Development Plan and one or more Work Plans, which Product incorporates the Development Technology. “Development Product” does not include the “First Product” but is a “Product” under the License Agreement.

**“Development Product Supply Agreement”** has the meaning set forth in Clause 9.

**“Development Technology”** means the technology which is developed by Elan and/or Acorda pursuant to this Agreement.

**“First Product”** means that specific formulation (twice daily) of the Product that is marketed as of the Effective Date in the United States under the trademark “Ampyrafl”.

**“Further Development** means the development plan for the Development Product, Plan” which as of the Effective Date is set out in Schedule 1, as it may be amended by Elan and Acorda from time to time and set out in any amendment to the Further Development Plan that may be generated in accordance with Clause 3.2 of this Agreement.

**“Non-Elan Developer”** means any individual or entity other than Elan (including Acorda).

**“Non-Elan Development** means a formulation of Compound or an Alternate **Product”** Compound developed or to be developed by a Non-Elan Developer to meet the Selection Criteria. For clarity, “Non-Elan Development Product” shall not be regarded as a “Product” for the purposes of the License and Supply Agreement or this Agreement.

---

Certain portions of this Exhibit have been omitted pursuant to a request for confidentiality. Such omitted portions, which are marked with brackets [ ] and an asterisk\*, have been separately filed with the Securities and Exchange Commission.

<b>“Non-Elan Party Election”</b>	has the same meaning as that set forth in Clause 10.2.
<b>“Selection Criteria”</b>	means the target criteria for the Development Product and for each Non-Elan Development Product, as specified to Non-Elan Developers and as may be amended from time to time, which as of the Effective Date are set forth in Schedule 3.
<b>“Work Plan”</b>	means each written plan for development of Product agreed upon by Acorda and Elan, which Work Plan sets forth the goals of the work, allocates the responsibilities of the parties for conducting the work, timelines, and any other terms and conditions agreed upon between the parties. All Work Plans shall be consecutively numbered and, upon execution by authorized representatives of the parties, shall be incorporated by reference into this Agreement.

1.2 **Interpretation:** In this Agreement:

- 1.2.1 capitalised expressions not specifically defined in this Agreement shall have the same meaning as in the License and Supply Agreement, as applicable;
- 1.2.2 references to clauses are to clauses of this Agreement unless stated otherwise; and
- 1.2.3 this Agreement shall otherwise be interpreted in the same manner as the License and Supply Agreement.

2. **Effect on Existing Agreements**

- 2.1 Except as expressly provided herein, the parties agree and acknowledge that the development, commercialization and commercial supply of the Development Product shall be governed by the License Agreement, the agreements incorporated by reference in the License Agreement, the Development Product Supply Agreement and in each case any amendments thereto (including but not limited to Amendment No 1). For clarity, the Development Plan does not apply to the Development Product or the Non-Elan Development Product.
- 2.2 For the purposes of clarity, the License Agreement as amended, the agreements incorporated by reference in the License Agreement, Supply Agreement and Amendment No. 1 shall continue to govern the development, commercialization and commercial supply of the First Product. For clarity and avoidance of doubt, the Parties hereby acknowledge that the consent granted by Elan to Acorda in Section 1 of the Amendment No. 1 is not modified by this Agreement.
- 2.3 At appropriate times during the Term, Elan and Acorda agree that they will discuss in good faith any clarifications as may be required to any operational provisions in the License and Supply Agreement to support the development, commercialization and commercial supply of any Development Product. Any such clarifications shall be set forth in an amendment to this Agreement (or other written, duly executed Elan/Acorda agreements), executed by authorized representatives of Acorda and Elan. The Parties agree that to the extent this Agreement specifically states that certain provisions of the License Agreement and the Supply Agreement apply to Non-Elan Development Product, any capitalized terms used within the License Agreement and Supply Agreement as so referenced shall have the meaning set forth in the License Agreement or the Supply Agreement, as the case may be, unless this

---

Certain portions of this Exhibit have been omitted pursuant to a request for confidentiality. Such omitted portions, which are marked with brackets [ ] and an asterisk\*, have been separately filed with the Securities and Exchange Commission.

Agreement specifically states otherwise.

3. **Development and Project Management (Development Product)**

- 3.1 Without prejudice to Acorda’s rights to cease development of the Development Product at any time, throughout the Term and in accordance with the Further Development Plan and the applicable Work Plan(s), Elan and Acorda shall use commercially reasonable efforts to develop Development Product in accordance with the Further Development Plan(s). For the purpose of clarity, Acorda, in its sole discretion, may choose to cease development of the Development Product in the event that Acorda determines that continuing such development is no longer commensurate with the achievement of its own business aims. The decision not to further develop, if made by Acorda, shall not be subject to review by the Committee nor shall it be subject to arbitration under Section 12.14 of the License Agreement.
- 3.2 The Further Development Plan and the applicable Work Plan(s) set forth the agreed respective responsibilities of Elan and Acorda with respect to the development of the Development Product. Without prejudice to Acorda’s right to cease development at any time during the term of the Further Development Plan, Elan and Acorda shall undertake their respective obligations under the Further Development Plan and the applicable Work Plan(s) on a collaborative basis and using commercially reasonable efforts. Changes may be made to the Further Development Plan by mutual, written agreement of the parties through the Committee referenced in Section 10 of the License Agreement, which written agreement shall be set forth in an amendment to the Further Development Plan and/or Work Plan, as applicable.

- 3.3 Detailed development work shall be agreed and set out by the parties in one or more Work Plans, which shall be in a form broadly similar to the Work Plan format attached hereto as Schedule 2. Each Work Plan must be mutually agreed by both parties and accepted and signed by a duly authorized representative of both parties. Executed Work Plans shall form a part of this Agreement.
- 3.4 Within two (2) weeks of the Effective Date of this Agreement, the parties will establish a project team (“**Project Team**”), which shall convene regularly to keep the parties fully informed as to their progress with its respective tasks and obligations under the Further Development Plan and Work Plan(s). The Project Team shall monitor the progress of such activities.
- 3.5 Elan and Acorda shall update each other at meetings of the Committee as to the progress of their respective obligations under the Further Development Plan and the Work Plan(s).
- 3.6 The parties shall co-operate in good faith through the Project Team and the Committee particularly with respect to unknown problems and contingencies and shall perform their respective obligations in a commercially reasonable, diligent and workmanlike manner and in accordance with all applicable laws, regulations and guidelines.
- 3.7 Provided that a party uses reasonable endeavours to meet its obligations under this Agreement, it shall have no liability to the other as a result of any failure or delay of the Development Product to achieve any of the goals set out in the Further Development Plan or a Work Plan(s), nor for any failure of a Development Product to obtain NDA Approval or Regulatory Approval.

#### **4. Non-Elan Development Product**

- 4.1 Acorda shall afford Elan a reasonable opportunity to develop a formulation meeting the Selection
- 

Certain portions of this Exhibit have been omitted pursuant to a request for confidentiality. Such omitted portions, which are marked with brackets [ ] and an asterisk\*, have been separately filed with the Securities and Exchange Commission.

Criteria, and Elan and Acorda shall reasonably cooperate to enable that opportunity. The parties further agree that the entry into this Agreement and the performance of the Further Development Plan set out in Schedule 1 meet this obligation in respect of Elan being afforded a reasonable opportunity and provided with the Selection Criteria for the Development Product, as they exist as of the Effective Date.

- 4.2 Subject to Clause 4.3, in the event that Acorda selects to commercialize the formulation of a Non-Elan Developer, Acorda shall discuss the reasons for its selection with Elan.
- 4.3 Elan acknowledges and agrees that the final decision on which formulation to develop and commercialize is within Acorda’s sole discretion and that such decision is not subject to review or dispute by Elan through the Committee nor is subject to the arbitration provisions set out in Section 12.14 of the License Agreement. Acorda shall promptly disclose any agreed key financial terms of any commercialization agreement with the Non- Elan Developer to Elan, which Elan shall maintain as confidential under the confidentiality provisions of Section 12.1 of the License Agreement.
- 4.4 Subject to the foregoing and to the other terms and conditions of this Agreement, Acorda shall be entitled, through itself or any sublicensees, to select and commercialize one Non- Elan Development Product meeting the Selection Criteria.
- 4.5 Acorda shall afford Elan a reasonable opportunity to develop any other formulations containing Compound or Alternate Compound not covered by this Agreement. For the avoidance of any doubt, nothing in this Agreement shall be deemed to constitute (i) Elan’s consent to the commercialisation of any other subsequent Non-Elan Development Product nor any Non-Elan Development Product that meets different selection criteria or (ii) a limitation on Acorda’s existing development rights under Section 12.15 of the License Agreement.
- 4.6 Where Acorda elects to commercialize a Non-Elan Development Product, Acorda and Elan shall generally coordinate and manage their business relationship relating to the commercialization of the Non-Elan Development Product through the Committee that is referred to in Article 10 of the License Agreement. The Committee shall also resolve any disputed issues (excluding any issues which may arise over Acorda’s formulation selection under Clause 4.3 or ceasing to develop or not developing Development Product under Clause 3.1) that may arise between the Parties per Section 10.3 of the License Agreement including submission to arbitration under Article 12.14. Through the Committee, Acorda shall keep Elan reasonably informed of those matters relating to the Non-Elan Development Product which reasonably affect Elan’s interests, including the general progress of development, objectives for and commercial performance of the Non-Elan Development Product, clinical and regulatory filings, sales performance and sales forecasts and any actual or threatened litigation or “paragraph IV certifications” pertaining to the Non-Elan Development Product.
- 4.7 Elan hereby grants to Acorda a non-exclusive, non-transferable (other than to a lawful assignee of the License Agreement) license (the “Compound Know-How and First Product Know-How license”) under the Compound Know-How and First Product Know-How to develop, package, use, import, export, make and have made (subject to Clause 10) Non-Elan Development Product in the Territory and, in addition, to promote, distribute, market, offer for sale and sell the one particular Non-Elan Development Product (if any) that Acorda finally selects to commercialize under this Clause 4 in the Territory. The part of Compound Know-How and First Product Know-How License that enables Acorda to promote, distribute, market, offer for sale and sell any finally selected Non-Elan Development Product shall be sub-licensable to Acorda’s existing sublicensee without Elan consent and to other sublicensees in accordance with the terms as set out in Section 2.3 of the License Agreement
- 

Certain portions of this Exhibit have been omitted pursuant to a request for confidentiality. Such omitted portions, which are marked with brackets [ ] and an asterisk\*, have been separately filed with the Securities and Exchange Commission.

for Product; provided that in each case such entity is responsible for commercializing Non-Elan Development Product. Acorda and any sublicensee it appoints to commercialize Non-Elan Development Product shall only share Compound Know-How and First Product Know-How with Non-Elan Developers other than itself on a strictly need-to know-basis. This Compound Know-How and First Product Know-How License shall commence as

of the Effective Date and shall end upon the expiry of Acorda's obligations to make payments to Elan in respect of the Non-Elan Development Product, and subject to such payments being duly made shall be irrevocable during that period.

4.8 For clarity, the foregoing provisions shall not be construed as conferring any right or license to use any intellectual property arising from Further Development Plan activities developed solely by Elan or jointly with Elan in connection with the development, manufacture or sale of a Non-Elan Development Product, nor as conferring any liability or obligations on Elan with respect to a Non-Elan Development Product other than as expressly set out Clause 4.7 and in the Non-Elan Development Product Supply Agreement and/or other agreement(s) entered into relating to the supply of Non-Elan Development Product by Elan entered into pursuant to Clause 10 (if any).

## 5. **Manufacture and Supply of Pre-Commercial Batches of Development Product**

5.1 Elan shall use commercially reasonable efforts to manufacture and supply to Acorda such quantity of the Development Product as it may reasonably require to perform its activities under the Further Development Plan and each applicable Work Plan.

5.2 Per Section 3.4 of the License Agreement, supply of Development Product shall be EXW such facility as may be specified in the applicable Work Plan or as Elan may nominate and Acorda shall reasonably approve, [\*\*\*\*\*].

5.3 Acorda's requests for Development Product shall clearly specify whether such use is for pre-clinical or clinical supply. Where Acorda requests Development Product for clinical supply, Elan shall manufacture it in accordance with phase specific cGMPs in addition to applicable laws and regulations.

5.4 Clauses 13.2 to 13.8 inclusive of the Supply Agreement (liability) shall apply *mutatis mutandis* in respect of the supply of pre-commercial supplies of Development Product.

## 6. **Registration**

6.1 Acorda shall be responsible, at its own expense, for conducting such pre-clinical and clinical studies as are required to obtain Regulatory Approval for the Development Product. Elan shall reasonably cooperate with Acorda in obtaining such approvals at Acorda's expense.

6.2 Elan will prepare and utilize a DMF (or similar structure for international filings) at Acorda's expense for the Development Product and Acorda shall have a right of reference to the extent required by any regulatory jurisdiction until such time, if any, as Acorda terminates all development programs related to Non-Elan Development Product. Upon receipt of notice of such termination, Elan will discontinue use of the DMF and promptly provide the relevant CMC information to Acorda in support of Acorda's regulatory filing(s), at Acorda's expense and otherwise in accordance with the provisions of Section 3.8 of the License Agreement.

---

Certain portions of this Exhibit have been omitted pursuant to a request for confidentiality. Such omitted portions, which are marked with brackets [ ] and an asterisk\*, have been separately filed with the Securities and Exchange Commission.

## 7. **Additional Financial Provisions**

7.1 Development Fees for Development Product. Acorda shall pay to Elan fees in respect of Elan's activities under this Agreement at a rate of FTE plus [\*\*\*\*\*], invoiced and payable monthly. Each invoice shall identify the particular work requested by Acorda and performed by Elan under the Work Plan(s) and Further Development Plan(s), as applicable. Further, the provisions of Sections 5.1.3 (development records) and 5.1.4 (third party development costs) of the License Agreement shall apply *mutatis mutandis*; provided, however, that in reference to third party development costs Elan shall have the right to charge Acorda for the time spent by Elan employees in administering the work conducted by such third parties at [\*\*\*\*\*] as well as the third party development costs incurred by Elan.

7.2 Non-Elan Development Product Compensation. Notwithstanding any contrary provision of the License Agreement, in consideration of Elan's agreement to permit Acorda to commercialize the Non-Elan Development Product on the terms and conditions herein and in consideration of the grant of the Compound Know-How and First Product Know-How License, Acorda shall pay to Elan:

7.2.1 [\*];

7.2.2 [\*];

7.2.3 [\*]; and

7.2.4 [\*];

in each case as if (a) defined terms [\*\*\*\*\*] and [\*\*\*\*\*] referred to the Non-Elan Development Product instead of the Product and as if (b) the references in Section 5.3.1 of the License Agreement and defined terms used therein to "Product" additionally referred to the Non-Elan Development Product.

7.3 Application of Rush Payments Agreement. For the avoidance of doubt, Acorda shall remain responsible to make payments to Elan under the Rush Payments Agreement in respect of the Development Product or the Non-Elan Development Product, as applicable, on the basis that "NSP" as used therein refers to such products respectively.

## 7.4 Ancillary.

7.4.1 Section 5.9 of the License Agreement (payments, reports and records) shall apply in respect of the Non-Elan Development Product *mutatis mutandis*.

7.4.2 Payments under Clause 7.2.1 shall be made upon provision of the Statement;

7.4.3 Payments under Clause 7.2.2 shall be made in accordance with the applicable supply agreement entered into pursuant to Clause 10, if applicable, and otherwise upon provision of the Statement.

7.4.4 In respect of payments under Clause 7.2.4 [\*\*\*\*\*], Sections 5.3.2 to 5.3.5 (payment terms) of the license Agreement shall apply *mutatis mutandis*.

For clarity and as stated above, the manner and method of payment for Non-Elan Development Product are identical to the equivalent terms set out for Product payments in the License Agreement.

---

Certain portions of this Exhibit have been omitted pursuant to a request for confidentiality. Such omitted portions, which are marked with brackets [ ] and an asterisk\*, have been separately filed with the Securities and Exchange Commission.

## 8. Application of License Agreement

In relation to clarifying the precise manner in which the license Agreement applies to the Development Product, in addition to specific citations to sections of the license Agreement herein, Elan and Acorda agree as follows:

8.1 Intellectual Property. At appropriate times during the Term and from time to time, Elan and Acorda shall prepare revised schedules of Elan Patent Rights and Acorda Patent Rights, reflecting such patents and patent applications as are incorporated and/or used in the Development Product.

8.2 License Provisions. For the purpose of clarification, Elan and Acorda agree that:

8.2.1 the reference in the definition of “Elan Patent Rights” to the infringement by the manufacture, use or sale of the Product is to be read as a reference to infringement by the manufacture, use or sale of the First Product or the Development Product; and

8.2.2 the references in the definition of “Elan Patent Rights” and “Elan Know How” to development “in connection with the Project” is to be read as if it additionally referred to development pursuant to this Agreement.

8.3 Regulatory Expressions. The definitions of “NDA”, “NDA Approval”, “Regulatory Approval”, and terms referring to those defined terms shall be construed as they relate to the First Product or the Development Product, as applicable.

8.4 Diligence. Subject to Acorda’s formulation selection right under Clause 4.3, Section 2.11 (Diligence) of the License Agreement shall apply in respect of the Non-Elan Development Product *mutatis mutandis*. In performing its obligations under Section 2.11 of the License Agreement, Acorda shall be entitled to select a commercially reasonable strategy Development Product or Non-Elan Development Product, as the case may be, on the other.

8.5 Royalties. In the event that (a) the Development Product is being commercially sold and (b) Elan is manufacturing one, but not both, of the First Product and the commercially sold Development Product, the Elan Royalty specified in Section 5.6 of the License Agreement shall be calculated separately for the First Product and the Development Product.

8.6 Committee. Article 10 (Committee) of the License Agreement shall be read as if it additionally referred to the Further Development Plan and its budget as appropriate. For clarity, nothing in this Agreement is intended to expand upon the oversight responsibility of the Committee with respect to Product as set forth in Article 10 of the License Agreement.

## 9. Development Product Supply Agreement

9.1 Not less than eighteen (18) months prior to the anticipated date of commercial launch of the Development Product, Elan and Acorda shall negotiate in good faith an amendment to the Supply Agreement or a new substantially similar supply agreement in respect of such Development Product (“**Development Product Supply Agreement**”), which Development Product Supply Agreement shall contain the financial terms set out in this Agreement and any other provisions of this Agreement that pertain to the Development Product, together with one or more quality agreements as appropriate. The decision as to whether to amend the existing Supply Agreement or to create a substantially similar supply agreement for Development Product shall be decided by the Committee.

---

Certain portions of this Exhibit have been omitted pursuant to a request for confidentiality. Such omitted portions, which are marked with brackets [ ] and an asterisk\*, have been separately filed with the Securities and Exchange Commission.

9.2 The price of the Development Product manufactured by Elan under the applicable Development Product Supply Agreement (or under the applicable amendment to the Supply Agreement) shall [\*\*\*\*\*]. The foregoing shall be in lieu of the price stated in Clauses 9.3 and 9.4 of the Supply Agreement.

9.3 Elan shall enable the use of a mutually agreed independent second source for manufacture of the Development Product upon terms substantially similar set out in Clause 7 of the Supply Agreement, as agreed upon by the Committee and as set out in the Development Product Supply Agreement.

9.4 Except as set out in this Clause 9, as may be operationally necessary for the manufacture of a Development Product, or as may otherwise be agreed by Elan and Acorda in the Development Product Supply Agreement, the terms of the Development Product Supply Agreement shall be the same as those set out in the Supply Agreement.

## 10. Non-Elan Development Product Supply Option



- 10.1 In the event that Acorda, chooses to commercialize a Non-Elan Development Product in accordance with Clause 4.4 of this Agreement, Elan shall have the first option to manufacture or have manufactured by an Affiliate all or a portion of the selected Non-Elan Development Product.
- 10.2 Within forty-five (45) days of the decision to proceed to commercialization of a Non-Elan Development Product (a **“Non-Elan Party Election”**), Acorda shall notify Elan in writing, and shall procure that Elan is provided within that period with such information as would information as Elan may reasonably request for the purpose of determining whether it wishes to undertake such manufacture. To this end, Acorda shall procure that the applicable Non-Elan Developer is made available and with Acorda in attendance and shall cooperate fully to answer queries which Elan may have in this regard, subject to the terms of a three-way confidential disclosure agreement to be entered into between Acorda, Elan and the Non-Elan Developer.
- 10.3 Within ninety (90) days of receipt of all such requested information, Elan shall notify Acorda in writing whether it is willing to and believes that it is able to manufacture such Non-Elan Development Product, and the portion of the Non-Elan Development Product it wishes to manufacture. If Elan does not so notify Acorda within that period, and to the extent of the portion which Elan is not willing to or does not believe that it will be able to manufacture, Acorda shall be entitled (but not obliged) to have such Non-Elan Development Product manufactured elsewhere.
- 10.4 In the event that Elan agrees to and is able to manufacture such Non-Elan Development Product:
- 10.4.1 Elan and Acorda shall negotiate in good faith the terms and conditions of, and enter into, a supply agreement consistent with this Clause 10 and otherwise with (a) non-financial terms similar to those contained in the Supply Agreement, to the extent feasible, and (b) the financial terms set out in Clause 7.2.2 (**“Non-Elan Development Product Supply Agreement”**); and
- 10.4.2 Elan shall and Acorda shall procure that the Non-Elan Developer negotiates in good faith a technology transfer agreement and plan for the purposes of enabling Elan to manufacture the Non-Elan Development Product. Each party shall be responsible for its own costs of all such activities and Acorda shall be responsible for any costs or expenses that may be invoiced by the Non-Elan Developer. Acorda shall be responsible at its own cost for
- 

Certain portions of this Exhibit have been omitted pursuant to a request for confidentiality. Such omitted portions, which are marked with brackets [ ] and an asterisk\*, have been separately filed with the Securities and Exchange Commission.

obtaining for Elan all intellectual property rights and licenses required to undertake such manufacture.

- 10.5 Elan shall maintain the right to protect and control any confidential or proprietary data of Elan as set forth in the License Agreement or any applicable confidentiality or other agreement which may be entered into by Elan.

## 11. **Term and Termination**

- 11.1 This Agreement shall commence on the Effective Date and shall continue in force until the expiry or termination of the License Agreement, howsoever arising, unless terminated earlier as set forth herein. In the event that any of the terms or provisions hereof are incurably breached by either Party, the non-breaching Party may immediately terminate this Agreement by written notice. In the event of any other breach, the non-breaching Party may terminate this Agreement by the giving of written notice to the breaching Party that this Agreement will terminate on the sixtieth (60th) day from notice unless cure is sooner effected. If the breaching Party has proposed a course of action to rectify the breach and is acting in good faith to rectify same but has not cured the breach by the sixtieth (60th) day, the said period shall be extended, at the sole discretion of the non-breaching party, by such period as is reasonably necessary to permit the breach to be rectified.
- 11.2 For the avoidance of doubt, termination of this Agreement pursuant to Clause 11.3 or 11.1 shall not of itself result in termination of the License Agreement or the Supply Agreement.
- 11.3 Upon Acorda’s notice to Elan of a Non-Elan Party Election, Elan’s and Acorda’s obligations in respect of those Work Plans concerning the Development Product not selected shall automatically terminate, subject to Clause 11.4 below.
- 11.4 Upon expiry or termination of this Agreement or upon the termination of obligations in respect of specific Work Plans, Elan shall provide Acorda with a timely estimate of any wind down costs and Acorda shall be responsible for:
- 11.4.1 payment in full for all work conducted by Elan under this Agreement (and authorized under the Further Development Plan and/or, as applicable, the specific Work Plans) up to the effective date of termination and the wind down costs of all terminated Work Plan and Further Development Plan activities; and
- 11.4.2 all uncancellable out of pocket costs reasonably incurred or committed prior to the effective date of termination by Elan in contemplation of the applicable Work Plan(s) and/or terminated Further Development Plan.
- 11.5 Clause 8 shall remain in force until expiry or termination of the License Agreement and Clause 3.7 shall remain in force indefinitely.
- 11.6 On a country by country basis, in respect of the Development Product, the following provisions shall continue in force until the latest of the following dates (the **“Development Product End Date”**):
- (a) ten (10) years starting from the date of First Commercial Sale of the Development Product in that country;
- 

Certain portions of this Exhibit have been omitted pursuant to a request for confidentiality. Such omitted portions, which are marked with brackets [ ] and an asterisk\*, have been separately filed with the Securities and Exchange Commission.

- (b) the expiry of the last to expire patent or patent application included in the Elan Patent Rights in that country;
- (c) the date on which no Elan Know-How remains capable of enforcement against third parties;
- (d) the loss of regulatory exclusivity in respect of the Development Product in that country; and
- (e) the existence of Competition in that country.

the said surviving provisions being: (i) Acorda's obligations under Sections 5.3, 5.5, 5.6 and 5.9 of the License Agreement; (ii) Acorda's obligations under the Rush Payments Agreement; (iii) the equivalent provisions in the applicable Development Product Supply Agreements to Clause 9.5 of the Supply Agreement, as if that provision referred to any Development Product purchased up to and including the Development Product End Date otherwise than pursuant to such Development Product Supply Agreement; and (iv) Clauses 4, 7.2 to 7.4 inclusive, 10, 13, 14 and 15 of this Agreement.

11.7 On a country by country basis, in respect of the Non-Elan Development Product selected for commercialisation, the provisions referred to below shall continue in force until the latest of the following dates (the "**Non-Elan Product End Date**"):

- (a) ten (10) years starting from the date of First Commercial Sale (as said term is defined in the License Agreement but in reference to Non-Elan Development Product rather the Product) of that Non-Elan Development Product in that country;
- (b) the expiry of the last to expire patent or patent application covering such Non-Elan Development Product which Acorda or any Affiliate or Designee owns, licenses or controls;
- (c) the date on which no knowledge, information, trade secrets, data or expertise covering such Non-Elan Development Product which Acorda or any Affiliate or Designee owns, licenses or controls remains capable of enforcement against third parties;
- (d) the loss of regulatory exclusivity in respect of such Non-Elan Development Product in that country; and
- (e) the existence of Competition in that country.

the said surviving provisions being Clauses 4, 7.2 to 7.4 inclusive, 10, 13, 14 and 15 of this Agreement.

11.8 Acorda and its Affiliates will not directly or indirectly market as a prescription medicine any other sustained release oral dosage form or transdermal form, containing the Compound or any other mono- or di-aminopyridine active agent, other than Product (including a Development Product), or the one Non-Elan Development Product (if any) selected for commercialisation, during the period in which Acorda has an obligation to make payments to Elan under this Agreement and for one year thereafter. The foregoing shall be in addition to the restrictions contained in Section 2.2 of the License Agreement, but for the purposes of that Section such selected Non-Elan Development Product shall not be considered an "Acorda Competing Product". For the avoidance of doubt this Clause 11.8 shall survive termination of this Agreement.

---

Certain portions of this Exhibit have been omitted pursuant to a request for confidentiality. Such omitted portions, which are marked with brackets [ ] and an asterisk\*, have been separately filed with the Securities and Exchange Commission.

## 12. Warranties

Elan and Acorda each represent and warrant to the other that:

- 12.1 it has the right to enter into this Agreement and perform its obligations under it;
- 12.2 there are no agreements between that party and any third party that conflict or may conflict with this Agreement; and
- 12.3 it does not require any consents from any third party to enter into and/or perform its obligations under this Agreement, including in the case of Acorda, from its sub-licensee.

## 13. Confidentiality

The provisions of Section 12.1 of the License Agreement shall apply to information disclosed between the parties for the purposes of this Agreement, including the terms of this Agreement, as if set out in full.

## 14. Assignment

- 14.1 Either party may assign this Agreement to any person or entity to whom it could properly assign its rights and obligations under the License Agreement.

---

Certain portions of this Exhibit have been omitted pursuant to a request for confidentiality. Such omitted portions, which are marked with brackets [ ] and an asterisk\*, have been separately filed with the Securities and Exchange Commission.

- 14.2 Except as set out above, neither party may assign this Agreement without the prior written consent of the other party.

## 15. General

- 15.1 **Limitation of Liability.** UNLESS RESULTING FROM A PARTY'S WILLFUL MISCONDUCT OR FROM A PARTY'S BREACH OF CLAUSE 13 OF THIS AGREEMENT (ARTICLE 12.1 OF THE LICENSE AGREEMENT) OR AS MAY BE EXPRESSLY SET FORTH IN THE DEVELOPMENT SUPPLY AGREEMENT OR THE NON-ELAN DEVELOPMENT PRODUCT SUPPLY AGREEMENT, AS APPLICABLE, NEITHER PARTY SHALL BE LIABLE TO THE OTHER PARTY OR ITS AFFILIATES FOR SPECIAL, INCIDENTAL, CONSEQUENTIAL, EXEMPLARY, PUNITIVE, MULTIPLE OR OTHER INDIRECT DAMAGES, OR FOR LOSS PROFITS, LOSS OF DATA, LOSS OF REVENUE OR LOSS OF USE DAMAGES, ARISING FROM OR RELATING TO THIS AGREEMENT OR THE DEVELOPMENT PRODUCT SUPPLY AGREEMENT OR THE NON-ELAN DEVELOPMENT PRODUCT SUPPLY AGREEMENT, WHETHER BASED UPON WARRANTY, CONTRACT, TORT, NEGLIGENCE, STRICT LIABILITY OR OTHERWISE, REGARDLESS OF ANY NOTICE OF SUCH DAMAGES. NOTHING IN THIS CLAUSE 15.1 IS INTENDED TO LIMIT OR RESTRICT THE INDEMNIFICATION RIGHTS OR OBLIGATIONS OF EITHER PARTY UNDER THIS AGREEMENT, THE DEVELOPMENT PRODUCT SUPPLY AGREEMENT OR THE NON-ELAN DEVELOPMENT PRODUCT SUPPLY AGREEMENT.
- 15.2 **Method of Calculation of Payments.** The parties acknowledge and agree that the methods for calculating the royalties, fees, supply prices, compensating payments and other payments under this Agreement and under the license Agreement (as interpreted in accordance with this Agreement Supply Agreement, Development Product Supply Agreement (if any) and Non-Elan Development Product Supply Agreement (if any are for the convenience of the parties, are freely chosen and not coerced.
- 15.3 **Parties Bound:** This Agreement shall be binding upon and run for the benefit of the parties, their successors and permitted assigns.
- 15.4 **Relationship of the Parties:** In this Agreement, nothing shall be deemed to constitute a partnership between the parties or make either party an agent for the other, for any purpose whatsoever.
- 15.5 **Entire Agreement:** Without prejudice to the license Agreement and Supply Agreement and any other agreements incorporated by reference therein, this Agreement constitutes the entire agreement and understanding between the parties with respect to its subject matter. Except as expressly provided, this Agreement supersedes all prior representations, writings, negotiations or understandings with respect to that subject matter. The parties acknowledge that, in entering into this Agreement, they have not relied on, and shall have no right or remedy in respect of, any statement, representation, assurance or warranty (whether made negligently or innocently) other than as expressly set forth in this Agreement. Nothing in this clause shall limit or exclude any liability for fraud.
- 15.6 **Severability:** If any provision in this Agreement is deemed to be, or becomes invalid, illegal, void

---

Certain portions of this Exhibit have been omitted pursuant to a request for confidentiality. Such omitted portions, which are marked with brackets [ ] and an asterisk\*, have been separately filed with the Securities and Exchange Commission.

or unenforceable under applicable laws, such provision will be deemed amended to conform to applicable laws so as to be valid and enforceable, or if it cannot be so amended without materially altering the intention of the parties, it will be deleted, but the validity, legality and enforceability of the remaining provisions of this Agreement shall not be impaired or affected in any way

- 15.7 **Further Assurance:** Each party shall do and execute, or arrange for the doing and executing of, each necessary act, document and thing reasonably within its power to implement this Agreement.
- 15.8 **Counterparts:** This Agreement may be executed in any number of counterparts, each of which when so executed shall be deemed to be an original and all of which when taken together shall constitute this Agreement.
- 15.9 **Waivers:** A failure to exercise or delay in exercising a right or remedy provided by this Agreement or by law does not constitute a waiver of the right or remedy or a waiver of other rights or remedies. No single or partial exercise of a right or remedy provided by this Agreement or by law prevents further exercise of the right or remedy or the exercise of another right or remedy.
- 15.10 **Variations.** No modification, amendment, or waiver of any provision of this Agreement shall be valid unless in writing and signed by a duly authorised officer or representative of each of the parties hereto.
- 15.11 **Notices:**
- 15.11.1 Elan and Acorda hereby acknowledge that pursuant to Section 12.12.1 of the license Agreement, the following addresses, fax numbers and contact names shall apply in lieu or those originally stated therein:

(a) in the case of Elan (which constitutes notice):

Address: Elan Pharma International limited  
Monksland  
Athlone, Co. Westmeath, Ireland

Fax: +(353) 9064 95402

Marked for the attention of: Vice President and General Counsel with a copy (receipt of which shall not constitute notice) to:

Address: Elan Pharma International limited  
Treasury Building  
Grand Canal Street Lower  
Dublin 2, Ireland

Fax: +(353) 1709 4700

(b) in the case of Acorda (which constitutes notice):

Address: Acorda Therapeutics, Inc.  
15 Skyline Drive  
Hawthorne, New York 10532

Certain portions of this Exhibit have been omitted pursuant to a request for confidentiality. Such omitted portions, which are marked with brackets [ ] and an asterisk\*, have been separately filed with the Securities and Exchange Commission.

Fax: (914) 347-4560

Marked for the attention of: Ron Cohen, President and Chief Executive Officer with a copy (receipt of which shall not constitute notice) to the attention of:

General Counsel, at the same address

15.11.2 Subject to those changes, Section 12.12 of the License Agreement shall apply to any notice required under this Agreement as if set out in full.

15.12 Governing Law and Arbitration: This Agreement is construed under and ruled by the laws of the State of New York, excluding its conflict of laws rules. For the purpose of this Agreement, the Parties submit to the jurisdiction of the United States District Court for the State of New York. Section 12.14 of the License Agreement (arbitration) is hereby incorporated as if it were set out at length herein and is applicable to Non-Elan Development Product as provided herein, and reading references in that Clause to Article 10 of the License Agreement (Committee) as interpreted in accordance with this Agreement.

\*\*\*

Signatures begin on next page

Certain portions of this Exhibit have been omitted pursuant to a request for confidentiality. Such omitted portions, which are marked with brackets [ ] and an asterisk\*, have been separately filed with the Securities and Exchange Commission.

EXECUTED by the parties on the date appearing at the top of page 1.

SIGNED

/s/ William F. Daniel  
*Duly authorised for and on behalf of*  
ELAN PHARMA INTERNATIONAL LIMITED

SIGNED

/s/ Ron Cohen  
*Duly authorised for and on behalf of*  
ACORDA THERAPEUTICS, INC.

Certain portions of this Exhibit have been omitted pursuant to a request for confidentiality. Such omitted portions, which are marked with brackets [ ] and an asterisk\*, have been separately filed with the Securities and Exchange Commission.

**SCHEDULE 1**

[\*\*\*\*\*]

[\*\*\*\*\*]

Certain portions of this Exhibit have been omitted pursuant to a request for confidentiality. Such omitted portions, which are marked with brackets [ ] and an asterisk\*, have been separately filed with the Securities and Exchange Commission.

**SCHEDULE 2**

**WORK PLAN FORMAT**

**Compound:** (INSERT DETAILS)

**Scope of Work:** (INSERT DETAILS)

**Elan Activities:** (INSERT DETAILS)

**Acorda Activities:** (INSERT DETAILS)

**Estimated Fee:** (INSERT DETAILS)

The Estimated Fee for the Elan services contemplated by this WorkPlan is U.S. dollars (US \$0000.00), including all out-of-pocket expenses (“Total Estimated Fee”). With respect to any potential cost overruns, the Parties agree that such overruns shall not exceed [\*] of the Total Estimated Fee. Acorda shall not be required to pay and Elan shall have the right to discontinue it services if the cost of performing the services under this workplan exceeds [\*\*\*\*\*] of the Estimated Fee. Elan shall resume unperformed services if an amendment to this work plan or a new work plan to complete the services is agreed and executed by Acorda and Elan.

Acorda shall reimburse Elan as set out in this Work Plan for labour at Elan’s FTE plus [\*\*\*\*\*] and actual out-of-pocket expenses incurred by Elan in conducting work under this Work Plan.

Elan shall invoice Acorda for such costs no more than once per month. Elan shall provide a reasonably detailed invoice to identify the work performed and costs incurred under the invoice. Invoices shall be paid by Acorda within thirty (30) days of invoicing and Elan shall, without prejudice to other remedies, be entitled to stop work if payment is not made within this time period.

**Estimated Timelines:** (INSERT DETAILS)

Elan estimates that the Elan activities detailed in this Work Plan will be completed approximately \_\_\_\_\_ weeks/months after this Work Plan has been executed.

Should a conflict arise between the terms and conditions of this Work Plan and the terms and conditions of the Development and Supplemental Agreement, Elan and Acorda agree that the terms and conditions of the Development and Supplemental Agreement shall prevail.

**Agreed and Accepted by:**

*Duly authorised for and on behalf of*  
**Elan Pharma International Ltd.**

*Duly authorised for and on behalf of*  
**Acorda Therapeutics, Inc.**

By: \_\_\_\_\_

By: \_\_\_\_\_

Name:  
Title:  
Date:

Name:  
Title:  
Date:

Certain portions of this Exhibit have been omitted pursuant to a request for confidentiality. Such omitted portions, which are marked with brackets [ ] and an asterisk\*, have been separately filed with the Securities and Exchange Commission.

**SCHEDULE 3  
SELECTION CRITERIA**

Criteria for Evaluation:

- Specific criteria are to be developed based on [\*\*\*\*\*].
- The new formulation must be assessed [\*\*\*\*\*].
- Timing: [\*\*\*\*\*]
- Cost: [\*\*\*\*\*]

End of Schedule 3

Certain portions of this Exhibit have been omitted pursuant to a request for confidentiality. Such omitted portions, which are marked with brackets [ ] and an asterisk\*, have been separately filed with the Securities and Exchange Commission.

**EXECUTION COPY**

**Date: 26, September 2003**

**ELAN CORPORATION, PLC.**

**AND**

**ACORDA THERAPEUTICS, INC.**

**SUPPLY AGREEMENT**

*Fampridine SR*

Certain portions of this Exhibit have been omitted pursuant to a request for confidentiality. Such omitted portions, which are marked with brackets [ ] and an asterisk\*, have been separately filed with the Securities and Exchange Commission.

**INDEX**

<b>CLAUSE 1</b>	<b>PRELIMINARY</b>
<b>CLAUSE 2</b>	<b>EXCLUSIVE SUPPLY</b>
<b>CLAUSE 3</b>	<b>REGULATORY MATTERS</b>
<b>CLAUSE 4</b>	<b>FORECASTS AND ORDERS</b>
<b>CLAUSE 5</b>	<b>SUPPLY OF THE PRODUCT</b>
<b>CLAUSE 6</b>	<b>DISPUTES AS TO SPECIFICATION</b>
<b>CLAUSE 7</b>	<b>SECOND SOURCE</b>
<b>CLAUSE 8</b>	<b>ADVERSE EVENTS AND PRODUCT RECALL</b>
<b>CLAUSE 9</b>	<b>FINANCIAL PROVISIONS</b>
<b>CLAUSE 10</b>	<b>PAYMENTS, REPORTS AND AUDITS</b>
<b>CLAUSE 11</b>	<b>DURATION AND TERMINATION</b>
<b>CLAUSE 12</b>	<b>CONSEQUENCES OF TERMINATION</b>
<b>CLAUSE 13</b>	<b>REPRESENTATIONS AND WARRANTIES; INDEMNIFICATION</b>
<b>CLAUSE 14</b>	<b>MISCELLANEOUS PROVISIONS</b>
<b>SCHEDULE 1</b>	<b>MANUFACTURING COST</b>

Certain portions of this Exhibit have been omitted pursuant to a request for confidentiality. Such omitted portions, which are marked with brackets [ ] and an asterisk\*, have been separately filed with the Securities and Exchange Commission.

**THIS SUPPLY AGREEMENT** is made the                      September 2003

**BETWEEN:**

- (1) **Elan Corporation, plc.**, a public limited company incorporated under the laws of Ireland, and having its registered office at Lincoln House, Lincoln Place, Dublin 2, Ireland (“ **Elan** ”); and
- (2) **Acorda Therapeutics, Inc.**, a corporation organized under the laws of the State of Delaware and having its principal office at 15 Skyline Drive, Hawthorne, New York 10532, United States of America (“ **Acorda** ”).

**RECITALS:**

- (A) Elan and Acorda have entered into a Licence Agreement concerning the Product (as each of those terms are defined below).
- (B) Elan is prepared to manufacture and supply the Product to Acorda for onward commercial supply.
- (C) Elan and Acorda are desirous of entering into this Agreement to give effect to the arrangements described at Recitals (A) and (B).

**NOW IT IS HEREBY AGREED AS FOLLOWS:**

**CLAUSE 1      PRELIMINARY**

1.1. Definitions:

“**Act**” shall mean the United States Federal Food Drug and Cosmetic Act of 1934, and the rules and regulations promulgated thereunder, or any successor act, as the same shall be in effect from time to time.

“**Affiliate**” shall mean any corporation or entity controlling, controlled or under common control with Elan or Acorda, as the case may be. For the purposes of this Agreement, “control” shall mean the direct or indirect ownership of more than 50% of the issued voting shares or other voting rights of the subject entity to elect directors, or if not meeting the preceding criteria, any entity owned or controlled by or owning or controlling at the maximum control or ownership right permitted in the country where such entity exists.

“**Agreement**” shall mean this supply agreement (which expression shall be deemed to include the Recitals and Schedules hereto).

1

---

Certain portions of this Exhibit have been omitted pursuant to a request for confidentiality. Such omitted portions, which are marked with brackets [ ] and an asterisk\*, have been separately filed with the Securities and Exchange Commission.

“**Batch**” shall mean a specific quantity of Product that is produced according to a single manufacturing order during the same cycle of manufacture, which quantity shall be agreed in the Technical Agreement.

“**cGMP**” shall mean current Good Manufacturing Practice as defined in the Act and FDA guidance documents; or as applicable current Good Manufacturing Practice under applicable regulations in the European Union.

“**EEA**” shall mean the countries comprising the European Economic Area, as the same may change from time to time .

“**Effective Date**” shall mean the date of this Agreement.

“**Elan’s Facility**” shall mean Monksland, Athlone, Co. Westmeath, Ireland or such other facility as Elan may use to perform its obligations hereunder and is in compliance with the NDA and other regulatory requirements.

“**Elan Territory**” shall mean any country or countries in which Elan, or any licensee of Elan other than Acorda, is permitted to commercialise the Product, by virtue of termination of the License Agreement in that country or the grant of a license by Acorda to Elan pursuant to Article 2.11.3 of the License Agreement.

“**EXW**” or “**Ex Works**” shall have the meaning as such term is defined in the ICC Incoterms, 2000, International Rules for the Interpretation of Trade Terms, ICC Publication No. 560.

“**Force Majeure**” shall mean any cause or condition beyond the reasonable control of the party obliged to perform, including acts of God, acts of government (in particular with respect to the refusal to issue necessary import or export licenses), fire, flood, earthquake, war, riots or embargoes, strikes or other labour difficulties affecting a party, or either party’s inability to obtain supplies of components of the Product howsoever arising.

“**FTE**” means Elan’s full time equivalent charging rate for its appropriate employees or consultants from time to time (based on cost without mark-up) which as of the Amendment Date is [\*\*\*\*\*] per day.

“**Governmental Authority**” shall mean the FDA and /or all other governmental and regulatory bodies, agencies, departments or entities, whether or not located in the Territory, which regulate, direct or control commercial and other related activities in or with the Territory.

“**Launch Stocks**” shall mean the quantities of stocks of the Product required by Acorda in relation to the launch of the Product following Regulatory Approval in a Major Market, as more fully described in Clause 4.7.

“**Launch Year**” shall mean the period commencing on the date of First Commercial Sale and expiring on the last day of the month that is the twelfth (12<sup>th</sup>) month following the

2

---

Certain portions of this Exhibit have been omitted pursuant to a request for confidentiality. Such omitted portions, which are marked with brackets [ ] and an asterisk\*, have been separately filed with the Securities and Exchange Commission.

date in which the First Commercial Sale occurs. For example, if the First Commercial Sale occurs on March 15 of any year, the Launch Year shall commence on March 15 of such year and expire on March 31 of the following year.

“**Licence Agreement**” shall mean that certain Amended and Restated Licence Agreement between Elan and Acorda of even date herewith.

“**Major Market(s)**” shall mean the US, the UK, France, Germany, Italy and Japan.

“**Manufacturing Cost**” shall mean the costs described in **Schedule 1** as they relate to the Product, PROVIDED THAT if Elan is manufacturing the Product for sale in an Elan Territory, in no event shall Manufacturing Cost exceed Elan’s own costs for such manufacture, as calculated based on GAAP.

“**Maximum Capacity**” shall mean Elan’s maximum quarterly manufacturing capacity for the Product from time to time, as agreed in, or determined pursuant to, the Technical Agreement.

“**Minimum Elan Requirements**” shall mean for any Year, at least seventy five percent (75%) of Acorda’s total requirements of the Product .

“**Minor Deficiencies**” shall mean shortfalls or delays that are not inconsistent with industry accepted standards, which standards applicable to the Product shall be clarified in the Technical Agreement.

“**Permitted Elan Assignee**” shall mean any entity that purchases all or substantially all of the assets of Elan’s Facility and has entered into a written agreement with Elan for the benefit of Acorda whereby (inter alia) it represents to Acorda that it is (i) reasonably experienced in the field of pharmaceutical manufacturing (including the existing management of Elan’s Facility), (ii) in possession of sufficient financial resources and liquidity to perform the obligations of Elan under this Agreement and (iii) in good standing with the FDA.

A Permitted Elan Assignee shall also include any entity that has been formed for the purpose of acquiring Elan’s Facility, and shall, following such acquisition, be under the management of individuals reasonably experienced in pharmaceutical manufacturing (including the said existing management), in possession of sufficient financial resources and liquidity to perform the obligations of Elan under this Agreement, and none of which are debarred individuals or entities within the meaning of 21 U.S.C. section 335(a) or (b) and have the capacity of being in good standing with the FDA.

“**Product**” shall mean the oral product developed pursuant to the Project, in final packaged and labelled form for commercial sale or for distribution as promotional samples and as defined in the approved NDA or NDA Equivalent.

“**Recall**” means a company’s removal or correction of a marketed Product that the FDA or equivalent Governmental Authority considers to be in violation of law and against

---

Certain portions of this Exhibit have been omitted pursuant to a request for confidentiality. Such omitted portions, which are marked with brackets [ ] and an asterisk\*, have been separately filed with the Securities and Exchange Commission.

which such agency might reasonably be expected to initiate legal action (e.g., a seizure). A Recall does not include market withdrawal for other reasons, or a stock recovery.

“**Serious Failure to Supply**” shall mean that in a period of a Year, for reasons other than Force Majeure or the default of Acorda, Elan fails on at least two occasions to supply Acorda’s properly forecasted and ordered requirements of the Product in accordance with the terms of this Agreement, except for Minor Deficiencies, and the cumulative shortfall for such Year attributable to such failure(s) is at least 25% of the aggregate amount properly forecasted and ordered from Elan for delivery in such Year.

“**Term**” shall mean the term of this Agreement, as set out in Clause 11.

“**\$**” and “**US\$**” shall mean United States Dollars.

“**Year**” means each consecutive four Calendar Quarters.

#### 1.2. Further Definitions:

In addition, the following definitions have the meanings in the Clauses corresponding thereto, as set forth below:

<u>Definition</u>	<u>Clause</u>
“Discount”	9.4
“First Approval”	4.1.1
“Manufacturer”	7.1
“Resumption Quarter”	7.6.1
“Second Source”	7.1
“Second Source Quantity”	7.2.1
“Supply Price”	9.3.1
“Technical Agreement”	5.5

#### 1.3. Definitions in Licence Agreement:

Except as otherwise defined in this Agreement, all capitalised terms used in this Agreement shall have the same meaning as in the Licence Agreement.

#### 1.4. Interpretation:

In this Agreement:



- 1.4.1 the singular includes the plural and vice versa, the masculine includes the feminine and vice versa and references to natural persons include corporate bodies, partnerships and vice versa.

---

Certain portions of this Exhibit have been omitted pursuant to a request for confidentiality. Such omitted portions, which are marked with brackets [ ] and an asterisk\*, have been separately filed with the Securities and Exchange Commission.

- 1.4.2 any reference to a Clause or Schedule, unless otherwise specifically provided, shall be respectively to a Clause or Schedule of this Agreement.
- 1.4.3 the headings of this Agreement are for ease of reference only and shall not affect its construction or interpretation.
- 1.4.4 the expressions “include”, “includes”, “including”, “in particular” and similar expressions shall be construed without limitation.

## CLAUSE 2 EXCLUSIVE SUPPLY

- 2.1. Subject to the terms and conditions of this Agreement, during the Term, Acorda shall purchase its Minimum Elan Requirements of the Product in the Territory from Elan, except as provided in Clause 2.3.
- 2.2. Subject to the terms and conditions of this Agreement, during the Term, Elan shall not supply the Product to:
- 2.2.1 any person other than Acorda outside the Elan Territory; or
- 2.2.2 any person other than Acorda in the Elan Territory who intends, to the actual knowledge of Elan, to sell the Product outside the Elan Territory —
- except as requested by Acorda, **PROVIDED THAT** to extent required by applicable law, Elan shall be permitted to:
- (a) sell the Product to a person in a country which is both part of the Elan Territory and within the EEA, notwithstanding that such person may re-sell the Product in another part of the EEA which is not part of the Elan Territory; and
- (b) if any country of the EEA is part of the Elan Territory, sell the Product to a person in another country of the EEA which is not part of the Elan Territory, provided further that Elan shall not actively solicit any such sales.
- 2.3. Elan shall not have the obligation to use commercially reasonable efforts to supply the Product where 140% of Manufacturing Cost would exceed the Supply Price, subject to Clauses 2.4 and 2.5
- 2.4. In the event that either party is of the opinion that the circumstances in Clause 2.3 apply or may shortly apply, it shall promptly notify the other. In such event the parties shall meet to discuss, *inter alia*, the manner in which Manufacturing Cost is calculated by Elan and Acorda’s commercialisation plans.
- 2.5. If after such discussions Elan is of the opinion that if it continues to supply the Product to Acorda, the circumstances in Clause 2.3 will apply, Elan shall promptly formally so notify Acorda. In such event

---

Certain portions of this Exhibit have been omitted pursuant to a request for confidentiality. Such omitted portions, which are marked with brackets [ ] and an asterisk\*, have been separately filed with the Securities and Exchange Commission.

- 2.5.1 Elan shall use commercially reasonable efforts to supply Acorda with Product the subject of binding orders issued prior to Acorda’s receipt of such notification, provided that such orders relate to Product scheduled for delivery in the period of three (3) months after the date of the purchase orders, and that such Product shall be invoiced at the applicable price under Clause 9.2 or 9.3; and
- 2.5.2 After the expiration of the period referred to in Clause 2.5.1, Acorda shall have no further obligation to purchase Product under this Agreement, provide, however, that Acorda may at its option place further purchase orders for delivery during up to a six (6) month period immediately following the period referred to in Clause 2.5.1, subject always to Clause 4 and Clause 5, provided, further, that (i) any such purchase orders are placed not later than three (3) months from the date of Elan’s notice under this Clause 2.5; and (ii) any such Product ordered shall be invoiced at a price equal to Manufacturing Cost plus [\*\*\*\*\*].

If following the period referred to in Clause 2.5.2, Acorda wishes to continue to purchase the Product from Elan and Elan is prepared to supply the same, the Parties shall negotiate in good faith the terms of any such supply and purchase.

As from the time of Elan’s notice, Acorda shall be entitled to purchase the Product from the Second Source, but without prejudice to binding purchase orders already placed with Elan and subject to the foregoing paragraph.

## CLAUSE 3 REGULATORY MATTERS

- 3.1. Elan shall be responsible, at Elan’s expense, for filing for and maintaining all license and permits pertinent to Elan’s Facility, as distinct from the Regulatory Approvals specific to the Product, without prejudice to Elan’s responsibilities under the Licence Agreement in respect of preparation and delivery to Acorda for incorporation into the NDA or any NDA Equivalent, of the CMC Section.

- 3.2. Upon Elan's prior written notice, Acorda shall permit Elan or any Affiliate to have access to the NDA and any NDA Equivalent and Regulatory Approvals and to take photocopies of same, as required by Elan to fulfil reporting requirements or as otherwise may reasonably be required by Elan in connection with this Agreement.
- 3.3. **Inspections or Inquiries by Governmental Authorities.** With respect to Product supplied by it, Elan shall be responsible for all process and equipment validation and quality control tests and procedures required by any Governmental Authority and shall take all steps necessary to pass inspection by any Governmental Authorities in the Major Markets, but without prejudice to Article 6.3 of the License Agreement. Elan shall:
- 3.3.1 notify Acorda as soon as possible, but in any event within the time period to be set forth in the Technical Agreement, of any notification received by Elan from a Governmental Authority to conduct an inspection of its manufacturing or other

6

---

Certain portions of this Exhibit have been omitted pursuant to a request for confidentiality. Such omitted portions, which are marked with brackets [ ] and an asterisk\*, have been separately filed with the Securities and Exchange Commission.

facilities used in the development, manufacturing, packaging, storage or handling of the Product;

- 3.3.2 without delay make available to Acorda a copy of any inspection report received by Elan resulting from any inspection of any of such facilities by such Governmental Authority to the extent such report relates to Product, the formulation, manufacture, testing, storage and delivery of the Product or any premises used by Elan in performing Elan's obligations under this Agreement;
- 3.3.3 provide Acorda with a written copy of any proposed response(s) thereto at least three Business Days prior to submitting such response to any Governmental Authority as well as a copy of the response actually submitted.

Representatives of Acorda or its Designee shall have the right to be present during the inspection and/or during the close-out session with the inspectors. Any Form 483 observations or warning letter related to the Product shall be provided promptly to Acorda, which shall have the right to review and discuss the proposed written response to such 483 observations or warning letter, and a copy of the response actually submitted shall be promptly provided to Acorda. Copies of all other correspondence with any Governmental Authority relating to that any party's activities under this Agreement will be provided to the other party within forty-eight (48) hours.

- 3.4. **Inspection by Acorda / Governmental Authority.** Elan shall make (i) any licenses and permits relating to Elan's Facility; and (ii) that portion of Elan's facility where the Product is manufactured, packaged, tested or stored, including all record and reference samples, available for inspection:
- 3.4.1 by Acorda's duly qualified employee or Designee or, with the consent of Elan, by Acorda's agent or contractor; or
- 3.4.2 by the relevant Governmental Authority.

An inspection under Clause 3.4.1 shall be limited to determining whether there is compliance with cGMP and other requirements of applicable law, including production or quality issues relating to the Product. Any consent required under this Clause 3.4 shall not be unreasonably withheld or delayed.

- 3.5. **Preservation Samples/Retained Samples.** Pursuant to all applicable laws, rules and regulations and to the Specifications, Elan shall assign and apply lot numbers and shall take from each lot of (i) the API used to manufacture Product pursuant to this Agreement; (ii) inactive ingredients used in the manufacture of Product pursuant to this Agreement; and (iii) the Product shipped to Acorda or its designee pursuant to this Agreement, preservation samples/retained samples. Elan shall retain and store the particular lot of API, other ingredients or Product, as applicable, in accordance with FDA and other applicable regulations, which currently provide for a period expiring no earlier than two years after the expiration of the shelf life of the particular lot of Product shipped to Acorda or its Designee pursuant to this Agreement. Preservation samples/retained

7

---

Certain portions of this Exhibit have been omitted pursuant to a request for confidentiality. Such omitted portions, which are marked with brackets [ ] and an asterisk\*, have been separately filed with the Securities and Exchange Commission.

samples, as referred to herein, do not include samples retained for purposes of stability testing.

- 3.6. Elan shall at its option be entitled to change the manufacturing process or site for manufacture of the Product, provided that (a) Elan provides Acorda with all required information in form and substance necessary to file any related amendments or supplements to the NDA or any NDA Equivalent or, if applicable, Elan files with applicable regulatory authorities any required amendments or supplements to any DMF; (b) no such change shall take effect until all requisite regulatory approvals have been obtained, and (c) Elan shall be responsible for the costs associated with such change. Acorda shall reasonably co-operate with Elan in obtaining any such changes requested.

#### CLAUSE 4 FORECASTS AND ORDERS

- 4.1. **Forecasts.** Acorda shall provide Elan with bona fide written forecasts of its estimated Minimum Elan Requirements of the Product as follows:
- 4.1.1 within eighteen (18) months prior to the anticipated date of first Regulatory Approval in any Major Market (" **First Approval** "), Acorda shall provide Elan with an eighteen (18) month forecast, broken down on a quarterly basis, for the period beginning with the anticipated date of First Commercial Sale in such Major Market (which date shall be specified in the forecast);
- 4.1.2 thereafter, every three months until First Approval, Acorda shall provide Elan with an updated forecast on a quarterly basis;

- 4.1.3 within thirty (30) days of First Approval, and thereafter each calendar month not later than the 23<sup>rd</sup> of the month, a rolling 18 month forecast, broken down on a month-by-month and country-by-country basis, for the period commencing at the beginning of the following month; and
- 4.1.4 not later than 1 August in each year, a five (5) year forecast, broken down on an annual basis.

Except as otherwise provided herein, all forecasts made hereunder shall be made to assist Elan in planning its production and Acorda in planning marketing and sales, shall not be binding purchase orders, and shall be without prejudice to Acorda's subsequent firm orders for the Product in accordance with the terms of this agreement. Each forecast provided by Acorda shall supercede any previous forecast and may be expressed in a reasonable range. After receiving Acorda's forecasts, Elan shall notify Acorda within five (5) days if Elan becomes aware that it will be unable to supply Acorda's forecasted requirements of Product and, in such event, the provisions of Clause 4.6 shall be applicable.

- 4.2. **Purchase Requirements.** Subject to the agreement between the Parties relating to Launch Stocks under Clause 4.7, Acorda shall be bound to order one hundred percent

---

Certain portions of this Exhibit have been omitted pursuant to a request for confidentiality. Such omitted portions, which are marked with brackets [ ] and an asterisk\*, have been separately filed with the Securities and Exchange Commission.

(100%) of the forecasted quantities of the Product for each month of the first three (3) months of the most recent rolling forecast referred to in Clause 4.1.3, but otherwise forecasts shall not be binding.

- 4.3. Forecasts and orders shall not increase or decrease by more than 25% in the aggregate amount of Product required in a calendar quarter compared to the previous calendar quarter, except for Launch Stocks or unless otherwise agreed by Elan. However, Elan shall use reasonable efforts to fulfil Acorda's requirements in excess of duly forecasted and ordered amounts.
- 4.4. Forecasts and orders shall not exceed the Maximum Capacity during the applicable quarterly period.
- 4.5. **Firm Orders.** Acorda or its Designee shall provide Elan with purchase orders on the standard purchase order forms of Acorda or its Designee (without prejudice to Clause 5.4) of its Elan Minimum Requirements at least ninety (90) days before it requires each delivery of Product (subject to Clause 4.7 with respect to Launch Stocks), specifying the required delivery date in each purchase order and specifying the quantity of Product requested for commercial use and the quantity of Product for promotional and sample use.
- 4.6. **Shortages.** Elan agrees that it will use commercially reasonable efforts to prevent an interruption of supply to Acorda and shall immediately notify Acorda of any problems or unusual production situations which may adversely affect production or quality of Product or its Specifications or its timely delivery to Acorda or its designee. If, at any time during the term of this Agreement, Elan becomes aware that it will not be able to satisfy Acorda's forecasts or ordered requirements for Product, then Elan shall: (i) give Acorda prompt notice thereof, (ii) take all commercially reasonable steps to enable Acorda to procure adequate quantities of Product from the Second Source in accordance with the applicable provisions of Clause 7 and (iii) if such inability is partial, Elan shall fulfill firm orders with such quantities of Product as are available. and shall continue to use its commercially reasonable efforts to fulfill orders on a timely basis.
- 4.7. **Launch Stocks.** Within six months prior to an anticipated Regulatory Approval in a Major Market, the parties shall discuss and agree upon the manufacture and purchase of specific quantities of Launch Stocks for launch of the Product in the applicable Major Market.
- 4.7.1 Launch Stocks shall be ordered not later than 20 Business Days from receipt by Acorda of an approval letter, from the FDA or equivalent Governmental Authority in respect of the NDA or an NDA Equivalent in another Major Market.
- 4.7.2 Acorda may use the validation batches of the Product as Launch Stocks, subject to compliance with applicable laws, the Licence Agreement and other provisions of this Agreement, provided that in such event, any amounts previously paid by

---

Certain portions of this Exhibit have been omitted pursuant to a request for confidentiality. Such omitted portions, which are marked with brackets [ ] and an asterisk\*, have been separately filed with the Securities and Exchange Commission.

Acorda to Elan for such validation batches shall be credited against the applicable price for Launch Stocks under Clause 9.1.

## CLAUSE 5 SUPPLY OF THE PRODUCT

- 5.1. Save as otherwise provided in this Agreement, Elan shall use commercially reasonable efforts to produce and supply to Acorda its entire Elan Minimum Requirements of the Product as set forth in and in response to firm purchase orders, within ninety (90) days of the purchase order, or one hundred and fifty (150) days for Launch Stocks or samples (subject to any required extension due to the lead times of specific components of samples).
- 5.2. Elan shall have no obligation to supply Product:
- 5.2.1 For any period, in excess of Acorda's properly forecast requirements for such period (but Elan will nevertheless use its commercially reasonable efforts to fulfil Acorda's requirements in excess of such amounts, having regard to its manufacturing capacity);
- 5.2.2 for less than a minimum order of one Batch, or such other minimum quantity as may be agreed in the Technical Agreement;

- 5.2.3 in partial Batches;
- 5.2.4 where Clause 2.3 applies; or
- 5.2.5 pursuant to an order which does not conform in all material respects to the provisions of Clause 4 and this Clause 5; provided that if Elan does supply pursuant to such an order in its absolute discretion, that fulfilment shall not affect Elan's right to refuse to fulfil any subsequent order which does not comply in all material respects with those provisions.

5.3. The Product supplied by Elan to Acorda shall:

- 5.3.1 be delivered in finished packaged form in the dosages and configurations as set forth in the Specifications and agreed by the parties and included in the NDA and any NDA Equivalent;
- 5.3.2 be shipped EXW Elan's Facility;
- 5.3.3 be delivered with a certificate of analysis and certificate of release in respect of the Product, in a form reasonably acceptable to Acorda (and Acorda shall be entitled to rely upon such certificate of analysis without the necessity of performing additional testing), in accordance with the terms of the Technical Agreement, cGMPs and the NDA or any NDA Equivalent; and

10

---

Certain portions of this Exhibit have been omitted pursuant to a request for confidentiality. Such omitted portions, which are marked with brackets [ ] and an asterisk\*, have been separately filed with the Securities and Exchange Commission.

5.3.4 have a shelf life to be determined in the Technical Agreement.

5.4. The terms of this Agreement are hereby incorporated by reference into each order of Product submitted by Acorda and accepted by Elan. In the event of any conflict between an order or other written instructions and this Agreement, the terms of this Agreement shall prevail.

5.5. Not less than eighteen (18) months before the anticipated First Approval, or such later date as may be determined by the Committee, the parties shall negotiate in good faith to conclude a detailed technical agreement (the "**Technical Agreement**") regulating the parties' respective obligations from a technical and quality perspective for the supply of the Product by Elan to Acorda, subject in all cases to compliance with cGMPs, the requirements and commitments of the NDA and any NDA Equivalent and any other applicable laws or regulations governing manufacture and supply of Product. Such agreement will include commercially reasonable terms as to:

- 5.5.1 the precise procedures regulating the alleged failure of any shipment of the Product to conform to the Specifications as a result of an alleged latent defect and the procedures to be adopted for the return and replacement of such Product;
- 5.5.2 the inspection and testing for compliance with specifications of API to be conducted by Elan prior to incorporation into Product, the testing and quality analysis of Product to be conducted by Elan prior to shipment of the Product and the format of the certificate of analysis and certificate of release to be furnished by Elan to Acorda as well as any quality analysis to be conducted by Acorda or its Designee;
- 5.5.3 the batch manufacturing records and other documentation to be prepared and maintained by Elan and delivered with each shipment to Acorda to show compliance with cGMP as well as other applicable United States of America and foreign laws and regulations;
- 5.5.4 the agreed shelf life of the Product as of the date of shipment;
- 5.5.5 the quantity of Product constituting a Batch and minimum Batch size of each shipment of the Product;
- 5.5.6 the manner in which Elan may provide Acorda with assistance in relation to field alerts, recalls, complaints and adverse events;
- 5.5.7 the notification of change by both parties;
- 5.5.8 the responsibility to collate and write annual product review and annual reports;
- 5.5.9 technical agreements with any subcontracted parties;
- 5.5.10 the stability commitments in NDA or amendments thereto;

11

---

Certain portions of this Exhibit have been omitted pursuant to a request for confidentiality. Such omitted portions, which are marked with brackets [ ] and an asterisk\*, have been separately filed with the Securities and Exchange Commission.

- 5.5.11 active drug substance, excipient and component supplier agreements, including audits/inspections of related manufacturing facilities;
- 5.5.12 procedures for determining and monitoring the marginal unit variable element of Manufacturing Cost for purposes of Clause 9.5.1;
- 5.5.13 such other matters relating to the manufacturing and supply of Product, including any amendments to any of the terms of this Agreement, any matters that this Agreement refers to be included in the Technical Agreement or any other matters that the Parties may mutually agree to or as may be required by the NDA or any NDA Equivalent.

## CLAUSE 6 DISPUTES AS TO SPECIFICATION

- 6.1. All claims for failure of any delivery of the Product to conform to the Specifications must be made by Acorda in writing within sixty (60) days following delivery of Product to Acorda or its Designee except in the case of latent defects. Acorda shall promptly upon Elan's request provide reasonable details of the alleged non-conformance and supporting evidence, and shall upon request permit Elan to re-test the Product. If Elan does not agree with Acorda's determination of non-conformance, then Elan shall provide Acorda with a written notice of such disagreement within twenty (20) days of receipt of the non-conformance notice (adjusted for any delay in providing appropriate details or permitting re-testing), responding to Acorda's claim. The Parties shall use commercially reasonable efforts to resolve such disagreement within ten (10) Business Days of Acorda's receipt of Elan's notice of disagreement.
- 6.2. Claims for latent defects, not discovered during the routine testing protocol (to be agreed in the Technical Agreement) shall be made in accordance with the Technical Agreement in writing within thirty (30) days of discovery. Failure to make timely claims in the manner to be prescribed in the Technical Agreement shall constitute acceptance of the delivery.
- 6.3. In the event that the Product supplied by Elan is not in compliance with the Specifications, or is otherwise adulterated, misbranded or defective, Elan shall, in addition to any other applicable remedies:
- 6.3.1 be responsible, at the sole cost and expense of Elan, for re-analysis, sampling, processing, return, disposal or destruction, including certification of destruction, of such non-conforming Product; and
- 6.3.2 at its cost, replace the nonconforming Product with Product meeting the Specifications as soon as reasonably practicable.
- 6.4. In the event that the nonconformity was due to a fault of Acorda, then, according to Elan's orders, the Product shall either be destroyed by Acorda, or returned to Elan for

12

---

Certain portions of this Exhibit have been omitted pursuant to a request for confidentiality. Such omitted portions, which are marked with brackets [ ] and an asterisk\*, have been separately filed with the Securities and Exchange Commission.

destruction by Elan, at Acorda's expense. In such an event Acorda will not be entitled to any credit as to the non-conforming Product.

- 6.5. In the event of an unresolved dispute as to:

- 6.5.1 conformity of the Product with Specifications; or
- 6.5.2 whether defects in the Product are attributable to the negligent acts or omissions of Elan,

the parties shall within 30 days after expiration of the ten (10) Business Day period referred to in Clause 6.1 appoint an independent laboratory to undertake the relevant testing and its findings shall be conclusive and binding upon the parties.

All costs relating to this process shall be borne solely by the party whose testing was in error.

If the parties are unable to agree as to the independent laboratory to be used, the matter shall be referred to arbitration in accordance with Article 12.14 of the License Agreement.

## CLAUSE 7 SECOND SOURCE

- 7.1. Process Transfer to Second Source:

Acorda shall be entitled to qualify the facility of Patheon Inc. at 2100 Syntex Court, Mississauga, Ontario as a second source of the Product (" **Second Source** "), subject to Patheon, Inc. (the " **Manufacturer** ") undertaking to Elan to protect the confidentiality of Elan's manufacturing processes related to Product and not use them for any other purpose, in terms reasonably satisfactory to Elan provided that Elan hereby acknowledges that the Manufacturer is in the process of being qualified as a Second Source Manufacturer.

At Acorda's request, Elan shall use commercially reasonable efforts to assist in qualifying the Second Source as an alternative site of manufacture of the Product. Pursuant to this obligation, Elan shall:

- 7.1.1 provide Acorda or the Manufacturer (at Acorda's request) with any information necessary to manufacture the Product;
- 7.1.2 provide to Acorda or the Manufacturer (at Acorda's request) the documentation constituting the required material support, more particularly practical performance advice, shop practice, specifications as to materials to be used and control methods;
- 7.1.3 assist Acorda and/or the Manufacturer (at Acorda's request) with the working up and use of the technology and with the training of Manufacturer's personnel to

13

---

Certain portions of this Exhibit have been omitted pursuant to a request for confidentiality. Such omitted portions, which are marked with brackets [ ] and an asterisk\*, have been separately filed with the Securities and Exchange Commission.

the extent which may reasonably be necessary in relation to the manufacture of the Product by the Manufacturer. In this regard, Elan will receive the Acorda's and/or Manufacturer's scientific staff, as applicable, in its premises for certain periods, the term of which will be agreed by the parties; and

- 7.1.4 comply with the other obligations and responsibilities of Elan relating to technology transfer to Patheon, as set forth in the Technology Transfer Responsibilities Schedule.

Acorda shall comply with its obligations and responsibilities relating to technology transfer to Patheon, as set forth in the Technology Transfer Responsibilities Schedule.

7.2. Supply of Product from Second Source:

Acorda may purchase the following quantities of Product from the Second Source and, accordingly, if so purchased, Acorda shall have no obligation to purchase such quantities from Elan and Elan shall have no obligation to supply such quantities to Acorda:

- 7.2.1 In any Year, up to twenty five percent (25%) of Acorda's total requirements of Product for such Year, subject to Clauses 7.3.2 and 9.5 (the "**Second Source Quantity**");
- 7.2.2 quantities of the Product which Elan is not obligated to, and declines to, supply pursuant to Clause 2.3;
- 7.2.3 quantities of Product in addition to the Second Source Quantity required to make up any portion of a valid purchase order which is either (i) not delivered by Elan by its due date for delivery (regardless of the cause of late or short delivery), except for Minor Deficiencies, or (ii) by reason of Force Majeure, to the extent not capable of being delivered by its due date for delivery, for so long as the Force Majeure continues;
- 7.2.4 where there is a Serious Failure To Supply, its entire requirements of the Product, subject to Clause 7.6.

7.3. Notification of Supply from Second Source; Equitable Purchase of Samples:

- 7.3.1 If Acorda purchases Product from the Second Source, the amount of the same, together with the quantity so purchased as samples, shall be notified to Elan in the applicable Statement.
- 7.3.2 Acorda shall purchase from the Second Source at least the same proportion of samples of the Product to commercial supply of Product as the proportion of samples to commercial supply purchased by Acorda from Elan.

Certain portions of this Exhibit have been omitted pursuant to a request for confidentiality. Such omitted portions, which are marked with brackets [ ] and an asterisk\*, have been separately filed with the Securities and Exchange Commission.

7.4. No Supply Restrictions On Second Source:

Acorda shall not place or attempt to place any restriction on supply from the Second Source to Elan or its licensees for sale in the Elan Territory, except to the extent of the restrictions on supply by Elan under Clause 2.2. In particular, Acorda shall not place or attempt to place any restriction on supplies from the Second Source to Elan for sale in the Elan Territory or its licensees after the end of the Term.

7.5. Responsibility for Second Source:

Assuming compliance by Elan with Clause 7.1, Acorda shall be solely responsible for:

- 7.5.1 all process and equipment validation in the Second Source required by applicable law or regulations and shall take all steps reasonably necessary to pass inspection by the Governmental Authority;
- 7.5.2 Product supplied to Acorda or its Designees by the Second Source.

7.6. Resumption of Elan Supply:

- 7.6.1 In the event that Product is being purchased from a Second Source as a result of Serious Failure To Supply, at such time as Elan has remedied the situation that caused it and is once again able to fulfil its obligations to supply Product pursuant to the terms and conditions of this Agreement, Elan shall so notify Acorda. Commencing on the first calendar quarter beginning after the date of such notice (the "**Resumption Quarter**"), Acorda shall resume purchasing and Elan shall resume its obligations to supply the Minimum Elan Quantities from Elan, subject to the provisions of Clause 7.6.2.
- 7.6.2 Acorda shall be entitled to:
- 7.6.2.1 honor its binding purchase commitments from the Second Source, incurred reasonably and consistently with its practice of ordering from Elan and for delivery within three (3) months of the date of such commitments, prior to the notice referred to in Clause 7.6.1; and
- 7.6.2.2 subsequent to the commencement of the Resumption Quarter, in addition to the Second Source Quantity, purchase from the Second Source up to twenty five percent (25%) of Minimum Elan Requirements, to the exclusion of Elan, for two consecutive calendar quarters in order to be satisfied of Elan's ability to fulfil its obligations in respect of the supply of Product pursuant to the terms and conditions of this Agreement.

7.6.3 The Technical Agreement shall contain terms applicable to the resumption of supply where the cessation is by reason of Force Majeure, which shall be not less favourable to Elan than the provisions of Clauses 7.6.1 and 7.6.2 applicable to resumption following Serious Failure to Supply.

---

Certain portions of this Exhibit have been omitted pursuant to a request for confidentiality. Such omitted portions, which are marked with brackets [ ] and an asterisk\*, have been separately filed with the Securities and Exchange Commission.

7.7. No Termination Right:

Absent Elan's failure to use commercially reasonable efforts to supply Product in accordance with the terms of this Agreement, Acorda shall have no right to terminate this Agreement by reason of failure to supply, except as otherwise expressly provided herein.

7.8. Have Made License:

The Parties acknowledge and confirm that:

- (a) to the extent that Acorda is permitted hereunder to purchase the Product from Patheon; and
- (b) following termination of this Agreement, and until termination of the License Agreement —

Acorda is regarded for the purposes of Article 2.1 of the License Agreement as being permitted to have the Product made by Patheon at the Second Source (subject always to the terms and conditions of this Agreement) and that the license grant under such Article 2.1 to make and have made Product extends accordingly.

**CLAUSE 8      ADVERSE EVENTS AND PRODUCT RECALL**

8.1. Each party shall give the other prompt notice, which shall be promptly confirmed in writing, of any occurrence that involves:

- 8.1.1 any material complaint about the safety or effectiveness of a Product, including a claim for death or injury following administration of such Product (that is plausibly related to the administration of such Product); and
- 8.1.2 any other matter arising out of this Agreement that must be reported to a Governmental Authority.

In the case of Acorda reporting to Elan matters described in Clause 8.1.2, reporting quarterly, or in such other timescale as may be agreed in the Technical Agreement, shall be considered "prompt".

For the avoidance of doubt, Acorda shall have overall responsibility for adverse event reporting and medical complaints.

8.2. If a party:

- 8.2.1 is notified by a Governmental Authority that a Recall of a Product is required, requested or otherwise advisable as being probably needed; or
- 8.2.2 establishes a need to Recall a Product for non-conformities with the Specifications —

---

Certain portions of this Exhibit have been omitted pursuant to a request for confidentiality. Such omitted portions, which are marked with brackets [ ] and an asterisk\*, have been separately filed with the Securities and Exchange Commission.

it shall promptly give to the other party written notice of the same with full details.

8.3. Unless otherwise agreed, after consultation with Elan, Acorda shall take the lead role in any Recall, market withdrawal, stock recovery or any other corrective action related to Product in a commercially reasonable manner and Elan shall afford all reasonable assistance. A final report shall be completed by Acorda and delivered promptly to Elan.

8.4. If the Recall, market withdrawal, stock recovery or other corrective action relating to a Product arises from Elan's negligent acts or omissions in manufacturing the Product, or failure of the Product to conform to Specifications, the costs, including the cost of replacement quantities of Products, of such Recall, market withdrawal, stock recovery or other corrective action relating to a Product shall be borne by Elan provided that Acorda could not have discovered the said act(s) or omission(s) prior to the sale of the Product by exercising reasonable diligence. In all other circumstances, such costs shall be borne by Acorda. For purposes of this Agreement, such costs shall include the expenses of notification and destruction or return of the Recalled Product and all other documented out-of-pocket costs incurred in connection with such Recall, market withdrawal, stock recovery or other corrective action relating to a Product, but shall not include lost profits or opportunity costs of either Party.

In the event that Elan should bear the costs of any recall hereunder, Elan shall be entitled but not obliged to take over and perform the recall of the Product and Acorda shall provide Elan at no cost with all such reasonable assistance as may be required by Elan.

**CLAUSE 9      FINANCIAL PROVISIONS**

9.1. Price of Launch Stocks:

Elan shall invoice Acorda for Launch Stocks at a price equivalent to Manufacturing Cost plus [\*\*\*\*\*], subject to reconciliation pursuant to Clause 9.3.3.

9.2. Price of Samples:

The price to be charged to Acorda for Product intended for distribution as free-of-charge promotional samples in its marketing and promotion of the Product shall be equivalent to Manufacturing Cost plus [\*\*\*\*\*] which price shall apply to Product supplied EXW Elan's Facility to Acorda. For the avoidance of doubt, the Parties confirm that if Acorda requires the samples to be supplied in sample packaging, Manufacturing Cost shall include all costs referable to such packaging.

9.3. Price of Product (General):

- 9.3.1 Except for Product referred to in Clauses 9.1 and 9.2, the price of the Product manufactured by Elan to be charged to Acorda under this Agreement shall be equivalent to eight per cent (8%) of the NSP as determined by the provisions of Clause 9.3.3 (the "Supply Price"), less the Discount to the extent applicable, and

17

---

Certain portions of this Exhibit have been omitted pursuant to a request for confidentiality. Such omitted portions, which are marked with brackets [ ] and an asterisk\*, have been separately filed with the Securities and Exchange Commission.

subject to Clause 2.5. The foregoing price shall apply to Product supplied EXW Elan's Facility packaged and labelled in final market form and consistent with the NDA.

- 9.3.2 For the avoidance of doubt the Parties agree that if for whatever reason the Product supplied by Elan to Acorda which meets the Specifications and the applicable law and regulatory requirements is not sold by Acorda, payment to Elan for such Product shall nonetheless be effected and the price of the Product shall be determined by reference to the NSP calculated pursuant to the provisions of Clause 9.3.3.
- 9.3.3 Upon supply, Elan shall render an invoice in respect of the quantities of Product delivered to Acorda for a sum calculated by reference to eight per cent (8%) of then-applicable Notional NSP. The Parties shall adjust their account as of the end of each calendar quarter during such calendar year by Acorda paying to Elan, or by Elan crediting Acorda (as the case may be), the difference between the sum paid pursuant to the previous sentence and the actual Supply Price calculated each calendar quarter pursuant by reference to actual NSP in such quarter, within the period specified in Clause 9.6.

9.4. Discount:

Where Acorda purchases from Elan for delivery in any Year more than [\*\*\*\*\*] tablets of the Product, Acorda shall be entitled to a discount (the "Discount") in respect of the excess equal to [\*\*\*\*\*] of Elan's Manufacturing Cost for such excess tablets.

The Discount is without prejudice to Clause 2.3.

9.5. Compensating Payment:

- 9.5.1 In respect of all Product purchased from the Second Source pursuant to Clause 7.2.1 and 7.6.2.2, Acorda shall make a compensating payment to Elan calculated per unit as  $X - Y$ , where "X" is the unit price that would have applied if the Product were purchased from Elan, under Clause 9.2 or 9.3 as applicable; and "Y" is the marginal unit variable element of Elan's Manufacturing Cost applicable to such Product.
- 9.5.2 Such compensating payment shall be made in respect of a particular quarter at the time of provision of the Statement, based on the then Notional NSP and estimated Manufacturing Cost. The Parties shall adjust their account as of the end of each calendar year by Acorda paying to Elan, or by Elan crediting Acorda (as the case may be), the difference between the sum paid pursuant to Clause 9.5.1 and the actual payment calculated on the basis of actual applicable NSP and actual Manufacturing Cost calculated at the end of the calendar year, or such other period as may be specified in the Technical Agreement within sixty (60) days after the end of the calendar year.

18

---

Certain portions of this Exhibit have been omitted pursuant to a request for confidentiality. Such omitted portions, which are marked with brackets [ ] and an asterisk\*, have been separately filed with the Securities and Exchange Commission.

9.6. Time For Payment:

For the first two years following First Commercial Sale of the Product in any country of the Territory, payment for the Product supplied to Acorda shall be effected in \$ within sixty (60) days of the date of the relevant invoice issued on supply by Elan pursuant to Clause 9.3.3. Thereafter, payment shall be effected by Acorda in \$ within thirty (30) days of the date of the relevant invoice issued on supply by Elan pursuant to Clause 9.3.3.

The adjusting payments referred to in Clause 9.3.3 shall be made on provision of the relevant Statement.

For the avoidance of doubt, in respect of Product ordered for a particular country prior to Regulatory Approval in that country, Acorda shall be responsible for the price of such Product as from its readiness for delivery, notwithstanding that applicable law or regulations may prevent such Product from being supplied before Regulatory Approval.



9.7. Process Transfer Costs:

Except as otherwise set forth in this Agreement, in respect of the establishment, qualification and operation of the Second Source, Acorda shall be solely responsible for:

- 9.7.1 Acorda's own costs and expenses;
- 9.7.2 all third party costs and expenses, including out of pocket expenses incurred by Elan, for products or services previously approved by the Committee; and
- 9.7.3 work conducted by Elan, its Affiliates, and their employees and consultants, under the Technology Transfer Responsibilities schedule, or as may otherwise be agreed to by the Parties, at the rate of FTE plus 45%.

9.8. VAT:

All prices for the Product and other amounts in this Agreement are exclusive of any applicable value added or any other sales tax, for which Acorda will be additionally liable, if payable, subject to Clause 10.

**CLAUSE 10 PAYMENTS, REPORTS AND AUDITS**

Article 5.9 of the Licence Agreement is hereby incorporated by reference herein as if restated in its entirety herein.

**CLAUSE 11 DURATION AND TERMINATION**

11.1. This Agreement shall be deemed to have come into force on the Effective Date and will expire upon expiry or termination of the Licence Agreement, howsoever arising.

19

---

Certain portions of this Exhibit have been omitted pursuant to a request for confidentiality. Such omitted portions, which are marked with brackets [ ] and an asterisk\*, have been separately filed with the Securities and Exchange Commission.

11.2. In addition to the rights of termination provided for elsewhere in this Agreement, either party will be entitled forthwith to terminate this Agreement by written notice to the other party if:

- 11.2.1 that other party commits any breach of any of the provisions of this Agreement or the Licence Agreement, and in the case of a breach capable of cure, fails to cure the same within 60 days after receipt of a written notice giving full particulars of the breach and requiring it to be remedied; provided, that if the breaching party has proposed a course of action to cure the breach and is acting in good faith to cure same but has not cured the breach by the 60th day, such period shall be extended by such period as is reasonably necessary to permit the breach to be cured, provided that such period shall not be extended by more than 90 days, unless otherwise agreed in writing by the parties;
- 11.2.2 that other party goes into liquidation (except for the purposes of amalgamation or reconstruction and in such manner that the company resulting therefrom effectively agrees to be bound by or assume the obligations imposed on that other party under this Agreement);
- 11.2.3 an encumbrancer takes possession or a receiver is appointed over any of the property or assets of that other party;
- 11.2.4 any proceedings are filed or commenced by that other party under bankruptcy, insolvency or debtor relief laws or anything analogous to any of the foregoing under the laws of any jurisdiction occurs in relation to that other party.

11.3. For the purposes of Clause 11.2, a breach will be considered capable of cure if the party in breach can comply with the provision in question in all respects other than as to the time of performance (provided that time of performance is not of the essence).

11.4. Elan may terminate this Agreement by giving twelve (12) months' written notice to do so to Acorda.

**CLAUSE 12 CONSEQUENCES OF TERMINATION**

12.1. Upon exercise of those rights of termination specified in Clause 11 or elsewhere in this Agreement, this Agreement shall, subject to the provisions of the Agreement which survive the termination of the Agreement and Clause 12.2 automatically terminate forthwith and be of no further legal force or effect, provided, however, that if the Agreement is terminated by Elan under Clause 11.4 such termination shall not be effective until the expiration of such twelve (12) month period

12.2. Upon termination of this Agreement by either party, the following shall be the consequences:

20

---

Certain portions of this Exhibit have been omitted pursuant to a request for confidentiality. Such omitted portions, which are marked with brackets [ ] and an asterisk\*, have been separately filed with the Securities and Exchange Commission.

- 12.2.1 any sums that were due from Acorda to Elan under the provisions of Clause 9 or otherwise prior to the exercise of the right to terminate this Agreement as set forth herein shall be paid in full forthwith provided, that Elan has delivered Product in accordance with the Specifications and cGMP; and Elan shall not be liable to repay to Acorda any amount of money paid or payable by Acorda to Elan up to the date of the termination of this Agreement;

- 12.2.2 all confidentiality provisions set out herein shall remain in full force and effect for a period of 7 years from the date of termination of this Agreement;
- 12.2.3 all representations and warranties shall insofar are appropriate remain in full force and effect;
- 12.2.4 the rights of inspection and audit shall continue in force for the period referred to in the relevant provisions of this Agreement; and
- 12.2.5 if Elan terminates the Agreement under Clause 11.4, Acorda shall be entitled to purchase all of Acorda's requirements of Product from the Second Source as from termination becoming effective.

**CLAUSE 13 REPRESENTATIONS AND WARRANTIES; INDEMNIFICATION**

- 13.1. The following clauses of the License Agreement are hereby incorporated by reference herein as if stated herein in their entirety, except that for purposes of this Agreement, all references in such clauses to "the Agreement" or "this Agreement" shall be deemed to mean this Supply Agreement: Articles 8.2, 8.3, 8.4, 8.5, and 8.7.
- 13.2. Elan represents and warrants that the Product supplied to Acorda by Elan under this Agreement shall be free of any lien, security, interest or other encumbrance on title, conform to the Specifications and all applicable laws and regulations and requirements of the FDA and other Governmental Authorities including, without limitation, the cGMP regulations which apply to the manufacture, storage, packaging and supply of the Product. Elan represents and warrants that the Product supplied to Acorda under this Agreement shall be free of defects in material and workmanship, shall not be adulterated or mis-branded as defined by the Act (or applicable foreign law) and shall not be a product which would violate any section of such Act if introduced in interstate commerce and shall be fit for use as a pharmaceutical product. Acorda agrees not to assert its right to rescind this Agreement in the event of a breach of the representations of Elan contained in this Clause 13.2.
- 13.3. Elan shall indemnify, defend and hold harmless Acorda and its officers, directors, employees and agents from all actions, losses, claims, demands, damages, costs and liabilities (including reasonable attorneys' fees) due to Third Party claims to which Acorda is or may become subject insofar as they arise out of or are alleged or claimed to arise out of (i) any breach by Elan of any of its obligations under this Agreement, (ii) any breach of a representation or warranty of Elan made in this Agreement, (iii) any failure of

21

Certain portions of this Exhibit have been omitted pursuant to a request for confidentiality. Such omitted portions, which are marked with brackets [ ] and an asterisk\*, have been separately filed with the Securities and Exchange Commission.

the Product provided under this Agreement to meet the Specifications, or (iv) the manufacture or shipment of the Product provided under this Agreement by Elan, except in each case to the extent due to the negligence or wilful misconduct of Acorda.

- 13.4. Acorda shall indemnify, defend and hold harmless Elan and its officers, directors, employees and agents from all actions, losses, claims, demands, damages, costs and liabilities (including reasonable attorneys' fees) due to Third Party claims to which Elan is or may become subject insofar as they arise out of or are alleged or claimed to arise out of (i) any breach by Acorda of any of its obligations under this Agreement, (ii) any breach of any representation or warranty of Acorda made in this Agreement, (iii) damages for personal injury (including death) and/or for costs of medical treatment, caused by or attributed to the Product, or (iv) the acts or omissions of any sub-licensee appointed pursuant to the Licence Agreement, except in each case to the extent due to the negligence or wilful misconduct of Elan or to the relative extent that Elan is obliged to indemnify Acorda pursuant to Clause 13.3.
- 13.5. The party seeking an indemnity shall:
  - 13.5.1 fully and promptly notify the other party of any claim or proceedings, or threatened claim or proceedings;
  - 13.5.2 permit the indemnifying party to take full control of such claim or proceedings, with counsel of the indemnifying party's choice, provided that the indemnifying party shall reasonably and regularly consult with the indemnified party in relation to the progress and status of such claim or proceedings;
  - 13.5.3 co-operate in the investigation and defence of such claim or proceedings; and
  - 13.5.4 take all reasonable steps to mitigate any loss or liability in respect of any such claim or proceedings.

The indemnifying party may settle a Claim on terms which provide only for monetary relief and do not include any admission of liability. Save as aforesaid, neither the indemnifying party nor the party to be indemnified shall acknowledge the validity of, compromise or otherwise settle any Claim or proceedings without the prior written consent of the other, which shall not be unreasonably withheld.

- 13.6. TO THE FULLEST EXTENT PERMITTED BY LAW, APART FROM THE FOREGOING REPRESENTATIONS, WARRANTIES, COVENANTS AND INDEMNITIES, AND THOSE SET FORTH IN THE LICENSE AGREEMENT ELAN MAKES NO ADDITIONAL REPRESENTATIONS OR WARRANTIES AND HEREBY DISCLAIMS ALL WARRANTIES, REPRESENTATIONS, AND LIABILITIES, WHETHER EXPRESS OR IMPLIED, ARISING FROM CONTRACT OR TORT (EXCEPT FRAUD), IMPOSED BY STATUTE OR OTHERWISE, RELATING TO THE PRODUCTS AND/OR ANY PATENTS OR TECHNOLOGY USED OR INCLUDED IN THE PRODUCTS, INCLUDING ANY WARRANTIES AS

22

TO MERCHANTABILITY, FITNESS FOR PURPOSE, CORRESPONDENCE WITH DESCRIPTION, OR NON-INFRINGEMENT.

- 13.7. NOTWITHSTANDING ANYTHING TO THE CONTRARY IN THIS AGREEMENT, ELAN AND ACORDA SHALL NOT BE LIABLE TO THE OTHER BY REASON OF ANY REPRESENTATION OR WARRANTY, CONDITION OR OTHER TERM OR ANY DUTY OF COMMON LAW, OR UNDER THE EXPRESS TERMS OF THIS AGREEMENT, FOR ANY CONSEQUENTIAL, SPECIAL OR INCIDENTAL OR PUNITIVE LOSS OR DAMAGE (WHETHER FOR LOSS OF CURRENT OR FUTURE PROFITS, LOSS OF ENTERPRISE VALUE OR OTHERWISE) AND WHETHER OCCASIONED BY THE NEGLIGENCE OF THE RESPECTIVE PARTIES, THEIR EMPLOYEES OR AGENTS OR OTHERWISE.
- 13.8. Elan and Acorda shall each maintain comprehensive general liability insurance, insuring against all liability, including product liability, personal injury, physical injury and property damage in respective amounts deemed reasonable in the industry for companies of their respective size and engaged in their respective activities under this Agreement for the duration of this Agreement and for a period of 5 years thereafter.

Each party shall provide the other party with a certificate from the insurance company verifying the above and shall notify the other party in writing at least 30 days prior to the expiration or termination of such coverage.

#### CLAUSE 14 MISCELLANEOUS PROVISIONS

14.1. Secrecy and Confidentiality. Article 12.1 of the License Agreement is hereby incorporated by reference herein as if stated herein in its entirety.

14.2. Licence to Elan:

Acorda hereby grants to Elan and Elan hereby accepts for the Term a non-exclusive royalty-free license to use such Acorda Patent Rights and Acorda Know-How as are necessary or useful for the purpose of manufacturing the Product. Such rights shall be sub-licensable by Elan to its Affiliates and sub-contractors, for the sole purpose of manufacturing the Product in accordance with this Agreement.

14.3. Assignment:

14.3.1 Subject to the provisions of this Clause 14.3, each party be entitled without the consent of the other:

14.3.1.1 to subcontract or delegate the whole or any part of its duties hereunder to its Affiliate(s) (but shall remain responsible for its obligations under this Agreement); and/or

23

14.3.1.2 to assign this Agreement to its Affiliate, provided that such assignment has no material adverse tax implications for the other Party or Parties hereto, and provided further that the assigning Party shall remain liable and responsible with such assignee to the other Party for the performance of any obligations, representations or warranties delegated, contracted, assigned or otherwise transferred to any such assignee.

14.3.2 In the event that Elan agrees to sell all or substantially all of the assets of Elan's Facility, Elan shall so notify Acorda. In such event, Elan may (a) terminate this Agreement by ninety (90) days' written notice to Acorda; or (b) assign all (but not, subject to the following sentences, a portion) of its rights and obligations under this Agreement to a Permitted Elan Assignee, provided that such transfer or assignment has no adverse tax implications for Acorda.

14.3.3 Each Party may assign all (but not a portion) of its rights and obligations under this Agreement to an entity that acquires all or substantially all of its business or assets to which this Agreement pertains, whether by merger, reorganisation, acquisition, sale or otherwise, provided, that in the case of an assignment by Elan, the assignee is a Permitted Elan Assignee.

14.3.4 Except as provided for in this Clause 14.3, this Agreement may not be assigned by a party without the prior written consent of the other Party, which shall not be unreasonably withheld or delayed.

14.3.5 Any permitted assignee of a Party under this Clause 14.3 shall assume all related obligations of its assignor under this Agreement.

14.4. Parties bound:

This Agreement shall be binding upon and enure for the benefit of parties hereto, their successors and permitted assigns.

14.5. Severability:

If any provision in this Agreement is deemed to be, or becomes invalid, illegal, void or unenforceable under applicable laws:

14.5.1 such provision will be deemed amended to conform to applicable laws so as to be valid and enforceable; or

14.5.2 if it cannot be so amended without materially altering the intention of the parties, it will be deleted the validity, legality and enforceability of the remaining provisions of this Agreement shall not be impaired or affected in any way.

Certain portions of this Exhibit have been omitted pursuant to a request for confidentiality. Such omitted portions, which are marked with brackets [ ] and an asterisk\*, have been separately filed with the Securities and Exchange Commission.

14.6. Force Majeure:

- 14.6.1 Neither party to this Agreement shall be liable for delay or failure in the performance of any of its obligations hereunder if such delay or failure results from Force Majeure.
- 14.6.2 If Force Majeure prevents or delays the performance by a party of any obligation under this Agreement, then the party claiming Force Majeure shall promptly notify the other party thereof in writing. The parties shall thereafter as soon as practicable discuss how best to continue their operations in accordance with this Agreement and shall thereafter continue such discussions on a regular basis while Force Majeure continues.
- 14.6.3 Where a party claims Force Majeure, the other party's obligations under this Agreement shall be suspended for the period while Force Majeure continues, but only to the extent reasonably required by the Force Majeure.
- 14.6.4 The party claiming Force Majeure shall use all reasonable efforts to avoid, minimise or remove the cause of such non-performance and to mitigate its effects and shall continue performance with due dispatch whenever such causes are removed.
- 14.6.5 Where Force Majeure continues for a period of six (6) months the other party shall have the right to terminate this Agreement, provided that it has complied with its obligations under this Clause 14.6.

14.7. Relationship of the parties:

- 14.7.1 Nothing contained in this Agreement is intended or is to be construed to constitute any of the parties hereto as partners or members of a joint venture or any party as an employee of another party.
- 14.7.2 No party hereto shall have any express or implied right or authority to assume or create any obligations on behalf of or in the name of any other party or to bind another party to any contract, agreement or undertaking with any third party.

14.8. Amendments:

No amendment, modification or addition hereto shall be effective or binding on any party hereto unless set forth in writing and executed by a duly authorised representative of all parties hereto.

14.9. Waiver:

No waiver of any right under this Agreement shall be deemed effective unless contained in a written document signed by the party charged with such waiver, and no waiver of any breach or failure to perform shall be deemed to be a waiver of any future breach or failure to perform or of any other right arising under this Agreement.

---

Certain portions of this Exhibit have been omitted pursuant to a request for confidentiality. Such omitted portions, which are marked with brackets [ ] and an asterisk\*, have been separately filed with the Securities and Exchange Commission.

14.10. Entire Agreement:

- 14.10.1 Each of the parties hereto hereby acknowledges that in entering into this Agreement it has not relied on any representation or warranty except as expressly set forth herein or in the License Agreement or in any other document referred to herein.
- 14.10.2 This Agreement and the Licence Agreement, together with the exhibits and schedules hereto and thereto, together set forth all of the agreements and understandings between the parties with respect to the subject matter hereof, and supersede and terminate all prior agreements and understandings between the parties with respect to the subject matter hereof, including the SCI Agreement and the MS Agreement.
- 14.10.3 Nothing in this Clause 14.10 shall exclude any liability which any party would otherwise have to the other party or any right which either of them may have to rescind this Agreement for fraud.

14.11. Governing law and jurisdiction:

- 14.11.1 This Agreement shall be governed by and construed in accordance with the laws of the State of New York, excluding its conflict of laws rules.
- 14.11.2 Article 12.14 of the License Agreement is hereby incorporated by reference herein as if stated herein in its entirety.

14.12. Notices:

- 14.12.1 Any notice to be given under this Agreement shall be sent in writing in English by registered or recorded delivery post, reputable overnight courier or fax to:

Elan at

c/o Elan Pharma Ltd.  
Monksland  
Athlone  
Co. Westmeath  
Ireland  
Attention: General Manager  
Fax: +353 906 492427

Acorda at

15 Skyline Drive  
Hawthorne, New York 10532  
United States of America  
Attention: President  
Fax: 914.347.4560

26

---

Certain portions of this Exhibit have been omitted pursuant to a request for confidentiality. Such omitted portions, which are marked with brackets [ ] and an asterisk\*, have been separately filed with the Securities and Exchange Commission.

or to such other address(es) and fax numbers as may from time to time be notified by either party to the other hereunder.

14.12.2 Any notice sent by mail shall be deemed to have been delivered within 7 working days after despatch or delivery to the relevant courier and any notice sent by fax shall be deemed to have been delivered upon confirmation of receipt. Notice of change of address shall be effective upon receipt.

14.13. Further assurances:

At the request of any of the parties, the other party or parties shall (and shall use reasonable efforts to procure that any other necessary third parties shall) execute and do all such documents, acts and things as may reasonably be required subsequent to the signing of this Agreement for assuring to or vesting in the requesting party the full benefit of the terms hereof.

14.14. Counterparts:

This Agreement may be executed in any number of counterparts, each of which when so executed shall be deemed to be an original and all of which when taken together shall constitute this Agreement.

14.15. Set-off:

Each of the parties will be entitled but not obliged to set-off against any amount of money payable to it by the other party hereunder, any amount of money payable by it to the other party hereunder.

**IN WITNESS WHEREOF** the parties have executed this Agreement on the day and date appearing at the top of page 1.

27

---

Certain portions of this Exhibit have been omitted pursuant to a request for confidentiality. Such omitted portions, which are marked with brackets [ ] and an asterisk\*, have been separately filed with the Securities and Exchange Commission.

#### **SCHEDULE 1 MANUFACTURING COST**

“Manufacturing Cost” shall mean fully absorbed cost of manufacture (including packaging) which shall be determined on the basis of the following elements:

- (a) Direct material, labour and overhead cost; and
- (b) Such indirect labour, factory, laboratory and other overhead costs properly allocable. Overhead allocations shall include, but not be limited to, expenses of plant maintenance and engineering, plant management, receiving and warehousing, disposal and treatment of waste, building occupancy, quality control, costs of services provided to manufacturing and insurance provided to manufacturing.

Such allocations shall be in a manner consistent with GAAP from time to time and in a manner consistent with expenses and overhead allocated to other products manufactured by Elan or its Affiliates.

Where some part(s) of the manufacture or packaging is/are conducted by unaffiliated third party(ies), Manufacturing Cost shall be the amount paid to such third party(ies) plus any of the aforementioned costs incurred by Elan or its Affiliates in completing the manufacture, packaging or delivery of the Product.

28

---

Certain portions of this Exhibit have been omitted pursuant to a request for confidentiality. Such omitted portions, which are marked with brackets [ ] and an asterisk\*, have been separately filed with the Securities and Exchange Commission.

**SIGNED**

Monksland Holdings BV

By: /s/ Pieter Bosse

By: /s/ Klaas van Blanken

for and on behalf of

**ELAN CORPORATION, PLC.**

Name: Monksland Holdings BV

Title: Proxyholder

**SIGNED**

By: /s/ Ron Cohen

for and on behalf of

**ACORDA THERAPEUTICS, INC.**

Name: Ron Cohen

Title: President & Chief Executive Officer

Certain portions of this Exhibit have been omitted pursuant to a request for confidentiality. Such omitted portions, which are marked with brackets [ ] and an asterisk\*, have been separately filed with the Securities and Exchange Commission.

LICENSE AGREEMENT

by and among

ELAN PHARMACEUTICAL RESEARCH CORP.,  
d/b/a  
NANOSYSTEMS

and

ELAN PHARMA INTERNATIONAL LIMITED

and

JANSSEN PHARMACEUTICA N.V.

March 31, 1999

This document is the confidential information of both parties hereto.  
It should be distributed on a need-to-know basis and kept in secure area.

Certain portions of this Exhibit have been omitted pursuant to a request for confidentiality. Such omitted portions, which are marked with brackets [ ] and an asterisk\*, have been separately filed with the Securities and Exchange Commission.

**TABLE OF CONTENTS**

	<u>Page</u>
ARTICLE 1 - Definitions	1
ARTICLE 2 - LICENSE GRANT	7
ARTICLE 3 - DEVELOPMENT ACTIVITIES	9
ARTICLE 4 - CLINICAL AND REGULATORY ACTIVITIES	10
ARTICLE 5 - PAYMENTS	12
ARTICLE 6 - ROYALTIES	13
ARTICLE 7 - ROYALTY PAYMENTS, REPORTS AND RECORDS	14
ARTICLE 8 - COMMERCIALIZATION	16
ARTICLE 9 - MANUFACTURING AND SUPPLY	17
ARTICLE 10 - RIGHTS IN TECHNOLOGY, INVENTIONS AND PATENTS	17
ARTICLE 11 - INFRINGEMENT	19
ARTICLE 12 - CONFIDENTIALITY	23
ARTICLE 13 - TERM	26
ARTICLE 14 - TERMINATION BY JANSSEN	27
ARTICLE 15 - TERMINATION FOR CAUSE	27
ARTICLE 16 - RIGHTS AND OBLIGATIONS UPON TERMINATION	27
ARTICLE 17 - REPRESENTATIONS AND WARRANTIES	28
ARTICLE 18 - INDEMNIFICATION	30
ARTICLE 19 - CHOICE OF LAW	32
ARTICLE 20 - FORCE MAJEURE	32
ARTICLE 21 - DISPUTE RESOLUTION	32
ARTICLE 22 - NOTICES	35
ARTICLE 23 - WAIVER	36
ARTICLE 24 - ENTIRE AGREEMENT	36
ARTICLE 25 - ASSIGNMENT	36
ARTICLE 26 - TITLES	38
ARTICLE 27 - PUBLICITY	38
ARTICLE 28 - UNENFORCEABLE PROVISIONS	38
ARTICLE 29 - CONSTRUCTION	38
ARTICLE 30 - EXECUTION	39
ARTICLE 31 - NON-SOLICITATION	39
Exhibit A	NANO PATENTS
Exhibit B	SELECTION PATENTS
Form 1	STATEMENT

Certain portions of this Exhibit have been omitted pursuant to a request for confidentiality. Such omitted portions, which are marked with brackets [ ] and an asterisk\*, have been separately filed with the Securities and Exchange Commission.

This License Agreement is made as of this 31st day of March, 1999 (the "Effective Date") by and among Elan Pharmaceutical Research Corp., a corporation organized and existing under the laws of the State of Georgia and doing business as NanoSystems ("EPRC"), and Elan Pharma International Limited, a corporation organized and existing under the laws of Ireland ("EPIL") (EPRC and EPIL collectively referred to herein as "NANO"), and Janssen Pharmaceutica N.V., a corporation organized and existing under the laws of Belgium ("JANSSEN").

WITNESSETH THAT:

WHEREAS, NANO possesses, among other things, certain proprietary information in connection with a technology for the formulation of crystalline drug substances into pharmaceutically acceptable dosage forms; and

WHEREAS, NANO owns or controls patents and patent applications, as well as know-how with respect to its technology and has the right to grant certain rights and licenses thereunder as set forth herein; and

WHEREAS, JANSSEN possesses proprietary information, as well as patents and patent applications in relation to a proprietary compound developed by it; and

WHEREAS, NANO and JANSSEN wish to engage in a development and license agreement with a view towards developing certain crystalline forms of a proprietary JANSSEN compound utilizing NANO's proprietary technology; and

WHEREAS, NANO is willing to grant such rights and licenses to JANSSEN under the terms and conditions hereinafter set forth;

NOW, THEREFORE, in consideration of the mutual promises, covenants and agreements hereinafter set forth, the parties to this Agreement mutually agree as follows:

**ARTICLE 1 - DEFINITIONS**

For purposes of this Agreement, the following capitalized terms in this Agreement shall have the following meanings, unless the context clearly requires otherwise:

1.1 "Affiliate" shall mean, with respect to any party hereto, any corporation, company, partnership, joint venture or any other entity which directly or indirectly controls, is controlled by, or is under common control with such party. For purposes of this definition, "control" shall mean direct or indirect ownership of fifty percent (50%) or more of the stock or shares entitled to vote for the election of directors. For the purposes of this Agreement, EPRC and EPIL shall not be considered Affiliates of JANSSEN and JANSSEN shall not be considered an Affiliate of EPRC or EPIL.

1

---

Certain portions of this Exhibit have been omitted pursuant to a request for confidentiality. Such omitted portions, which are marked with brackets [ ] and an asterisk\*, have been separately filed with the Securities and Exchange Commission.

1.2 "Agreement" shall mean this License Agreement.

1.3 "Analogue" shall mean a structural analogue of Compound falling under the claims of any Janssen Patent, which is developed and commercialized under this Agreement as a substitute for, and for the same indications as, 9 O-H risperidone palmitate (R 92670) or any salt or derivative thereof.

1.4 "Compound" shall mean (i) the active ingredient 9 O-H risperidone palmitate (R 92670), or any salt or derivative thereof, falling under the claims of any Janssen Patent, or (ii) in the event that JANSSEN ceases development of R 92670 prior to commercialization, an Analogue selected by JANSSEN, or (iii) in the event that JANSSEN ceases development of an Analogue prior to commercialization, another Analogue selected by JANSSEN.

1.5 "Competition" shall mean a situation in which one or more Persons in a country are marketing a product containing Compound that competes with the Product and such Persons' sales of such product for a calendar quarter are at least fifteen percent (15%) of the total sales of all Products in such country, as measured by comparing equivalent units of products sold. Sales of a competing product in a country during any calendar quarter shall be conclusively deemed to be at least fifteen percent (15%) of the total sales of Products in such country if IMS America or IMS International makes such a determination based on its conduct of a market share study in such country during such quarter. Once a determination is made that Competition exists for the Product in any country, such determination shall be made again each calendar quarter for so long as the Product is marketed in that country.

1.6 "Control, Controlled" shall mean the legal authority or right of a party hereto to grant a license or sublicense of intellectual property rights to another party hereto, or to otherwise disclose proprietary or trade secret information to such other party, without breaching the terms of any agreement with a Third Party, infringing upon the intellectual property rights of a Third Party, or misappropriating the proprietary or trade secret information of a Third Party. Information that is generally known or available to the public shall not be deemed Controlled by a party hereto.

1.7 "Development Candidate" shall mean a Sterile, injectable pharmaceutical formulation of the Compound selected by JANSSEN for further development under the terms of this Agreement.

1.8 "Development Plan" shall mean the plan directed towards the development of a Development Candidate as more fully set forth in Article 3.

2

---



Certain portions of this Exhibit have been omitted pursuant to a request for confidentiality. Such omitted portions, which are marked with brackets [ ] and an asterisk\*, have been separately filed with the Securities and Exchange Commission.

- 1.9 “Development Program” shall mean the program of activities specified in the Development Plan for a Development Candidate as further detailed in Article 3.
- 1.10 “Development Team” shall mean a team comprised of representatives of NANO and JANSSEN monitoring the Development Program.
- 1.11 “Dollars” shall mean United States dollars.
- 1.12 “Elan-Independent” shall mean incorporating, embodying or derived from patent rights, know-how or technology owned, licensed or developed by Elan Corporation, plc or any of its Affiliates (i) prior to the date on which Elan Corporation, plc acquired NanoSystems, LLC, or (ii) thereafter but wholly independent of any patent rights, know-how or technology obtained by Elan Corporation, plc or any of its Affiliates as a result of such acquisition.
- 1.13 “EU” shall mean the member states of the European Union.
- 1.14 “FDA” shall mean the United States Food and Drug Administration and, when appropriate herein, shall also mean any corresponding regulatory agency in any other country in the Territory.
- 1.15 “Feasibility Agreement” shall mean the Feasibility Collaboration Agreement between JANSSEN and NanoSystems, LLC dated August 29, 1996.
- 1.16 “First Commercial Sale” shall mean the first sale of the Product by JANSSEN, its Affiliates or Licensees, or any of their distributors in any country following receipt of all regulatory approvals, including those relating to pricing and reimbursement, necessary to commence commercial sales of the Product in such country. Reasonably limited sales made prior to the receipt of all approvals necessary to commence commercial sales, such as so-called “named patient sales”, “compassionate use” sales and the like, shall not be deemed First Commercial Sales.
- 1.17 “Highly Confidential Information” shall mean specific processing conditions and/or parameters included in NanoCrystal Technology (excluding specific processing conditions and/or parameters specifically described in any NANO Patent) that are reasonably necessary for specialized JANSSEN or NANO employees to become skilled in the art of making nanoparticles, including, but not limited to, information concerning (i) work-up and composition of starting materials, size reduction, harvesting and sizing of nanoparticles; (ii) stabilization of nanoparticles; and (iii) specific downstream processing to make nanoparticle formulations. “Highly Confidential Information” shall not include information that is aimed at providing JANSSEN or NANO employees with a general understanding of the methods, processes and equipment used to manufacture or

---

Certain portions of this Exhibit have been omitted pursuant to a request for confidentiality. Such omitted portions, which are marked with brackets [ ] and an asterisk\*, have been separately filed with the Securities and Exchange Commission.

formulate nanoparticles, but that is not intended to enable JANSSEN or NANO employees to become skilled in the art of making or formulating nanoparticles. In addition, “Highly Confidential Information” shall include only information that is (A) disclosed to JANSSEN in written or other tangible form clearly labeled as “Highly Confidential” at the time of disclosure, or (B) initially disclosed to JANSSEN in non-tangible form and identified as “Highly Confidential” at the time of such disclosure and, within thirty (30) days following the initial disclosure, summarized and designated as “Highly Confidential” in written or other tangible form delivered to JANSSEN.

- 1.18 “Improvement” shall mean any enhancement of or improvement to NanoCrystal Technology developed, invented or acquired by, or coming under the Control of, any party hereto (i) as a consequence of activities conducted or information disclosed under this Agreement or the Feasibility Agreement, or (ii) during the period between the Effective Date and the filing of the IRF for the Product; provided, however, that “Improvements” shall not include any enhancements of or improvements to NanoCrystal Technology that (A) are made by Janssen and are useful solely with respect to Compound or Product; (B) concern a commercial scale manufacturing process developed by JANSSEN for Product, but do not utilize and are not derived from NanoCrystal Technology; or (C) are Elan-Independent inventions, discoveries or findings.
- 1.19 “IND” shall mean (i) an Investigational New Drug Application filed by JANSSEN, its Affiliates or Licensees pursuant to the requirements of the FDA, as more fully defined in 21 C.F.R. § 312.3, as well as (ii) equivalent submissions with similar requirements to the appropriate health authorities in other countries in the Territory as herein defined.
- 1.20 “IRF” shall mean the International Registration File owned by JANSSEN, compiled in such a way as is:
- (a) necessary to satisfy the requirements of an NDA in the United States;
  - (b) necessary to satisfy the requirements of the Notice to Applicants for marketing authorization for Proprietary Medicinal Products for use in the EU; and
  - (c) satisfactory to be submitted as such to the national health authorities in any country or to be used as a basis for a national application for marketing authorization for the Product in the specific format required by such national health authorities.

---

Certain portions of this Exhibit have been omitted pursuant to a request for confidentiality. Such omitted portions, which are marked with brackets [ ] and an asterisk\*, have been separately filed with the Securities and Exchange Commission.

- 1.21 “Janssen Patent” shall mean all patents (including all additions, divisions, continuations, continuations-in-part, substitutions, extensions, patent term extensions and renewals thereof) and patent applications (including patents issued thereon) that are or become owned or Controlled by JANSSEN. For the purpose hereof, “Janssen Patents” shall also include JANSSEN’s interests, if any, in Selection Patents.
- 1.22 “Licensee” shall mean any person, corporation, unincorporated body, or other entity that is not an Affiliate of JANSSEN and to whom JANSSEN grants a sublicense of the rights granted to JANSSEN pursuant to Article 2.
- 1.23 “Major Markets” shall mean the United States, Japan, the United Kingdom, France and Germany.
- 1.24 “Nano Know-How” shall mean all information and materials, including, without limitation, processes, techniques, formulas, data, methods, equipment designs, know-how, show-how and trade secrets, patentable or otherwise, tangible or intangible, that are owned or Controlled by NANO as of the Effective Date and that relate to the preparation, purification, characterization, stabilization, processing, formulation or delivery of small particles of pharmaceutical compounds prepared using a wet milling process; provided, however, that “Nano Know-How” shall not include any Elan-Independent information or materials.
- 1.25 “Nano Patents” shall mean all patents (including all additions, divisions, continuations, continuations-in-part, substitutions, extensions, patent term extensions and renewals thereof) and patent applications (including patents issued thereon) that are owned or Controlled by NANO as of the Effective Date or that claim or cover any Improvement; provided, however, that “Nano Patents” shall not include any Elan-Independent patents or patent applications. A worldwide list of the current Nano Patents (including pending patent applications) is attached hereto as Exhibit A. This list will be updated by NANO upon the reasonable request of JANSSEN.
- 1.26 “NanoCrystal Technology” shall mean the Nano Patents, the Nano Know-How and Improvements.
- 1.27 “NDA” shall mean (i) a New Drug Application and all supplements filed pursuant to the requirements of the FDA, including all documents, data and other information concerning the Product which are necessary for or included in FDA approval to market a Product as more fully defined in 21 C.F.R. § 314.50 *et seq.*, or (ii) any other similar application for marketing authorization filed with the appropriate regulatory authorities in any other country of the Territory.

Certain portions of this Exhibit have been omitted pursuant to a request for confidentiality. Such omitted portions, which are marked with brackets [ ] and an asterisk\*, have been separately filed with the Securities and Exchange Commission.

- 1.28 “Net Sales” shall mean, commencing with the First Commercial Sale of the Product in each country in the Territory, the aggregate of the gross invoiced sales price for such Product sold or commercially disposed of for value by JANSSEN, its Affiliates or the Licensees, or any of their distributors, to Third Parties, after deduction of the following amounts:
- (a) all normal and customary trade and quantity discounts, allowances and rebates, including government rebates actually taken or allowed except that such discounts granted in consideration of a Third Party’s agreement to purchase other products shall not be deducted;
  - (b) credits or allowances given or made for rejection, recall or return of previously sold Product to the extent actually taken or allowed;
  - (c) any tax or government charges, including any tax such as a value added or similar tax or government charge other than an income tax levied on the sale, transportation or delivery of the Product and borne by the seller thereof; and
  - (d) any charges for freight and insurance that are documented as billed to the final customer.
- 1.29 “Phase I” shall mean (i) that portion of the FDA submission and approval process which provides for the first introduction into humans of the Product with the purposes of determining human toxicity, metabolism, absorption, elimination and other pharmacological actions, as more fully defined in 21 C.F.R. § 312.21(a), as well as (ii) equivalent submissions with similar requirements in other countries in the Territory.
- 1.30 “Phase II” shall mean (i) that portion of the FDA submission and approval process which provides for the initial trials of the Product on a limited number of patients for the purposes of determining dose and evaluating safety and efficacy in the proposed therapeutic indication as more fully defined in 21 C.F.R. § 312.21(b), as well as (ii) equivalent submissions with similar requirements in other countries in the Territory.
- 1.31 “Phase III” shall mean (i) that portion of the FDA submission and approval process which provides for the continued trials of Product on sufficient numbers of patients to generate safety, efficacy and pharmacoeconomic data to support regulatory approval in the proposed therapeutic indication as more fully defined in 21 C.F.R. § 312.21(c), as well as (ii) equivalent submissions with similar requirements in other countries in the Territory.

Certain portions of this Exhibit have been omitted pursuant to a request for confidentiality. Such omitted portions, which are marked with brackets [ ] and an asterisk\*, have been separately filed with the Securities and Exchange Commission.

- 1.32 “Product” shall mean a Sterile, injectable pharmaceutical product containing Compound that (i) utilizes or is prepared using Nano Know-How or any Improvement, and/or (ii) is covered by a Selection Patent and/or (iii) would infringe any of the Nano Patents but for the licenses granted hereunder.
- 1.33 “Selection Patents” shall mean all patents (including all additions, divisions, continuations, continuations-in-part, substitutions, extensions, patent term extensions and renewals thereof) and patent applications (including patents issued thereon) that (i) claim findings or inventions made or conceived by JANSSEN or NANO (or any of their Affiliates) as a consequence of activities conducted or information disclosed under this Agreement or the Feasibility Agreement; and (ii) are directed to methods of preparing, purifying, characterizing, stabilizing, processing, formulating

or delivering small particles of Compound or Product. A worldwide list of the current Selection Patents (including pending patent applications) is attached hereto as Exhibit B. This list will be updated by JANSSEN at the reasonable request of NANO.

- 1.34 "Sterile" shall mean meeting the criteria of sterility as defined in the current United States Pharmacopeia.
- 1.35 "Territory" shall mean all countries of the world.
- 1.36 "Third Party" shall mean any person, corporation, unincorporated body, or other entity other than JANSSEN, NANO and their respective Affiliates and/or Licensees.
- 1.37 "Valid Claim" shall mean a claim in a patent that has not lapsed or become abandoned and that has not been declared invalid by an unreversed or an unappealable decision of a court of competent jurisdiction.

## **ARTICLE 2 - LICENSE GRANT**

- 2.1 NANO grants to JANSSEN a worldwide, exclusive license under the NanoCrystal Technology for the sole purpose of developing, having developed, making, having made, using, marketing, selling, having sold and distributing Product in the Territory, subject to the terms and conditions set forth in this Agreement, including the provisions of Article 9.
- 2.2 The rights and licenses granted hereunder shall be sublicensable by JANSSEN to Licensees in any country in the Territory, subject to the terms and conditions set forth in this Agreement, including the provisions of Article 9; provided, however, that no Licensee shall be permitted to sublicense any license granted to such sublicensee.

7

---

Certain portions of this Exhibit have been omitted pursuant to a request for confidentiality. Such omitted portions, which are marked with brackets [ ] and an asterisk\*, have been separately filed with the Securities and Exchange Commission.

- 2.3 JANSSEN may develop, make and/or sell Product through its Affiliates in any country in the Territory or grant sublicenses to its Affiliates in any country of the Territory, subject to the terms and conditions set forth in this Agreement, including the provisions of Article 9.
- 2.4 At the request of JANSSEN, NANO will extend the rights and licenses granted herein to an Affiliate of JANSSEN on a direct basis in any country of the Territory, subject to the terms and conditions set forth in this Agreement, including the provisions of Article 9.
- 2.5 Notwithstanding the granting of a sublicense to a Licensee or an Affiliate, or a direct license to an Affiliate, JANSSEN shall remain directly responsible to NANO for all obligations of JANSSEN, its Affiliates and Licensees.
- 2.6 Nothing herein shall preclude JANSSEN and/or its Affiliates from utilizing distributors to promote and distribute the Product in any country of the Territory.
- 2.7 In the event the JANSSEN would consider developing an oral formulation of the Product, the Parties will in good faith discuss the possibility and the terms and conditions under which NANO would grant JANSSEN a license under the NanoCrystal Technology to develop, make and sell such oral formulation and/or whether NANO would manufacture such oral formulation for JANSSEN.
- 2.8 Notwithstanding anything else herein to the contrary, in the event that JANSSEN's development, manufacture, use, marketing, sale or distribution of Product in the Territory would infringe any patent that would be a Nano Patent but for the fact that it is an Elan-Independent patent (an "Elan Patent"), NANO hereby grants to JANSSEN, to the extent NANO is legally able to do so, a non-exclusive, royalty-free license under such Elan Patent for the sole purpose of developing, having developed, making, having made, using, marketing, selling, having sold and distributing such Product in the Territory, which license shall be subject to the provisions of Article 9. The provisions of Article 11 shall not apply to any Elan Patents licensed hereunder, and NANO shall have no obligation to transfer or disclose to JANSSEN any processes, techniques, formulas, data, methods, equipment designs, know-how, show-how or trade secrets associated with any Elan Patents licensed hereunder. Notwithstanding the above, in the event NANO is legally not able to grant such a non-exclusive, royalty free license under any Elan Patent and is for similar reasons not able to grant a commitment not to sue under such Elan Patent in relation to the development, manufacture, use, marketing, sale or distribution of Product, then JANSSEN shall be entitled to deduct all costs incurred or payments made (including royalty payments) in relation to any alleged infringement of such Elan Patent or settlement or other final disposition thereof, in accordance with the provisions of Section 11.1

8

---

Certain portions of this Exhibit have been omitted pursuant to a request for confidentiality. Such omitted portions, which are marked with brackets [ ] and an asterisk\*, have been separately filed with the Securities and Exchange Commission.

## **ARTICLE 3 - DEVELOPMENT ACTIVITIES**

- 3.1 The selection and development of Development Candidate(s) that are suitable for development into a Product for commercialization and approval of the development and final commercial formulation and specifications for the Product will be the sole responsibility of JANSSEN and JANSSEN will bear all costs and expenses related thereto. At any stage in the Development Program, it will be JANSSEN's sole decision to evaluate whether the results generated warrant the continuation of the Development Program with respect to a Development Candidate.
- 3.2 NANO will disclose to JANSSEN within a reasonable period of time the Nano Know-How and any Improvements that NANO believes are necessary or useful in connection with the Development Program, based on the information, requests and reports provided to it by JANSSEN during the term of this Agreement. JANSSEN will disclose to NANO within a reasonable period of time any Improvements developed or invented during the term of this Agreement by JANSSEN or its Affiliates.

- 3.3 From the Effective Date hereof, JANSSEN will proceed with the development of the Development Candidate selected by JANSSEN, such development already having been initiated under the terms of the Feasibility Agreement.
- 3.4 The activities to be undertaken in the course of the Development Program will be monitored by the Development Team. The Development Team shall review and monitor the progress made during the Development Program and will discuss important milestone events. The Development Team will be chaired by JANSSEN.
- 3.5 Prior to NANO commencing supporting activities in relation to the Development Program, JANSSEN and NANO will agree on the specific activities to be undertaken by NANO, including timelines and related budget and such timelines and budget will be attached to the Development Plan. JANSSEN acknowledges that in the event it requests additional support activities from NANO that are not contemplated under this Agreement or in the Development Plan, NANO may not be in a position to readily provide such support in view of other commitments NANO may have to Third Parties. In such event, JANSSEN and NANO will in good faith discuss how and within what timeframe such additional support activities may be performed by NANO. In performing such support activities in relation to the Development Program, NANO will use reasonable efforts to comply with its commitments, including the commitment to dedicate sufficient staff with adequate skills to such Development Program, as set forth in the

---

Certain portions of this Exhibit have been omitted pursuant to a request for confidentiality. Such omitted portions, which are marked with brackets [ ] and an asterisk\*, have been separately filed with the Securities and Exchange Commission.

Development Plan and as agreed upon prior to the start of the Development Program.

- 3.6 If NANO's development efforts include the use of a Third Party, NANO will, prior to appointing such Third Party, discuss with JANSSEN the activities to be undertaken by such Third Party and the terms and conditions thereof. NANO will not proceed with such Third Party without the prior written approval of JANSSEN, which approval shall not be unreasonably withheld.
- 3.7 NANO will provide JANSSEN with regular written reports on the progress of the support activities to be undertaken by it under the Development Program(s) and will create detailed descriptions of any methodologies, development formulations or processes directed to Development Candidates in order to enable JANSSEN to prepare and file any regulatory filings in relation to the Product.
- 3.8 JANSSEN will provide NANO on a quarterly basis with written reports on the progress of activities undertaken by it relating to the Development Program. JANSSEN agrees to use reasonable efforts, consistent with its normal business practices and in line with the efforts it devotes to projects of similar sales and technical potential, to carry out the development activities directed to a Development Candidate with the aim of developing the Product that can be commercialized.

#### **ARTICLE 4 - CLINICAL AND REGULATORY ACTIVITIES**

- 4.1 JANSSEN will be responsible for planning and conducting, at its own cost and expense, Phase I, Phase II and Phase III clinical trials in connection with a Development Candidate. The protocols of any Phase I, Phase II or Phase III clinical trial directed to the Development Candidate will be solely determined by JANSSEN. JANSSEN shall keep NANO apprised on a quarterly basis of the progress of any such trials and any results thereof. It will be JANSSEN's sole decision to evaluate whether the results of any clinical trial warrant the continuance of the Development Program with respect to a given Development Candidate.
- 4.2 JANSSEN shall be responsible, at its own cost and expense, for the preparation and filing of any IND or any other regulatory approvals necessary to start clinical trials with respect to a Development Candidate, and for compliance of such trials with the FDA's IND and related requirements. NANO shall give JANSSEN such support as may be reasonably requested by JANSSEN in relation thereto, provided such requests are restricted to the activities undertaken by NANO in accordance with the provisions of Section 3.5, or relate to requests raised by any regulatory

---

Certain portions of this Exhibit have been omitted pursuant to a request for confidentiality. Such omitted portions, which are marked with brackets [ ] and an asterisk\*, have been separately filed with the Securities and Exchange Commission.

authorities in relation to the NanoCrystal Technology in general, as more fully described in Sections 4.7 and 4.8.

- 4.3 JANSSEN shall be responsible for and shall have exclusive authority for compiling the IRF, including the indications pursued therein, and for filing and obtaining NDA's in any country in the Territory where JANSSEN decides to commercialize the Product.
- 4.4 Upon compilation of the IRF for the Product, JANSSEN shall use reasonable efforts consistent with its normal business practices and its overall business strategy to apply for the necessary regulatory approvals in the Major Markets with respect to the Product, including regulatory approvals pertaining to pricing and reimbursement. JANSSEN will inform NANO promptly upon the filing of any application for regulatory approval, and any subsequent approval, in any Major Market and will furthermore keep NANO apprised on a quarterly basis of the filings and approvals outside the Major Markets.
- 4.5 All regulatory data pertaining to the Product and relating to any regulatory filing and/or approval, license or permit granted by a regulatory authority in connection with the Product will be owned by JANSSEN; provided, however, that all Drug Master Files and other submissions filed by NANO with respect to NanoCrystal Technology shall be owned by NANO.
- 4.6 NANO will provide JANSSEN with reasonable regulatory support related to NanoCrystal Technology in connection with the regulatory approvals to be filed by JANSSEN and the compilation of the IRF of the Product. Amongst other things, NANO will (i) prepare all necessary supporting documentation related to NANO's activities under the Development Plan requested by JANSSEN, such as certificates or other administrative

documents required for reference in any regulatory filing, and (ii) issue a letter of authorization to the FDA permitting the FDA to reference NANO's relevant drug master files in reviewing applications for regulatory approval of Product. NANO will further assist JANSSEN with the preparation of supporting data related to the NanoCrystal Technology to allow JANSSEN to apply for and pursue the regulatory approvals in any country where JANSSEN decides to register Product. JANSSEN will keep NANO informed in connection with questions raised by regulatory authorities specifically related to the NanoCrystal Technology and NANO will assist JANSSEN whenever such regulatory questions or issues arise during the review process in any country. JANSSEN may reasonably request NANO to participate in critical meetings scheduled with the health authorities in relation to requests raised by such authorities with respect to the NanoCrystal Technology.

- 4.7 During the term of this Agreement NANO will promptly inform JANSSEN of any information or finding (including questions or remarks raised by regulatory

11

---

Certain portions of this Exhibit have been omitted pursuant to a request for confidentiality. Such omitted portions, which are marked with brackets [ ] and an asterisk\*, have been separately filed with the Securities and Exchange Commission.

authorities) in relation to the NanoCrystal Technology that NANO believes or has reason to believe may have a regulatory bearing on the further making or commercialization of the Product in accordance with the regulatory approvals in any country in the Territory. In addition, NANO will provide JANSSEN with reasonable assistance whenever questions specifically related to the NanoCrystal Technology are raised by regulatory authorities during the review process in any country in the Territory, which assistance shall include participation in critical meetings scheduled with health authorities in any such country.

- 4.8 Each party shall promptly inform the other of any actions, questions or remarks raised by regulatory authorities in relation to the NanoCrystal Technology, or the use thereof with respect to the Product. In addition, JANSSEN will report and cause its Affiliates and Licensees to report to NANO, and NANO will report and cause its Affiliates to report to JANSSEN, all information concerning any known or suspected side effect, injury, toxicity, sensitivity reaction, customer complaint, alleged defect or other adverse experience (including the severity thereof) associated with exposure to or use of Compound or Product that is alleged, believed or suspected to be attributable to the application of NanoCrystal technology to Compound or Product. JANSSEN shall be responsible for reporting adverse experiences with respect to Product to the FDA in conformity with applicable laws and regulations. Each party shall promptly inform the other of any threatened or pending actions by the FDA or any other regulatory authority concerning Product or NanoCrystal Technology.
- 4.9 Any regulatory support provided by NANO under this Article 4 shall be provided free of charge; provided, however, that JANSSEN shall reimburse NANO for (i) all out-of-pocket expenses NANO or its Affiliates incur in relation to any activities requested by JANSSEN, and (ii) any extraordinary activities requested by JANSSEN, including, without limitation, attending any meetings with regulatory authorities concerning the Product.

#### **ARTICLE 5 - PAYMENTS**

- 5.1 In consideration of the rights and licenses granted to JANSSEN under Article 2 of this Agreement, JANSSEN shall pay to NANO the following amounts:

- (a) the non-refundable sum of [\*] due and payable upon the Effective Date of this Agreement;
- (b) in connection with Development Candidates and Product the following sums:

12

---

Certain portions of this Exhibit have been omitted pursuant to a request for confidentiality. Such omitted portions, which are marked with brackets [ ] and an asterisk\*, have been separately filed with the Securities and Exchange Commission.

- (i) the sum of [\*] payable within thirty (30) days of the date a Development Candidate is first administered to six (6) human subjects;
- (ii) the sum of [\*] payable within thirty (30) days of the date the first IND for a Development Candidate is filed;
- (iii) the sum of [\*] payable within thirty (30) days of JANSSEN's commencement of the first Phase III clinical trial of a Development Candidate;
- (iv) the sum of [\*] payable within thirty (30) days of the date the first NDA for the Product is submitted in a Major Market; and
- (v) the sum of [\*] payable within thirty (30) days following the date the first NDA for the Product is approved in a Major Market.

- 5.2 The milestone payments due under Section 5.1(b) shall only be paid once by JANSSEN. NANO will send valid VAT invoices to JANSSEN in relation to all milestone payments payable under this Agreement.

#### **ARTICLE 6 - ROYALTIES**

- 6.1 In consideration of the rights and licenses granted under the NanoCrystal Technology, JANSSEN shall pay a royalty of one and one-half percent (1 1/2%) on the Net Sales of Products in all countries of Territory where Nano Patents or Selection Patents containing Valid Claims are filed or subsist (hereinafter "Patent Royalty").

- 6.2 In further consideration of the rights and licenses under the NanoCrystal Technology, JANSSEN shall pay on its annual Net Sales in Territory a royalty in accordance with the following brackets (hereinafter "Know How Royalty"):
- (a) three and one-half percent (3 1/2%) on aggregate Net Sales below 250,000,000 Dollars;
  - (b) five and one-half percent (5 1/2%) on aggregate Net Sales between 250,000,000 Dollars and 500,000,000 Dollars; and
  - (c) seven and one-half percent (7 1/2%) on aggregate Net Sales above 500,000,000 Dollars.

Certain portions of this Exhibit have been omitted pursuant to a request for confidentiality. Such omitted portions, which are marked with brackets [ ] and an asterisk\*, have been separately filed with the Securities and Exchange Commission.

- 6.3 With respect to each country in the Territory, JANSSEN shall pay the Patent Royalties until expiration of the last to expire of the Nano Patents and the Selection Patents that are applicable in such country; provided, however, that any Nano Patent or Selection Patent consisting of a patent application pending for more than five (5) years after the Effective Date shall no longer be considered a Nano Patent or a Selection Patent, as applicable, until such time as the patent on such application issues.
- 6.4 With respect to each country in the Territory, JANSSEN shall pay the Know-How Royalties until the later of (i) fifteen (15) years following the First Commercial Sale in such country, or (ii) twenty (20) years following the Effective Date. The sales in any country where the Know-How Royalties are no longer due in accordance with the above provisions shall not be used in the computation of the aggregate Net Sales in accordance with Section 6.2.
- 6.5 If in a country a Third Party (other than a Person acting on behalf of or through a license from JANSSEN or any of its Affiliates) is selling a product in such a manner sufficient to achieve Competition, the Know-How Royalties for sales of the Product with respect to which Competition exists shall be reduced by fifty percent (50%) in such country (i.e., only fifty percent (50%) of the sales of such Product in such country shall be considered in calculating the aggregate Net Sales in accordance with Section 6.2), until such time as there is a discontinuance of Competition. Notwithstanding the foregoing, no such reduction of the Know-How Royalties shall apply in the event such Competition has caused any party hereto to take action under Section 11.2 against such Third Party; provided, however, that the reduction of the Know-How Royalties set forth in Section 11.2(g) shall be applied if Competition is caused by an infringement of Product and such infringement is not overcome within one hundred twenty (120) days following NANO's receipt of JANSSEN's written notice evidencing a prima facie case of infringement.

#### **ARTICLE 7 - ROYALTY PAYMENTS, REPORTS AND RECORDS**

- 7.1 JANSSEN shall keep and shall cause its Affiliates and Licensees to keep, and to maintain for at least two years, true and accurate records of sales of Product and Net Sales and the royalties payable to NANO under Article 6 hereof and shall deliver to NANO a written statement thereof on or before the sixtieth (60th) day following the end of each calendar quarter (or any part thereof in the first or last calendar quarter of this Agreement) for such calendar quarter. Said written statements shall set forth on a country-by-country basis, a calculation of the Net Sales from gross revenues for the Product during that calendar quarter, the applicable percentage royalty rates, and a computation of the royalties due to

Certain portions of this Exhibit have been omitted pursuant to a request for confidentiality. Such omitted portions, which are marked with brackets [ ] and an asterisk\*, have been separately filed with the Securities and Exchange Commission.

NANO (the "Royalty Statement"). Upon NANO's receipt of each Royalty Statement from JANSSEN, NANO will send valid VAT invoices to JANSSEN confirming the royalties due and payable by JANSSEN under this Agreement.

- 7.2 All royalty payments to be made by JANSSEN to NANO shall be converted into Dollars at the average rate of exchange for the calendar quarter for which royalty payments are being remitted according to JANSSEN's normal procedures, as consistently applied by JANSSEN for its other products (which procedures shall be subject to NANO's review and approval, such approval not to be unreasonably withheld), and shall be made by wire transfer to a designated NANO account on or before the sixtieth (60th) day following the end of each JANSSEN accounting quarter. In the event that royalties are payable with respect to Net Sales in a country whose currency cannot be freely converted to Dollars, such currency shall be converted in accordance with the normal procedures consistently applied by JANSSEN (which procedures shall be subject to NANO's review and approval, such approval not to be unreasonably withheld).
- 7.3 Any income or other taxes which JANSSEN is required by law to pay or withhold on behalf of NANO with respect to royalties and any other monies payable to NANO under this Agreement shall be deducted from the amount of such royalties and monies due. JANSSEN shall furnish NANO with proof of such payments. Any such tax required to be paid or withheld shall be an expense of and borne solely by NANO. JANSSEN shall promptly provide NANO with a certificate or other documentary evidence to enable NANO to support a claim for a refund or a foreign tax credit with respect to any such tax so withheld or deducted by JANSSEN. The parties hereto will reasonably cooperate in completing and filing documents required under the provisions of any applicable tax treaty or under any other applicable law, in order to enable JANSSEN to make such payments to NANO without any deduction or withholding.
- 7.4 NANO shall have the right to nominate an independent certified public accountant acceptable to and approved by JANSSEN who shall have access, on reasonable notice, to JANSSEN and its Affiliates' or Licensees' records during reasonable business hours for the purpose of verifying the royalties payable as provided in this Agreement for the two preceding years. This right may not be exercised more than once in any calendar year, and once a calendar year is audited it may not be reaudited, and said accountant shall disclose to NANO only information relating solely to the accuracy of the Royalty Statements provided to NANO and the royalty payments made to NANO under this Agreement.

7.5 Any adjustment required as a result of an audit conducted under Section 7.4 shall be made within twenty-five (25) days after the date on which the accountant conducting the audit issues a written report to NANO and JANSSEN containing the results of the audit. Any underpayment by JANSSEN shall bear interest from

---

Certain portions of this Exhibit have been omitted pursuant to a request for confidentiality. Such omitted portions, which are marked with brackets [ ] and an asterisk\*, have been separately filed with the Securities and Exchange Commission.

the date that such amount should have been paid to NANO as royalties to the date that the underpayment is actually paid to NANO by JANSSEN. The interest rate shall be the prime interest rate published in the Wall Street Journal at the close of business on the day prior to the date the underpayment is made, plus two percent (2%). In addition, if any underpayment by JANSSEN is greater than five percent (5%) of the amount previously paid to NANO for the relevant period, the costs and expenses of the audit shall be paid for by JANSSEN.

7.6 All payments due hereunder shall be made to the designated bank account of EPIL in accordance with such timely written instructions as NANO shall from time to time provide.

7.7 Each payment due from JANSSEN to NANO under this Agreement shall bear interest from the due date of such payment at the prime rate published in the Wall Street Journal on the due date for such payment plus two percent (2%), provided JANSSEN does not make such payment within thirty (30) days following the due date for such payment.

#### **ARTICLE 8 - COMMERCIALIZATION**

8.1 All business decisions, including, but not limited to, decisions concerning pricing, reimbursement, package design, sales and promotional activities for the Product, and the decision to launch or continue to market the Product in particular countries in the Territory, shall be within the sole discretion of JANSSEN. Notwithstanding the foregoing sentence, JANSSEN agrees to make a First Commercial Sale of the Product in each of the Major Markets within nine (9) months after obtaining the necessary regulatory approvals, including approvals concerning acceptable pricing and reimbursement, if applicable, in such Major Market. Said nine (9) month period will be extended, but not by more than six (6) months, upon JANSSEN's reasonable request for sound business reasons, including, but not limited to, the launch by JANSSEN, its Affiliates or Licensees of other products that do not directly compete with the Product in the Major Markets, or the intended simultaneous launch of the Product in several countries.

8.2 JANSSEN will promptly inform NANO of the First Commercial Sale of the Product in each of the Major Markets and will provide NANO with calendar quarterly updates on the First Commercial Sales of the Product in other countries.

8.3 All trademarks utilized by JANSSEN or its Affiliates or Licensees on Product under this Agreement shall be chosen and owned by JANSSEN or its Affiliates or Licensees. Upon termination of this Agreement under Article 14 or Article 15, all rights to said trademarks shall remain with JANSSEN or its Affiliates or Licensees. Notwithstanding the foregoing, JANSSEN shall not use the terms

---

Certain portions of this Exhibit have been omitted pursuant to a request for confidentiality. Such omitted portions, which are marked with brackets [ ] and an asterisk\*, have been separately filed with the Securities and Exchange Commission.

"nano", "nanosystem" or "nanocrystal", or any terms derived therefrom, in any trademark used by JANSSEN for any purpose without the prior written approval of NANO.

#### **ARTICLE 9 - MANUFACTURING AND SUPPLY**

9.1 JANSSEN shall have the right to make or have made Products, but the latter subject to the provisions herein concerning JANSSEN's obligations with respect to Highly Confidential Information. In order to enable JANSSEN to so manufacture or have manufactured Products, NANO will, upon JANSSEN's reasonable request and subject to the terms and conditions herein, provide JANSSEN with all NanoCrystal Technology reasonably necessary in order to enable JANSSEN to commercially manufacture Product in accordance with the specifications for manufacture set forth in the IRF and as communicated by JANSSEN to NANO.

9.2 JANSSEN shall not sublicense or disclose any Highly Confidential Information to any party, including without limitation its Affiliates and Licensees, without the prior written consent of NANO, such consent not to be unreasonably withheld. Notwithstanding the foregoing, JANSSEN may, without such prior written consent, sublicense and disclose Highly Confidential Information (subject to the limitations set forth in Article 12) to a maximum of two of its Affiliates for the sole purpose of enabling such Affiliates to manufacture Product in accordance with the terms and conditions set forth herein.

9.3 In the event that, pursuant to the terms and conditions of this Agreement, JANSSEN or one of its Affiliates seeks to manufacture Product hereunder, NANO shall supply the polymeric grinding media, if any, required for such manufacture, in accordance with reasonable commercial terms to be negotiated in good faith between the parties.

9.4 JANSSEN hereby agrees to manufacture Product, and to cause all of its Affiliates permitted hereunder to manufacture Product, in conformity with all applicable laws, regulations and regulatory filings and in accordance with generally accepted standards and practices for such activities in the pharmaceutical industry.

#### **ARTICLE 10 - RIGHTS IN TECHNOLOGY, INVENTIONS AND PATENTS**

10.1 NANO agrees to use its good faith efforts to continue, at its sole cost and expense, the prosecution and maintenance of the Nano Patents listed in Exhibit A. Prosecution of pending patent applications, shall mean through final patent office appeal and any opposition proceedings or the like,

---

Certain portions of this Exhibit have been omitted pursuant to a request for confidentiality. Such omitted portions, which are marked with brackets [ ] and an asterisk\*, have been separately filed with the Securities and Exchange Commission.

issue applications and re-examination proceedings in the United States and any foreign counterparts thereto. Upon either party's request, but not more frequently than once per year, the parties shall in good faith review the patents and patent applications set forth in Exhibit A. If both parties agree, the prosecution of any patent applications and/or maintenance of any patents may be abandoned.

10.2 Whenever any findings or inventions made or discovered during the course of the Development Program, or as a consequence of activities conducted under this Agreement or the Feasibility Agreement, are deemed patentable, both Parties will promptly inform each other thereof and ownership and filing of any patent applications related thereto will be done in accordance with the following principles:

(a) NANO shall own and shall have the right to apply for and maintain patents at its own cost with respect to findings or inventions that are Improvements but that are not useful with respect to Compound and/or Product, irrespective whether such inventions or findings were made or discovered solely or jointly by employees of NANO and/or JANSSEN.

(b) JANSSEN shall own and shall have the right to apply for and maintain patents at its own cost with respect to findings or inventions that are useful solely with respect to Compound and/or Product, irrespective whether such inventions or findings were made or discovered solely or jointly by employees of JANSSEN and/or NANO. Each such patent shall be a Janssen Patent or a Selection Patent as the case may be.

(c) With respect to any finding or invention not covered by (a) or (b) above, irrespective whether such inventions or findings were made or discovered solely or jointly by employees of JANSSEN and/or NANO, the parties shall in good faith evaluate the possibility of simultaneously applying for separate patent applications and of separately maintaining any patents issuing thereon. Should the parties agree that separate patent applications are feasible and appropriate, (i) the claims of any such patent applications filed by JANSSEN shall be limited to Compound or Product, and any patents issuing thereon shall be deemed Janssen Patents or Selection Patents as the case may be; and (ii) the claims of any such patent applications filed by NANO shall specifically exclude Compound or Product.

(d) In the event either party is of the reasonable opinion that the filing of separate applications is not feasible or appropriate, (i) NANO shall own and have the right to apply for and maintain patents with respect to findings or inventions that are Improvements (which shall be included within NanoCrystal Technology and covered by the license grant to

---

Certain portions of this Exhibit have been omitted pursuant to a request for confidentiality. Such omitted portions, which are marked with brackets [ ] and an asterisk\*, have been separately filed with the Securities and Exchange Commission.

JANSSEN under Article 2); and (ii) JANSSEN shall own and have the right to apply for and maintain patents with respect to other findings and inventions, and the patents on such other findings and inventions shall be deemed Janssen Patents and/or Selection Patents as the case may be.

10.3 Each of JANSSEN and NANO shall provide prompt notice to the other of all findings and inventions covered under Section 10.2, and shall consult and cooperate with the other in good faith with respect to the filing of patent applications for findings and inventions covered under Section 10.2 and the maintenance of patents issued thereon including, without limitation, by executing and obtaining from employees and other Persons all assignments and other documents reasonably required in connection therewith. In addition, prior to filing any simultaneous patent applications under Section 10.2(c), each of JANSSEN and NANO shall provide the other with reasonable opportunity to comment on the proposed text of such applications and shall give due consideration to any comments received from the other concerning such applications; provided, however, that JANSSEN and its Affiliates shall not include any Highly Confidential Information in any patent applications they file hereunder without the prior written consent of NANO.

10.4 The parties agree to cooperate in order to avoid loss of any rights which may otherwise be available to the parties under the U.S. Drug Price Competition and Patent Term Restoration Act of 1984, the Supplementary Certificate of Protection of the Member States of the European Community and other similar measures in any other country in the Territory. Without limiting the foregoing, each of JANSSEN and NANO agrees to provide the other with reasonable information and assistance in order to permit the timely filing of an application for patent term extension within the sixty (60) day period following NDA approval to market Product in the United States. Upon similar approvals by the health authorities in a country of the European Community or in other countries in the Territory, each party shall provide the other with reasonable information and assistance in order to permit the timely filing of a Supplementary Certificate of Protection of the Member States of the European Community and related filings.

## **ARTICLE 11 - INFRINGEMENT**

11.1 If, as a result of the use of the NanoCrystal Technology in the manufacture, use or sale of the Product in any country of the Territory, JANSSEN and/or its Affiliate or Licensee is sued for patent infringement or threatened with such a lawsuit or other action by a Third Party, JANSSEN and NANO shall meet to analyze the infringement claim and the avoidance of same. If it is necessary in the judgment of JANSSEN to obtain a license from such Third Party with respect to such Product, and JANSSEN obtains an written opinion from outside counsel



Certain portions of this Exhibit have been omitted pursuant to a request for confidentiality. Such omitted portions, which are marked with brackets [ ] and an asterisk\*, have been separately filed with the Securities and Exchange Commission.

concurring with JANSSEN's judgment that such a license is necessary, JANSSEN, with NANO's reasonable assistance, may negotiate for such a license and in such negotiations shall make every effort to minimize any license fees and/or royalties payable to such Third Party.

- (a) If the settlement or other resolution of a lawsuit or threatened lawsuit or other action requires any payments for pre-settlement or pre-litigation resolution damages to a Third Party, including but not limited to royalty payments for past sales of an allegedly infringing Product in a country, then JANSSEN, its Affiliates and Licensees on the one hand and NANO on the other hand shall [\*].
- (b) For any required royalty payments on post-settlement or post-litigation sales of the allegedly infringing Product in a country, JANSSEN and/or its Affiliates or Licensees, but not NANO, shall [\*].
- (c) The [\*] due and payable to NANO under this Section 11.1 shall only apply to the extent that the infringement is due to the use of NanoCrystal Technology in such Product and is not the result of (i) a modification of the nanoparticle formulation or nanoparticle manufacturing process of such Product, or (ii) refusal by JANSSEN to modify the Product to avoid infringement, unless JANSSEN shows that its manufacturing and regulatory costs to so avoid infringement would be commercially unreasonable. In the event that in connection with (ii) above, the parties fail to agree on whether such costs are commercially unreasonable, such matter shall be resolved in accordance with the provisions of Article 20.
- (d) In the event that JANSSEN manufactures Product using a manufacturing process that does not utilize the NanoCrystal Technology and such manufacturing process is alleged by a Third Party to infringe certain patented technology of such Third Party, and JANSSEN demonstrates to NANO's reasonable satisfaction that JANSSEN is required to obtain a royalty-bearing license from a Third Party to use such Third Party's patented technology to manufacture Product, [\*].

11.2 In the event that in any country in the Territory in which JANSSEN, its Affiliates or Licensees are marketing the Product, there is an infringement of a Nano Patent by a Third Party's product, JANSSEN or its Affiliates shall notify NANO in writing to that effect, including with said written notice evidence establishing a prima facie case of infringement by such Third Party. In the event of a potential multicountry infringement by the same Third Party with the same infringing product, the parties will promptly discuss the possible strategies to deal with such infringement on a global basis prior to deciding on a course of action in a single

---

Certain portions of this Exhibit have been omitted pursuant to a request for confidentiality. Such omitted portions, which are marked with brackets [ ] and an asterisk\*, have been separately filed with the Securities and Exchange Commission.

country, taking into consideration the conditions set forth hereinafter as well as the potential scope of the infringement and the countries involved.

- (a) NANO shall have the right at its sole discretion to take action to stop such infringement, including without limitation conducting patent infringement proceedings or starting settlement discussions. NANO shall bear all the costs and expenses of any suit brought by it. JANSSEN and/or its Affiliate or Licensee will cooperate with NANO in any such suit and shall have the right to consult with NANO and be represented by its own counsel at its own expense. NANO's failure to take action under this Article shall not be considered a breach of this Agreement and JANSSEN's sole remedy shall be to bring suit itself, subject to the terms and conditions of this Section 11.2.
- (b) If, within forty (40) days after NANO's receipt of JANSSEN's written notice evidencing a prima facie case of infringement, NANO has not overcome the case of infringement, obtained a discontinuance of such infringement, brought suit against the Third Party infringer, or taken steps to initiate such a suit, JANSSEN shall have the right, in its sole discretion, but not the obligation to bring such suit against the infringer, subject to the conditions set forth below, at its own expense and in its own name, if legally permissible. If necessary and legally permissible, NANO will permit the suit to be brought in its name. JANSSEN shall bear all the costs and expenses of any suit brought by it. NANO will cooperate with JANSSEN in any such suit and shall have the right to consult with JANSSEN and be represented by its own counsel at its own expense.
- (c) JANSSEN's right to bring suit in a country in accordance with the above provisions in connection with Nano Patents is subject to [\*]. If the parties disagree on whether the above conditions are satisfied in any specific case of infringement, the matter will be submitted for decision to an independent patent counsel selected in common agreement by JANSSEN and NANO, and the parties agree to abide by the decision of such patent counsel with respect to such conditions.
- (d) Notwithstanding the opinion of an independent patent counsel that the conditions in (c) above are satisfied, NANO shall have the right to withhold its consent to JANSSEN bringing suit against the Third Party infringer. [\*]
- (e) [\*]
- (f) Any damages, costs, awards, settlement amounts or other sums received by the party bringing suit arising out of any proceedings for infringement

---

Certain portions of this Exhibit have been omitted pursuant to a request for confidentiality. Such omitted portions, which are marked with brackets [ ] and an asterisk\*, have been separately filed with the Securities and Exchange Commission.

of the Nano Patents shall be retained by such party. Notwithstanding the foregoing, whenever the party bringing suit is JANSSEN, the damages, costs, awards, settlement amounts and other sums shall be divided as follows:

(i) JANSSEN shall be entitled to its out of pocket expenses actually incurred by JANSSEN or its designated Affiliate in respect of the proceedings for infringement of the Nano Patents insofar as such expenses have not already been deducted from the royalties payable to NANO pursuant to (e) above;

(ii) NANO shall be entitled to a sum equal to any royalties withheld pursuant to (e) above; and

(iii) JANSSEN and NANO shall equally share the remainder.

(g) If, within one hundred twenty (120) days after NANO's receipt of JANSSEN's written notice [\*], the infringement has not been overcome by either JANSSEN or NANO, and a Third Party's (other than a Person acting on behalf of or through a license from JANSSEN or any of its Affiliates) sales of the infringing product are or become sufficient to create Competition, then the Patent Royalties and the Know-How Royalties for sales of the Product being infringed shall each [\*] in the country where the infringement is occurring, irrespective of whether NANO or JANSSEN taking action against such infringer in accordance with the provisions of this Section 11.2, until such time as there is a discontinuance of such Competition. The provisions of this subsection (g) shall not apply whenever the royalties due to NANO [\*] in accordance with the conditions set forth in (d) above and the provisions of (d) shall apply to such reduction.

11.3 In the event of any infringement of a Janssen Patent by a Third Party, JANSSEN shall have the right at its sole discretion to take action to stop such infringement, including without limitation conducting patent infringement proceedings or starting settlement discussions. JANSSEN shall bear all the costs and expenses in connection with any such proceedings and discussions.

11.4 As of the Effective Date of this Agreement NANO declares that, according to the best of its current knowledge and belief, the application of the Nano Patents and Nano Know-How to the Compound does not infringe the patent rights of any Third Party in any country in the Territory.

22

---

Certain portions of this Exhibit have been omitted pursuant to a request for confidentiality. Such omitted portions, which are marked with brackets [ ] and an asterisk\*, have been separately filed with the Securities and Exchange Commission.

#### **ARTICLE 12 - CONFIDENTIALITY**

12.1 During the performance of this Agreement, either party will disclose to the other party information which the disclosing party considers to be confidential. This information may include, without limitation, any data, information, know-how and materials which in the case of JANSSEN relates to Compound and/or Product and which in the case of NANO relates to NanoCrystal Technology, including information which is discovered by or brought to the attention of any party hereto during or as a result of, directly or indirectly, the performance of the Agreement ("Information").

12.2 For purposes of this Agreement, each party hereto is a "Submitter" as to Information or Highly Confidential Information disclosed or provided by it under this Agreement and each is a "Recipient" as to Information or Highly Confidential Information disclosed or provided to it under this Agreement.

12.3 The confidentiality obligations contained herein shall not apply to any portion of the Information or Highly Confidential Information which:

- (a) is or becomes public or available to the general public otherwise than through the act or default of Recipient or any Authorized Party (as defined below);
- (b) is obtained by Recipient from a Third Party who is lawfully in possession of such Information and is not subject to an obligation of confidentiality or non-use owed to Submitter;
- (c) is previously known to Recipient prior to disclosure to Recipient by Submitter, as evidenced by the written records of Recipient;
- (d) is independently developed, discovered or arrived at by Recipient without use of the Information, as evidenced by written records of Recipient; or
- (e) is disclosed by Recipient pursuant to a requirement of law, including without limitation to governmental regulatory agencies, and is thereafter publicly disclosed or made available to the public by operation of law, provided that Recipient has complied with the provisions set forth in Section 12.9.

The Recipient shall have the burden of proof as to the existence of any of the conditions under (a) through (e) above. In addition, independent development, discovery or arrival at data, information, know-how or materials under (d) above must be established by clear and convincing evidence

23

---

Certain portions of this Exhibit have been omitted pursuant to a request for confidentiality. Such omitted portions, which are marked with brackets [ ] and an asterisk\*, have been separately filed with the Securities and Exchange Commission.

12.4 Recipient shall employ at least the same degree of care to keep all Information confidential as it employs with respect to its own information of like importance; and shall, in any event, take all steps reasonably necessary to maintain and preserve the confidentiality of all Information.

- 12.5 Information will only be submitted to Recipient's employees or employees of Recipient's Affiliates and Licensees on a need to know basis. Without the prior written consent of the Submitter, Recipient shall not disclose any Information to any Third Party, Affiliate or Licensee, except to those who need to know such Information to achieve the purpose of this Agreement. Each such Third Party, Affiliate and Licensee, being referred to herein as an "Authorized Party," and Recipient, including, without limitation, its representatives, agents and employees, shall use the Information only in accordance with the terms and conditions of this Agreement.
- 12.6 Recipient warrants that each Authorized Party or employee to whom any Information is revealed shall (i) previously have been informed of the confidential nature of the Information and (ii) will prior to any disclosure have agreed to be bound by terms and conditions of (A) a written secrecy agreement with Recipient to protect Recipient's information whenever it concerns an employee, or (B) a written confidentiality agreement with Recipient containing terms and conditions substantially equivalent to those in this Article 12 applicable to Recipient whenever it concerns an Authorized Party. Recipient shall ensure that the Information is not used or disclosed by such Authorized Party or employee except for the purposes of developing and manufacturing Product in accordance with this Agreement, and shall be responsible for any breach of this Agreement by such Authorized Party or employee.
- 12.7 All Information shall remain the property of Submitter. Upon termination of this Agreement and upon the written request of Submitter (i) all tangible Information (including without limitation all copies thereof and all unused samples), except for Information consisting of analyses, studies and other documents prepared by or for the benefit of Recipient, shall be promptly returned to Submitter, and (ii) all portions of such analyses, studies and other documents prepared by or for the benefit of Recipient (including all copies thereof) which are within the definition of Information shall be destroyed; provided that Recipient may retain one copy of Information in a secure location for purposes of identifying its obligations under this Agreement and for no other purposes.
- 12.8 The obligations of Recipient as to confidentiality and non-use set forth in this Agreement, including, without limitation, the provisions of Section 12.4, shall survive the expiration or termination of this Agreement and shall continue for five

Certain portions of this Exhibit have been omitted pursuant to a request for confidentiality. Such omitted portions, which are marked with brackets [ ] and an asterisk\*, have been separately filed with the Securities and Exchange Commission.

(5) years thereafter, but in no event shall such confidentiality obligations terminate earlier than December 31, 2015.

- 12.9 If Recipient becomes legally required to disclose any Information, Recipient shall give Submitter prompt notice of such fact so that Submitter may seek to obtain a protective order or other appropriate remedy concerning any such disclosure and/or waive compliance with the non-disclosure provisions of this Agreement. Recipient shall fully cooperate with Submitter in connection with Submitter's efforts to obtain any such order or other remedy. If any such order or other remedy does not fully preclude disclosure, or if Submitter waives compliance with the non-disclosure provisions of this Agreement, Recipient shall make such disclosure only to the extent that such disclosure is legally required. Any Information required to be provided to regulatory authorities or other governmental agencies in connection with a regulatory filing in accordance with the terms of this Agreement in any country in the Territory shall be permitted and shall be exempt from the provisions of this Section 12.9; provided, however, that Recipient will use efforts to see to it that such regulatory authorities or other governmental agencies treat such Information as confidential, which efforts shall be no less diligent than those Recipient uses to secure confidential treatment by regulatory authorities or other governmental agencies of Recipient's own, similarly confidential and/or proprietary data, information, know-how and materials. Notwithstanding anything else contained herein, any disclosure by JANSSEN of NANO Information to regulatory authorities or governmental agencies will be made in accordance with JANSSEN's normal business practices as consistently applied to its other pharmaceutical products.
- 12.10 With respect to data concerning Product, including data contained in Information, NANO shall have the right to use and to disclose to Third Parties, with no financial obligation to JANSSEN, data related to Nano Crystal Technology; provided, however, that in any such disclosure NANO shall not (i) disclose that such data is derived from Compound or Product, or (ii) identify, directly or indirectly, JANSSEN or the Compound.
- 12.11 The parties recognize the importance of publishing Information developed in clinical studies undertaken by JANSSEN or on behalf of JANSSEN under the provisions of this Agreement. Therefore, subject to NANO's prior approval, which approval shall not be unreasonably withheld, JANSSEN shall have the right to publish such studies in furtherance of the purposes of this Agreement: provided however that such studies do not contain any Highly Confidential Information.
- 12.12 With respect to Highly Confidential Information, JANSSEN and any Authorized Party to whom JANSSEN discloses Highly Confidential Information, in addition to complying with the obligations set forth herein for Information, shall:

Certain portions of this Exhibit have been omitted pursuant to a request for confidentiality. Such omitted portions, which are marked with brackets [ ] and an asterisk\*, have been separately filed with the Securities and Exchange Commission.

- (a) disclose it only to employees on a need to know basis to the extent permitted hereunder;
- (b) treat it as confidential information and safeguard it against disclosure using strict standards and care as provided for in this Section 12.12 to protect it from disclosure to those not authorized to receive it hereunder;
- (c) use it only in developing and manufacturing Products in accordance with the terms of this Agreement;
- (d) require any employee that will receive it to sign for receipt of a numbered copy of it, acknowledging also such employee's receipt of the Statement attached hereto as Form 1;

- (e) not make copies of any documents embodying or containing it without the prior written authorization from NANO unless all copies thereof are numbered, a record is maintained of the recipient of each said numbered copy, and such records are provided promptly to NANO upon request;
- (f) retain all documents embodying or containing it under lock, separate from JANSSEN's other records and information and in the personal control of one employee of JANSSEN who shall be approved by NANO;
- (g) immediately notify NANO in writing in the event of any loss, theft or disclosure thereof; and
- (h) treat any modifications, advances, extensions, enhancements, or other changes to it made by JANSSEN or any Authorized Party to whom it is disclosed by JANSSEN as Highly Confidential Information as provided hereunder in the same manner as and in accordance with the provisions of this Agreement relating to Highly Confidential Information.

#### **ARTICLE 13 - TERM**

This Agreement shall become effective from the Effective Date and unless sooner terminated pursuant to any other provision of this Agreement continue in full force until the last to expire of the Nano Patents or Selection Patents, or for twenty (20) years from the Effective Date, whichever results in the longer period of time.

26

---

Certain portions of this Exhibit have been omitted pursuant to a request for confidentiality. Such omitted portions, which are marked with brackets [ ] and an asterisk\*, have been separately filed with the Securities and Exchange Commission.

#### **ARTICLE 14 - TERMINATION BY JANSSEN**

Notwithstanding any other provision herein, JANSSEN may terminate this Agreement with respect to the entire Territory or with respect to one or more of the Major Markets upon three (3) months prior written notice to NANO.

#### **ARTICLE 15 - TERMINATION FOR CAUSE**

- 15.1 In the event JANSSEN or NANO or their respective Affiliates and Licensees are in material breach of any of the respective obligations and conditions contained in this Agreement, the other party shall be entitled to give the party in breach notice requiring it to cure such material breach. If such material breach is not cured within ninety (90) days after receipt of such notice, the notifying party shall be entitled (without prejudice to any of its other rights conferred on it by this Agreement) to terminate this Agreement by giving notice thereof to the party in breach, which notice shall take effect immediately.
- 15.2 If either party elects not to terminate this Agreement under Section 15.1 in the event of a material breach by the other party hereto, the non-breaching party may seek a determination of damages for the breach from the breaching party by resorting to the dispute resolution procedures set forth in Article 22. Upon a determination of such damages under Article 22, the non-breaching party may, to the extent possible, offset such damages against such party's payment obligations under this Agreement. Nothing herein shall prevent either party hereto from exercising such party's right to obtain temporary or permanent injunctive relief or other equitable relief restraining the other party from engaging in conduct that would constitute a breach of Article 12 or Article 31.
- 15.3 In the event that one of the parties hereto becomes bankrupt or insolvent, a receiver or a trustee is appointed for the property or estate of such party and said receiver or trustee is not removed within sixty (60) days, or the party makes an assignment for the benefit of its creditors, and whether any of the aforesaid events be the outcome of the voluntary act of that party, or otherwise, the other party shall be entitled to terminate this Agreement forthwith by giving a written notice to the first party.

#### **ARTICLE 16 - RIGHTS AND OBLIGATIONS UPON TERMINATION**

- 16.1 Upon the expiration of the term of this Agreement under Article 13, but not upon its earlier termination, JANSSEN's license rights under Section 2.1 shall become fully paid-up and shall thereafter remain royalty-free and irrevocable, but shall be non-exclusive. In addition, the provisions of Article 1, Sections 7.4, 7.5, 7.6 and

27

---

Certain portions of this Exhibit have been omitted pursuant to a request for confidentiality. Such omitted portions, which are marked with brackets [ ] and an asterisk\*, have been separately filed with the Securities and Exchange Commission.

7.7, Sections 10.2, 10.3 and 10.4, Article 12 (as indicated in Section 12.8), and Articles 16, 17, 18, 19, 20, 21, 22, 23, 24, 26, 27, 28, 29 and 30 shall survive such expiration, and all payment obligations accruing under this Agreement prior to its expiration, including without limitation all payment obligations accruing under Articles 5 and 6, shall survive such expiration.

- 16.2 In the event that this Agreement is terminated by JANSSEN in the entire Territory or in all Major Markets in accordance with Article 14, or by either party pursuant to Article 15, the provisions of Article 1, Sections 7.4, 7.5, 7.6 and 7.7, Sections 10.2, 10.3 and 10.4, Article 12 (as indicated in Section 12.8), and Articles 16, 17, 18, 19, 20, 21, 22, 23, 24, , 26, 27, 28, 29, 30 and 31 (as indicated therein) shall survive such termination, and all payment obligations accruing under this Agreement prior to the effective date of termination, including without limitation all payment obligations accruing under Articles 5 and 6, shall survive such termination.
- 16.3 Subject to the parties' obligations under Article 21 and to the limitation of liability in Section 18.4, termination of this Agreement by either party shall not prejudice the rights of such party under this Agreement to seek damages for any breach of this Agreement by the other party hereto.

## **ARTICLE 17 - REPRESENTATIONS AND WARRANTIES**

17.1 NANO represents and warrants to JANSSEN that:

- (a) The execution, delivery and performance of this Agreement by NANO does not conflict with any agreement, instrument or understanding, oral or written, to which it is a party or by which it may be bound, and does not violate any law or regulation of any court, governmental body or administrative or other agency having authority over it;
- (b) NANO is not currently a party to, and during the term of this Agreement will not enter into, any agreements, oral or written, that are inconsistent with its obligations under this Agreement;
- (c) NANO is duly organized and validly existing under the laws of the state of its incorporation and has full legal power and authority to enter into this Agreement;
- (d) To the best of NANO's knowledge, all of the Nano Patents are subsisting and are valid and enforceable;

28

---

Certain portions of this Exhibit have been omitted pursuant to a request for confidentiality. Such omitted portions, which are marked with brackets [ ] and an asterisk\*, have been separately filed with the Securities and Exchange Commission.

- (e) NANO has not previously assigned, transferred, conveyed or otherwise encumbered its right, title and interest in Nano Patents or Nano Know-How as they relate to Compound or Product;
- (f) NANO is the sole and exclusive owner or licensee of the Nano Patents and the Nano Know-How, all of which, to the best of NANO'S knowledge, are free and clear of any liens, charges and encumbrances, and, except for NANO's Affiliates, no other person, corporate or other private entity, or governmental entity or subdivision thereof has, or shall have, any claim of control with respect to the Nano Patents and the Nano Know-How as they relate to Compound or Product; and
- (g) There are no claims, judgments or settlements against or owed by NANO pending or, to the knowledge of NANO, threatened, with respect to the Nano Patents and the Nano Know-How as they relate to Compound or Product.

17.2 JANSSEN represents and warrants to NANO that:

- (a) The execution, delivery and performance of this Agreement by JANSSEN does not conflict with any agreement, instrument or understanding, oral or written, to which it is a party or by which it may be bound, and does not violate any law or regulation of any court, governmental body or administrative or other agency having authority over it;
- (b) JANSSEN is not currently a party to, and during the term of this Agreement will not enter into, any agreements, oral or written, that are inconsistent with its obligations under this Agreement;
- (c) JANSSEN is duly organized and validly existing under the laws of the state of its incorporation and has full legal power and authority to enter into this Agreement;
- (d) JANSSEN will not bind or purport to bind NANO to any affirmation, representation or warranty provided to any Third Party with respect to the Compound or Product; and
- (e) To the best of JANSSEN's actual knowledge on the Effective Date, there is no reason to believe that the Selection Patent listed on the attached Exhibit B will not issue or will not be valid.

29

---

Certain portions of this Exhibit have been omitted pursuant to a request for confidentiality. Such omitted portions, which are marked with brackets [ ] and an asterisk\*, have been separately filed with the Securities and Exchange Commission.

17.3 THE LIMITED WARRANTIES CONTAINED IN THIS SECTION 17 ARE THE SOLE WARRANTIES GIVEN BY THE PARTIES AND ARE MADE EXPRESSLY IN LIEU OF AND EXCLUDE ANY IMPLIED WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, TITLE, INFRINGEMENT OR OTHERWISE, AND ALL OTHER EXPRESS OR IMPLIED REPRESENTATIONS AND WARRANTIES PROVIDED BY COMMON LAW, STATUTE OR OTHERWISE ARE HEREBY DISCLAIMED BY BOTH PARTIES.

## **ARTICLE 18 - INDEMNIFICATION**

18.1 Each party (the "Indemnifying Party") shall indemnify, defend and hold the other party and its Affiliates, Licensees, employees, officers, directors, agents and consultants (each an "Indemnified Party") harmless from, against and in respect of any damages, claims, losses, liabilities, charges, actions, suits, proceedings, penalties and reasonable costs and expenses (including without limitation reasonable attorneys' fees) (collectively, the "Losses") imposed on, sustained, incurred or suffered by or asserted against any Indemnified Party, to the extent such Losses are incurred in the defense or settlement of a Third Party lawsuit or in a satisfaction of a Third Party judgment arising out of :

- (a) any injuries to person and/or damage to property resulting from negligent acts that the Indemnifying Party or its Affiliates, Licensees, employees, officers, directors, agents or consultants, performed or failed to perform in carrying out activities contemplated under this Agreement or any Development Program conducted hereunder, including the negligent failure by the Indemnifying Party to provide the

Indemnified Party with any Information known by Indemnifying Party that, if timely received, would have enabled the Indemnified Party to avoid such injuries or damage; and

(b) personal injury to the Indemnified Party or damage to the Indemnified Party's property resulting from negligence or intentional misconduct on the part of the Indemnifying Party or its Affiliates, Licensees, employees, officers, directors, agents and consultants in carrying out the activities contemplated by this Agreement;

provided, however, that an Indemnified Party shall not be indemnified under this Section 18.1 to the extent that such party's own negligence or intentional misconduct caused or contributed to the events giving rise to the claim for indemnification.

---

Certain portions of this Exhibit have been omitted pursuant to a request for confidentiality. Such omitted portions, which are marked with brackets [ ] and an asterisk\*, have been separately filed with the Securities and Exchange Commission.

- 18.2 JANSSEN shall indemnify, defend and hold NANO and its Affiliates, and each of their officers, directors, employees, agents and consultants (each a "NANO Indemnitee") harmless from and against all Losses (other than those that are the subject of Section 18.1 hereof) arising out of or resulting from the use by or administration to any person of any Product sold or otherwise distributed by JANSSEN, its Affiliates or Licensees or any of their distributors, except to the extent such Losses arose or resulted from negligence or intentional misconduct on the part of NANO or its Affiliates, Licensees, employees, officers, directors, agents or consultants in carrying out the activities contemplated by this Agreement, so long as (i) the NANO Indemnitee allows JANSSEN to participate in or, at JANSSEN's sole option but without any obligation, to conduct at JANSSEN's expense the defense of the claim or action for which indemnification is sought under this Section 18.2, and (ii) the NANO Indemnitee does not compromise or settle such claim or action without JANSSEN's prior written consent, which shall not be unreasonably withheld.
- 18.3 NANO shall indemnify, defend and hold JANSSEN, its Affiliates and Licensees and each of their officers, directors, employees, agents and consultants (each a "JANSSEN Indemnitee") harmless from and against all Losses (other than those that are the subject of Section 18.1 hereof) arising out of or resulting from negligence or intentional misconduct on the part of NANO or its Affiliates, Licensees, employees, officers, directors, agents or consultants in carrying out the activities contemplated by this Agreement, so long as (i) the JANSSEN Indemnitee allows NANO to participate in or, at NANO's sole option but without the obligation, to conduct at NANO's expense the defense of the claim or action for which indemnification is sought under this Section 18.3, and (ii) the JANSSEN Indemnitee does not compromise or settle such claim or action without NANO's prior written consent, which shall not be unreasonably withheld.
- 18.4 IN NO EVENT SHALL ANY PARTY, OR SUCH PARTY'S DIRECTORS, OFFICERS, EMPLOYEES, AGENTS OR AFFILIATES, BE LIABLE TO THE OTHER PARTY OR PARTIES HERETO FOR ANY CONSEQUENTIAL, INCIDENTAL, INDIRECT, SPECIAL, PUNITIVE OR EXEMPLARY DAMAGES, COSTS OR EXPENSES (INCLUDING, BUT NOT LIMITED TO, LOST PROFITS, LOST REVENUES AND/OR LOST SAVINGS), WHETHER BASED UPON A CLAIM OR ACTION OF CONTRACT, WARRANTY, NEGLIGENCE, STRICT LIABILITY OR OTHERWISE, ARISING FROM A BREACH OR ALLEGED BREACH OF THIS AGREEMENT, EVEN IF SUCH OTHER PARTY OR PARTIES HAVE BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES.

---

Certain portions of this Exhibit have been omitted pursuant to a request for confidentiality. Such omitted portions, which are marked with brackets [ ] and an asterisk\*, have been separately filed with the Securities and Exchange Commission.

#### **ARTICLE 19 - CHOICE OF LAW**

The construction, validity and performance of this Agreement shall be governed in all respects by the laws of the State of New Jersey, without giving effect to principles of conflict of laws.

#### **ARTICLE 20 - FORCE MAJEURE**

No failure or omission by the parties hereto in the performance of any obligation of this Agreement shall be deemed a breach of this Agreement nor create any liability if the same shall arise from any cause or causes beyond the control of the parties, including but not limited to the following which, for the purposes of this Agreement, shall be regarded as beyond the control of the party in question; act of God, acts or omissions of any government or any rules, regulations or orders of any governmental authority or any officer, department, agency or instrument thereof; fire, storm, flood, earthquake, accident, acts of the public enemy, war, rebellion, insurrection, riot, invasion, strikes or lockouts.

#### **ARTICLE 21 - DISPUTE RESOLUTION**

21.1 Any dispute, controversy or claim arising out of or relating to the validity, construction, enforceability or performance of this Agreement, including disputes relating to an alleged breach or to termination of this Agreement (hereinafter "Disputes"), but excluding (i) any dispute, controversy or claim arising out of or relating to the validity, enforceability, or infringement of any Janssen Patent or any Nano Patent and (ii) other disputes which are expressly prohibited herein from being resolved by this mechanism, shall be settled by arbitration in the manner described below:

(a) Before either party institutes arbitration proceedings in accordance with Section 21.2 with respect to any Dispute, executive officers of both parties shall meet in order to attempt to resolve such Dispute in a mutual acceptable manner.

(b) In the event the negotiations do not result in a mutually acceptable resolution within a reasonably short period of time (not to exceed 30 days) or no meeting between the executive officers has occurred within 30 days following the notification of such Dispute, either party shall have the right to institute arbitration proceedings.

(c) If a party intends to begin an arbitration procedure to resolve a Dispute, such party shall provide written notice (the "Arbitration Request") to the other party informing the other party of such intention and the issues to be resolved. From the date of the Arbitration Request and

---

Certain portions of this Exhibit have been omitted pursuant to a request for confidentiality. Such omitted portions, which are marked with brackets [ ] and an asterisk\*, have been separately filed with the Securities and Exchange Commission.

until such time as any matter has been finally settled by Arbitration, the time periods provided for in Section 15.1 as to which a party must cure a breach of this Agreement shall be suspended as to the subject matter of the Dispute.

(d) Within fifteen (15) business days after receipt of the Arbitration Request, the other party may, by written notice to the party initiating the Arbitration, add additional issues to be resolved.

(e) Nothing herein shall prohibit either party hereto from seeking or obtaining temporary injunctive relief pending resolution of any Dispute in accordance with the provisions of this Article 21. In addition, nothing herein shall prohibit (i) a party hereto that is sued by a third party from filing a third party complaint against the other party hereto, or (ii) a party hereto from preserving its rights as a creditor of the other party hereto in the event that such other party becomes insolvent, voluntary or involuntary bankruptcy proceedings are instituted by or against such other party, a receiver or custodian is appointed for such other party, such other party makes an assignment for the benefit of its creditors, substantially all of the assets of such other party are seized or attached, such other party files for reorganization or dissolution, or such other person otherwise generally ceases to pay its debts when they become due.

21.2 The Arbitration shall be conducted in accordance with the Center For Public Resources Rules For Non-Administered Arbitration of Business Disputes, the arbitration proceeding shall be conducted in New York, New York. Notwithstanding those rules, the following provisions shall in any event apply to any issue submitted for arbitration hereunder.

(a) The arbitration shall be conducted by a panel of three neutral arbitrators ("Panel"). One member shall be appointed by each party and the third member shall be appointed by the two arbitrators appointed by the parties. The parties will select an arbitrator within fifteen (15) business days following the Arbitration request. The two arbitrators selected by the parties will appoint the third member within ten (10) days following their appointment.

Notwithstanding the above and in the interest of obtaining a judgment within the shortest possible period in connection with (i) certain technical or developmental matters that require referral to independent experts or (ii) Disputes where the aggregate damages sought by the claimant are stated to be less than [\*] and neither party seeks equitable relief, the parties will appoint only one single neutral selected in agreement by both parties and

---

Certain portions of this Exhibit have been omitted pursuant to a request for confidentiality. Such omitted portions, which are marked with brackets [ ] and an asterisk\*, have been separately filed with the Securities and Exchange Commission.

the provisions hereof shall apply *mutatis mutandis* to such single arbitrator.

(b) The language to be used in the arbitration shall be English.

(c) Any arbitrator selected by the parties may be of any nationality, and need not be a lawyer or hold any other professional status or membership but will be selected on the basis of his or her qualifications and expertise with respect to the matter under Dispute.

(d) The Panel shall resolve the Dispute on the basis of a written record consisting of an initial and rebuttal submission by each party (together with documentary evidence (including affidavits) supporting the positions taken in such submissions); provided that the Panel shall have the right to require the parties to make or participate in such other written or oral submissions, presentations, or examinations as the Panel shall deem necessary for the proper resolution of the matter under arbitration, all of which shall be made or submitted directly to the Panel and shall become part of the record in the proceeding.

(e) The specific pleading schedule for each proceeding shall be determined by the parties in consultation with the Panel within fifteen (15) business days following the selection of the arbitrators.

(f) Unless the parties otherwise agree at the time a particular issue is submitted for arbitration, the Panel shall be required as a condition to their engagement to agree to render a decision within thirty (30) days of the date on which the record in the proceeding is completed, but in no case more than one hundred and twenty (120) days after the date of their engagement.

(g) The parties shall use their best efforts to schedule and make their submissions, and to take all other necessary actions in connection with the proceeding, at a time and in a manner which will permit the Panel to render their decision in accordance with the schedule set forth herein.

(h) All communications with the arbitrator(s) during the proceeding shall be made in writing, with a copy thereof delivered simultaneously to the other party to the proceeding, or if made orally, made only in the presence of the other party to the proceeding or its representative.

(i) All decisions by the Panel shall be rendered by majority vote. The arbitration award or order shall be rendered in writing and shall be final and binding upon the parties. The arbitrator(s) hereunder (i) shall have no power or authority to grant or award punitive

Certain portions of this Exhibit have been omitted pursuant to a request for confidentiality. Such omitted portions, which are marked with brackets [ ] and an asterisk\*, have been separately filed with the Securities and Exchange Commission.

establish and enforce appropriate rules to ensure that the arbitration proceedings, including the decisions, are kept confidential and that all confidential and/or proprietary information of the parties is kept confidential and is used for no purpose other than for such arbitration proceedings.

(j) Judgment on any order or award shall be entered by any court of competent jurisdiction.

(k) Each party shall bear its own expenses and attorney's fees in connection with the arbitration. The fees and expenses of the arbitrator(s) shall be equally shared except that if, in the opinion of the arbitrators, any claim by a party hereto or any defense or objection thereto by the other party was unreasonable and frivolous, the arbitrators may in their discretion assess as part of the award all or any part of the arbitration expenses of the other party (including reasonable attorney's fees) and expenses of the arbitrators against the party raising such unreasonable and frivolous claim, defense or objection.

## **ARTICLE 22 - NOTICES**

Any notice required or permitted to be given under this Agreement shall be mailed by registered or certified air mail, postage prepaid, addressed to the party to be notified at its address stated below, or at such other address as may hereafter be furnished in writing to the notifying party or by telefax to the numbers set forth below or to such changed telefax numbers as may thereafter be furnished.

If to NANO, EPIL  
and/or EPRC:

Elan Pharma International Limited  
Lincoln House, Lincoln Place  
Dublin 2, Ireland  
Attention: Colin Sainsbury, Esq.  
Telefax: 353-1-709-4124

With a copy to:

NanoSystems  
3000 Horizon Drive  
King of Prussia, PA 19406  
Attention: President  
Telefax: 610-313-5180

If to JANSSEN:

Janssen Pharmaceutica N.V.  
Turnhoutseweg 30  
B-2340 Beerse Belgium

Certain portions of this Exhibit have been omitted pursuant to a request for confidentiality. Such omitted portions, which are marked with brackets [ ] and an asterisk\*, have been separately filed with the Securities and Exchange Commission.

Attention: Managing Director  
Telefax: 32-14-60-2841

Any notice sent under this Article 22 shall be deemed to have been received on the date actually received, or (i) five (5) business days after being mailed in the case of a notice mailed by registered or certified mail, postage prepaid; and (ii) one (1) business day after being transmitted in the case of a notice transmitted via telefax. The business days referred to in this Section 23.2 shall be business days of the recipient of the notice.

## **ARTICLE 23 - WAIVER**

The failure on the part of NANO or JANSSEN to exercise or enforce any rights conferred upon it hereunder (including any right to terminate this Agreement under Article 15) shall not be deemed to be a waiver of any such rights nor operate to bar the exercise or enforcement thereof at any time or times thereafter. The observance of any term of this Agreement may be waived (either generally or in a particular instance and either retroactively or prospectively) by the party entitled to enforce such term, but any such waiver shall be effective only if in a writing signed by the party against whom such waiver is to be asserted.

## **ARTICLE 24 - ENTIRE AGREEMENT**

24.1 Agreement constitutes the entire agreement between the parties hereto concerning the subject matter hereof and any representation, promise or condition in connection therewith, not incorporated herein, shall not be binding upon either party. This Agreement, including without limitation the exhibits attached hereto, are intended to define the full extent of the legally enforceable undertakings of the parties hereto, and no promise or representation, written or oral, which is not set forth explicitly herein is intended by either party to be legally binding.

24.2 This Agreement shall expressly supersede and replace the Feasibility Agreement as the same is related to Compound and, as of the Effective Date, the Feasibility Agreement as it relates to Compound shall be of no further force or effect and shall hereby be replaced in its entirety with the terms and conditions of this Agreement.



## **ARTICLE 25 - ASSIGNMENT**

25.1 Subject to the provisions of Section 9.2 in connection with Highly Confidential Information, JANSSEN may assign any or part of its rights under this Agreement

36

---

Certain portions of this Exhibit have been omitted pursuant to a request for confidentiality. Such omitted portions, which are marked with brackets [ ] and an asterisk\*, have been separately filed with the Securities and Exchange Commission.

to any of its Affiliates. Prior to any such assignment becoming effective, such Affiliate will undertake in writing to abide by all terms and conditions of this Agreement.

25.2 JANSSEN and NANO will discuss any assignment by JANSSEN to an Affiliate prior to its implementation in order to avoid or reduce any additional tax liability to NANO resulting solely from different tax law provisions applying after such assignment to an Affiliate. For the purpose hereof, an additional tax liability to NANO means that NANO would be subject to a higher net tax on payments made hereunder after taking into account any applicable tax treaty and available tax credits, than NANO was subject to before the proposed assignment. In case no reasonable solution can be found in order to reduce or eliminate the above referred additional tax liability to NANO and NANO can demonstrate by means of written documentation, certified by an independent external auditor, that NANO cannot take a full credit against such tax liability, then NANO shall be made whole by JANSSEN or the assignee as the case may be, whenever JANSSEN wants to proceed with such assignment to such Affiliate. To the extent that NANO is not a taxable entity, any references to NANO shall, solely for the purposes of this Article, deem to refer to its members.

25.3 JANSSEN and NANO will discuss any assignment by NANO to an Affiliate prior to its implementation in order to avoid or reduce any additional tax liability to JANSSEN resulting solely from different tax law provisions applying after such assignment to an Affiliate. For the purpose hereof, an additional tax liability to JANSSEN means that JANSSEN would be subject to a higher net tax on payments made hereunder after taking into account any applicable tax treaty and available tax credits, than JANSSEN was subject to before the proposed assignment. In case no reasonable solution can be found in order to reduce or eliminate the above referred additional tax liability to JANSSEN and JANSSEN can demonstrate by means of written documentation, certified by an independent external auditor, that JANSSEN cannot take a full credit against such tax liability, then JANSSEN shall be made whole by NANO or the assignee as the case may be, whenever NANO wants to proceed with such assignment to such Affiliate. To the extent that JANSSEN is not a taxable entity, any references to JANSSEN shall, solely for the purposes of this Article, deem to refer to its members.

25.4 NANO will be entitled to assign all or a portion of its rights and obligations under this Agreement to an Affiliate or to a Third Party that acquires all or substantially all of NANO's rights in the NanoCrystal Technology from NANO. Prior to any such assignment becoming effective, such Affiliate or Third Party assignee will undertake in writing to abide by all terms and conditions of this Agreement.

37

---

Certain portions of this Exhibit have been omitted pursuant to a request for confidentiality. Such omitted portions, which are marked with brackets [ ] and an asterisk\*, have been separately filed with the Securities and Exchange Commission.

## **ARTICLE 26 - TITLES**

It is agreed that the marginal headings appearing at the beginning of the numbered Articles hereof have been inserted for convenience only and do not constitute any part of this Agreement.

## **ARTICLE 27 - PUBLICITY**

Neither party shall originate any publicity, news release or public announcements, written or oral, whether to the public or press, stockholders or otherwise, relating to this Agreement, including its existence, the subject matter to which it relates, performance under it or any of its terms, to any amendment hereto or performances hereunder without the prior written consent of the other party, provided however, that this Article 27 shall not be applicable where either party hereto is legally required to make public, a summary or details of this Agreement, in any country. If a party believes that it has a legal requirement to make public the existence of or any details of or any events related in any way to this Agreement, it shall provide a copy of any such announcement to the other party for review and approval at least five (5) days prior to making said announcement. Nothing herein shall limit the parties' obligations under Article 12 with respect to Information and Highly Confidential Information.

## **ARTICLE 28 - UNENFORCEABLE PROVISIONS**

The provisions of this Agreement shall be deemed severable and the invalidity or unenforceability of any provision shall not affect the validity or enforceability of the other provisions hereof. If any provision of this Agreement, or the application thereof to any person or entity or any circumstance, is invalid or unenforceable, (i) a suitable and equitable provision shall be substituted therefore in order to carry out, so far as may be valid and enforceable, the intent and purpose of such invalid and unenforceable provision and (ii) the remainder of this Agreement and the application of such provision to other persons, entities or circumstances shall not be affected by such invalidity or unenforceability, nor shall such invalidity or unenforceability affect such provision, or the application thereof, in any other jurisdiction.

## **ARTICLE 29 - CONSTRUCTION**

As used in this Agreement, singular includes the plural and plural includes the singular, wherever so required by fact or context.

38

---

Certain portions of this Exhibit have been omitted pursuant to a request for confidentiality. Such omitted portions, which are marked with brackets [ ] and an asterisk\*, have been separately filed with the Securities and Exchange Commission.

**ARTICLE 30 - EXECUTION**

This Agreement shall be executed in two (2) counterparts, each of which shall for all purposes be deemed an original.

**ARTICLE 31 - NON-SOLICITATION**

From the Effective Date until two (2) years following the First Commercial Sale in any of the Major Markets, JANSSEN shall not, directly or indirectly, induce, encourage, or solicit any technical personnel employed by EPRC to (i) leave such employment or (ii) accept any other position or employment, nor shall JANSSEN assist any other entity to induce, encourage, or solicit any technical personnel employed by EPRC to (i) leave such employment or (ii) accept any other position or employment.

Certain portions of this Exhibit have been omitted pursuant to a request for confidentiality. Such omitted portions, which are marked with brackets [ ] and an asterisk\*, have been separately filed with the Securities and Exchange Commission.

IN WITNESS WHEREOF, the parties hereto have caused this Agreement to be executed by their respective duly authorized officers or representatives as of the day and year first above written.

ELAN PHARMACEUTICAL  
RESEARCH CORP., d/b/a  
NANOSYSTEMS

By: /s/ Seamus Mulligan  
Name: S. Mulligan  
Title: President 31/3/99

ELAN PHARMA INTERNATIONAL LIMITED

By: /s/ Seamus Mulligan  
Name: S. Mulligan  
Title: President 31/3/99

JANSSEN PHARMACEUTICA N.V.

By: /s/ G. Van Reet  
Name: Managing Director  
Title:

By: /s/ G. Vercauteren  
Name: International Vice President  
Business Development

Certain portions of this Exhibit have been omitted pursuant to a request for confidentiality. Such omitted portions, which are marked with brackets [ ] and an asterisk\*, have been separately filed with the Securities and Exchange Commission.

**EXHIBIT A: NANO PATENTS**

[\*]

Certain portions of this Exhibit have been omitted pursuant to a request for confidentiality. Such omitted portions, which are marked with brackets [ ] and an asterisk\*, have been separately filed with the Securities and Exchange Commission.

**EXHIBIT B: SELECTION PATENTS**

Certain portions of this Exhibit have been omitted pursuant to a request for confidentiality. Such omitted portions, which are marked with brackets [ ] and an asterisk\*, have been separately filed with the Securities and Exchange Commission.

**FORM 1: STATEMENT**

The information contained in this document is strictly confidential information and shall be treated accordingly by the receiver. In no event shall any copies be made or shall the information be disclosed to a third party. Any disclosure to an employee of JANSSEN or of a JANSSEN Affiliate shall be on a strict need to know basis. The receiver shall keep the document under lock in a safe place. The information shall be used only as authorized by JANSSEN in the development and/or manufacturing of a nanoparticle product.

July 31, 2003

Janssen Pharmaceutica N.V.  
Turnhoutseweg 30  
B-2340 Beerse Belgium  
Attention: Guy Vercauteren

RE: First Amendment 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 31 March 1999 ("the License Agreement")

Dear Sirs

We refer to the above identified License Agreement that the parties desire to amend as follows:

Defined terms used in this letter shall have the meanings assigned to them in the License Agreement unless such terms are expressly defined in this letter. All other provisions of the License Agreement not amended herein shall remain unchanged and in full force and effect.

**The License Agreement is modified as follows:**

**Section 3.2** is amended to add the following sentence to the end of the paragraph:

"The obligations of this Section 3.2 are limited to the disclosure of patents and patent applications only and in accordance with the provisions of Article 10."

**Section 3.8** is amended by deleting the first sentence.

**New Sections 10.5 and 10.6** are added:

- 10.5 Notwithstanding anything to the contrary in this Agreement, the parties have no obligation to disclose to each other any findings or inventions made or discovered during the course of the Development Program or as a consequence of activities conducted under this Agreement or the Feasibility Agreement unless and until such finding or invention is the subject of a patent application ("Patent Applications") filed by such party.
- 10.6 Notwithstanding anything to the contrary in this Agreement, Janssen hereby grants to NANO a non-exclusive, royalty-free, world-wide, sublicenseable license to Patent Applications filed by Janssen or its Affiliates, except as to Compound, Analogue, and Product. The license rights granted to NANO under this Article 10.6 only include Valid Claims that cover NanoCrystal Technology and specifically exclude Valid Claims

---

that do not cover NanoCrystal Technology. For the purposes of this Article 10.6 only, Valid Claims shall also include patent applications.

Please indicate your understanding and approval by executing this letter in duplicate at the place indicated below and returning one signed duplicate to us.

Sincerely,  
/s/ Nancy Neill

\_\_\_\_\_  
Nancy Neill  
Treasurer  
Elan Drug Delivery, Inc.

**Agreed for and on behalf of Janssen Pharmaceutica NV**

/s/ Guy Vercauteren  
\_\_\_\_\_  
Guy Vercauteren

Janssen Pharmaceutica NV

**Agreed for and on behalf of Elan Drug Delivery, Inc.**

By: /s/ Nancy Neill  
\_\_\_\_\_  
Name: Nancy Neill  
Title: Treasurer

**Agreed for and on behalf of Elan Pharma International Limited**

By: /s/ Debbie Buryj  
\_\_\_\_\_

Name: Debbie Buryj  
Title: Authorized Signatory



Certain portions of this Exhibit have been omitted pursuant to a request for confidentiality. Such omitted portions, which are marked with brackets [ ] and an asterisk\*, have been separately filed with the Securities and Exchange Commission.

**“Agreement Amendment No. 2”**

[17 March, 2011]

Janssen Pharmaceutica N.V.  
Turnhoutseweg 30  
B-2340 Beerse  
Belgium

Elan Drug Delivery, Inc.  
3500 Horizon Drive  
King of Prussia, PA 19046  
USA

Dear Sirs

RE: *License Agreement dated March 31, 1999 (the “Agreement”), as amended by letter amendment of July 31, 2003, between Elan Drug Delivery, Inc. (successor in interest in and to Elan Pharmaceutical Research Corp., d/b/a Nanosystems (“EDDI”) and Elan Pharma International Limited (“EPIL”) (EDDI and EPIL collectively hereinafter referred to as “Elan”) and Janssen Pharmaceutica N.V. (“Janssen”)*

Elan and Janssen hereby agree that with effect from July 31, 2009 this Agreement Amendment No. 2 (“**Agreement Amendment No. 2 Effective Date**”) the Agreement shall be amended as follows:

1. All references in the Agreement to EPRC shall read EDDI. All references to NANO shall read Elan.

2. **Article 22** Elan contact details only - shall be deleted and replaced with the following:

If to Elan: Elan Pharma International Limited

*EPIL Letter to Janssen and EDDI of 23 July 2009  
Amendment No 2 to license dated 31 March 1999, as amended*

Certain portions of this Exhibit have been omitted pursuant to a request for confidentiality. Such omitted portions, which are marked with brackets [ ] and an asterisk\*, have been separately filed with the Securities and Exchange Commission.

Monksland, Athlone, County Westmeath, Ireland

Attention: Vice President & Legal Counsel  
Telefax: 00 353 90 64 95402

With a copy to:

Elan Drug Delivery, Inc.  
3500 Horizon Drive, King of Prussia, PA 19406,  
USA

Attention: President  
Telefax: 001 610-313-5182

**3. Patent Schedules**

**3.1 Exhibit A: Nano Patents** shall be deleted and replaced with Exhibit A: Nano Patents — Updated January, 2011, attached hereto.

**Exhibit B: Selection Patents** shall be deleted and replaced with Exhibit B Selection Patents — Updated January 2011, attached hereto.

4. Defined texts used in this Agreement Amendment No. 2 shall have the meaning assigned to them in the Agreement unless such terms are expressly defined in this Agreement Amendment No. 2. All other provisions of the Agreement not amended herein shall remain unchanged and in full force and effect.

Yours faithfully,

Signed on behalf of:

**Elan Pharma International Limited**

/s/ William Daniel

**Name: William Daniel**

**Title: Director**

**Date: 1 April 2011**

Agreed and accepted for and on behalf of

**Elan Drug Delivery, Inc. successor in interest in and to Elan Pharmaceutical Research Corp., d/b/a Nanosystems**

2

---

Certain portions of this Exhibit have been omitted pursuant to a request for confidentiality. Such omitted portions, which are marked with brackets [ ] and an asterisk\*, have been separately filed with the Securities and Exchange Commission.

/s/ David Czekai

**Name: David Czekai**

**Title: VP and GM**

**Date: 18 Apr 2011**

Accepted for and on behalf of:

**Janssen Pharamceutica N.V.**

/s/ Ludo Lauwers

**Name: Ludo Lauwers**

**Title: Senior Vice President, Site Management**

**Date: 17 March 2011**

/s/ Dirk Collier

Member of the Board

3

---

Certain portions of this Exhibit have been omitted pursuant to a request for confidentiality. Such omitted portions, which are marked with brackets [ ] and an asterisk\*, have been separately filed with the Securities and Exchange Commission.

**Exhibit A: Nano Patents—Updated January, 2011**

\*\*\*\*\*

4

---

Certain portions of this Exhibit have been omitted pursuant to a request for confidentiality. Such omitted portions, which are marked with brackets [ ] and an asterisk\*, have been separately filed with the Securities and Exchange Commission.

**[Exhibit B: Selection Patents—Updated July 31, 2009]**

\*\*\*\*\*

5

---

**AMENDMENT NO. 3 AND WAIVER TO  
AMENDED AND RESTATED CREDIT AGREEMENT**

THIS AMENDMENT NO. 3 AND WAIVER TO AMENDED AND RESTATED CREDIT AGREEMENT (this "Amendment") dated as of May 22, 2013 is entered into by and among Alkermes, Inc., a corporation organized under the laws of the Commonwealth of Pennsylvania (the "Borrower"), Alkermes plc, a company incorporated under the laws of the Republic of Ireland ("Holdings"), Alkermes Pharma Ireland Limited, a private limited company organized under the laws of the Republic of Ireland ("Intermediate Holdco"), Alkermes US Holdings, Inc. ("Holdco"), Morgan Stanley Senior Funding, Inc., as administrative agent (in such capacity, the "Administrative Agent") and as collateral agent (in such capacity, the "Collateral Agent"), and the undersigned lenders. Capitalized terms not otherwise defined in this Amendment have the same meanings as specified in the Credit Agreement (as defined below).

**PRELIMINARY STATEMENTS:**

(1) The Borrower, Holdings, Intermediate Holdco, Holdco, the Administrative Agent and Collateral Agent, Morgan Stanley Senior Funding, Inc., Citigroup Global Markets, Inc. and JPMorgan Chase Bank, N.A., as co-syndication agents and the financial institutions from time to time party thereto as term lenders (the "Lenders") entered into that certain Amended and Restated Credit Agreement, initially dated as of September 16, 2011 and amended and restated on September 25, 2012, as further amended as of February 14, 2013 (the "Credit Agreement");

(2) The Borrower, Holdings, the other Loan Parties party thereto have requested that the Lenders and the Administrative Agent agree to amend the Credit Agreement and grant certain waivers thereunder, and the Lenders and the Administrative Agent have agreed to such amendments and waivers, as hereinafter set forth;

NOW, THEREFORE, in consideration of the premises and for other good and valuable consideration (the receipt and sufficiency of which are hereby acknowledged), the parties hereto hereby agree as follows:

SECTION 1. Amendments and Waivers to Credit Agreement.

1.1. Amendments

The Credit Agreement is, effective as of the date hereof and subject to the satisfaction of the conditions precedent set forth in Section 3, hereby amended as follows:

(a) The definition of "ECF Percentage" appearing in Section 1.1 of the Credit Agreement is hereby amended by deleting "March 31, 2014" appearing therein and substituting in lieu thereof "December 31, 2013".

(b) The definition of "Excess Cash Flow Payment Period" appearing in Section 1.1 of the Credit Agreement is hereby amended by deleting "March 31, 2014" appearing therein and substituting in lieu thereof "December 31, 2013".

---

(c) Section 3.2(c) of the Credit Agreement is hereby amended by deleting "March 31, 2014" appearing therein and substituting in lieu thereof "December 31, 2013".

1.2. Waiver

The Lenders, effective as of the date hereof and subject to the satisfaction of the conditions precedent set forth in Section 3, hereby waive Section 7.11(a) thereof in order to permit Holdings to change its fiscal year such that it will end on December 31 of each year, commencing with the fiscal year ending on December 31, 2013.

SECTION 2. Reference to and Effect on the Loan Documents.

(a) On and after the Effective Date, each reference in the Credit Agreement to "this Agreement", "hereunder", "hereof" or words of like import referring to the Credit Agreement, and each reference in the other Loan Documents to "the Credit Agreement", "the First-Lien Credit Agreement," "the Amended and Restated Credit Agreement," "thereunder", "thereof" or words of like import referring to the Credit Agreement, shall mean and be a reference to the Credit Agreement as amended by this Amendment.

(b) The Credit Agreement, as specifically amended and waived by this Amendment, and the other Loan Documents are, and shall continue to be, in full force and effect, and are hereby in all respects ratified and confirmed.

(c) Except as expressly provided herein, the execution, delivery and effectiveness of this Amendment shall not operate as a waiver of any right, power or remedy of any Lender or the Administrative Agent under the Credit Agreement or any other Loan Document, nor shall it constitute a waiver of any provision of the Credit Agreement or any Loan Document.

SECTION 3. Conditions of Effectiveness. This Amendment shall become effective as of the date (the "Effective Date") on which each of the following conditions shall have been satisfied (or waived):

(a) The Administrative Agent shall have received from (i) the Lenders under the Credit Agreement constituting Required Lenders, and (ii) the Administrative Agent, executed counterparts of this Amendment or written evidence reasonably satisfactory to the Administrative Agent that such party has executed this Amendment on, or prior to, 5 p.m., New York City time on May 8, 2013 (the "Consent Deadline").



(b) The Administrative Agent shall have received from the Loan Parties party hereto, executed counterparts of this Amendment or written evidence reasonably satisfactory to the Administrative Agent that such party has executed this Amendment.

(c) As of the Effective Date, no event shall have occurred and be continuing that would constitute a Default or Event of Default under the Agreement.

SECTION 4. Costs and Expenses.

The Borrower agrees that all reasonable out-of-pocket expenses incurred by the Administrative Agent in connection with the preparation, execution, delivery and administration,

2

---

modification and amendment of this Amendment and the other instruments and documents to be delivered hereunder or in connection herewith (including, without limitation, the reasonable fees, charges and disbursements of Shearman & Sterling LLP, counsel for the Administrative Agent), are expenses that the Borrower are required to pay or reimburse pursuant to Section 10.5 of the Credit Agreement.

SECTION 5. Miscellaneous.

(a) Execution in Counterpart. This Amendment may be executed in any number of counterparts and by different parties hereto in separate counterparts, each of which when so executed shall be deemed to be an original and all of which taken together shall constitute but one and the same agreement. Delivery of an executed counterpart of a signature page to this Amendment by telecopier or other electronic means shall be effective as delivery of a manually executed counterpart of this Amendment.

(b) Binding Effect. This Amendment shall be binding upon and inure to the benefit of the parties hereto and their respective successors and assigns.

(c) Headings. The headings listed herein are for convenience only and do not constitute matters to be construed in interpreting this Amendment.

(d) Waiver & Modification. No provision of this Amendment may be modified, altered or otherwise amended, except by an instrument in writing executed by each of the parties hereto.

(e) GOVERNING LAW. THIS AMENDMENT SHALL BE GOVERNED BY, AND CONSTRUED IN ACCORDANCE WITH, THE LAWS OF THE STATE OF NEW YORK.

(f) WAIVER OF RIGHT OF TRIAL BY JURY. EACH PARTY TO THIS AMENDMENT HEREBY EXPRESSLY WAIVES ANY RIGHT TO TRIAL BY JURY OF ANY CLAIM, DEMAND, ACTION OR CAUSE OF ACTION ARISING UNDER THIS AMENDMENT, OR IN ANY WAY CONNECTED WITH OR RELATED OR INCIDENTAL TO THE DEALINGS OF THE PARTIES HERETO OR ANY OF THEM WITH RESPECT TO THE CREDIT AGREEMENT AS AMENDED HEREBY, OR THE TRANSACTIONS RELATED THERETO, IN EACH CASE WHETHER NOW EXISTING OR HEREAFTER ARISING, AND WHETHER FOUNDED IN CONTRACT OR TORT OR OTHERWISE; AND EACH PARTY HEREBY AGREES AND CONSENTS THAT ANY SUCH CLAIM, DEMAND, ACTION OR CAUSE OF ACTION SHALL BE DECIDED BY COURT TRIAL WITHOUT A JURY, AND THAT ANY PARTY TO THIS AGREEMENT MAY FILE AN ORIGINAL COUNTERPART OR A COPY OF THIS SECTION WITH ANY COURT AS WRITTEN EVIDENCE OF THE CONSENT OF THE SIGNATORIES HERETO TO THE WAIVER OF THEIR RIGHT TO TRIAL BY JURY.

3

---

IN WITNESS WHEREOF, the parties hereto have caused this Amendment to be executed by their respective authorized officers as of the date first above written.

**BORROWER:**

**ALKERMES, INC., as Borrower**

By: /s/ James M. Frates

Name: James M. Frates

Title: Senior Vice President, Chief Financial Officer & Treasurer

Alkermes

May 2013 Amendment and Waiver

---

**GIVEN** under the common seal of  
**ALKERMES PLC, as Holdings**  
and **DELIVERED** as a **DEED**



**Stock Option Award Certificate**

(INCENTIVE STOCK OPTION)



«FIRST\_NAME» «MIDDLE\_NAME» «LAST\_NAME»  
 «ADDRESS\_LINE\_1»  
 «ADDRESS\_LINE\_2»  
 «ADDRESS\_LINE\_3»  
 «CITY», «STATE» «ZIP\_CODE»

**Option Number:** «NUM»  
**Plan:** «PLAN\_NAME»  
  
**ID:** «ID»

Effective «GRANT\_DATE», you have been granted an Incentive Stock Option to buy «SHARES\_GRANTED» shares of Alkermes plc (the “Company”) common stock at «OPTION\_PRICE» per share.

The total option price of the shares granted is «TOTAL\_OPTION\_PRICE».

The right to acquire the shares subject to the Incentive Stock Option will become fully vested on the dates shown below. The Incentive Stock Option shall expire on the earlier to occur of: the 10<sup>th</sup> anniversary of the date of grant or three months after termination of your service relationship with the Company (unless otherwise provided below).

Shares	Vesting Date
«SHARES_PERIOD_1»	
«SHARES_PERIOD_2»	
«SHARES_PERIOD_3»	
«SHARES_PERIOD_4»	

In the event of the termination of your employment with the Company (but not the termination of a non-employment relationship with the Company) by reason of death or permanent disability, the Incentive Stock Option shall vest and be exercisable in full on such termination of employment and the period during which the Incentive Stock Option (to the extent that it is exercisable on the date of termination of employment) may be exercised shall be three (3) years following the date of termination of employment by reason of death or permanent disability, but not beyond the original term of the Incentive Stock Option. For the purpose of the terms of this Incentive Stock Option, you will be deemed to be employed by the Company so long as you remain employed by a company which continues to be a subsidiary of the Company.

The foregoing Incentive Stock Option has been granted under and is governed by the terms and conditions of this Certificate and the Alkermes plc 2011 Stock Option and Incentive Plan.

\_\_\_\_\_  
 Alkermes plc.

\_\_\_\_\_  
 Date

2011 Plan — REVISED (4/2013)  
 US employees

Stock Option Award Certificate

(NON-QUALIFIED STOCK OPTION)



«FIRST\_NAME» «MIDDLE\_NAME» «LAST\_NAME»  
 «ADDRESS\_LINE\_1»  
 «ADDRESS\_LINE\_2»  
 «ADDRESS\_LINE\_3»  
 «CITY», «STATE» «ZIP\_CODE»

Option Number: «NUM»  
 Plan: «PLAN\_NAME»

ID: «ID»

Effective «GRANT\_DATE», you have been granted a Non-Qualified Stock Option to buy «SHARES\_GRANTED» shares of Alkermes plc. (the “Company”) common stock at «OPTION\_PRICE» per share.

The total option price of the shares granted is «TOTAL\_OPTION\_PRICE».

The right to acquire the shares subject to the Non-Qualified Stock Option will become fully vested on the dates shown below. The Non-Qualified Stock Option shall expire on the earlier to occur of: the 10<sup>th</sup> anniversary of the date of grant or three months after termination of your service relationship with the Company (unless otherwise provided below).

Shares	Vest Date
«SHARES_PERIOD_1»	
«SHARES_PERIOD_2»	
«SHARES_PERIOD_3»	
«SHARES_PERIOD_4»	

In the event of the termination of your employment with the Company (but not the termination of a non-employment relationship with the Company) by reason of death or permanent disability, the Non-Qualified Stock Option shall vest and be exercisable in full on such termination of employment and the period during which the Non-Qualified Stock Option (to the extent that it is exercisable on the date of termination of employment) may be exercised shall be three (3) years following the date of termination of employment by reason of death or permanent disability, but not beyond the original term of the Option. For the purpose of the terms of this Non-Qualified Stock Option, you will be deemed to be employed by the Company so long as you remain employed by a company which continues to be a subsidiary of the Company.

The foregoing Non-Qualified Stock Option has been granted under and is governed by the terms and conditions of this Certificate and the Alkermes plc 2011 Stock Option and Incentive Plan.

\_\_\_\_\_  
 Alkermes plc.

\_\_\_\_\_  
 Date

**SUBSIDIARIES**

<u>Name</u>	<u>Jurisdiction</u>
Alkermes Ireland Holdings Limited	Ireland
Alkermes Science Three Limited	Ireland
Alkermes Pharma Ireland Limited	Ireland
Alkermes Finance Ireland Limited	Ireland
Alkermes Science One Limited	Ireland
Alkermes Finance S.à r.l.	Luxembourg
Alkermes Finance Ireland (No. 2) Limited	Ireland
Alkermes U.S. Holdings, Inc.	Delaware
Alkermes, Inc.	Pennsylvania
Eagle Holdings USA, Inc.	Delaware
Alkermes Controlled Therapeutics, Inc.	Pennsylvania
Alkermes Europe, Ltd.	United Kingdom
Alkermes Gainesville LLC	Massachusetts

---

QuickLinks

[EXHIBIT 21.1](#)

[SUBSIDIARIES](#)

**CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

We hereby consent to the incorporation by reference in the Registration Statement on Form S-1 (No. 333-179550), Form S-4 (No. 333-175078) and Form S-8 (Nos. 333-179545 and 333-184621) of Alkermes plc of our report dated May 23, 2013 relating to the financial statements and the effectiveness of internal control over financial reporting, which appears in this Form 10-K.

/s/ PRICEWATERHOUSECOOPERS LLP  
Boston, Massachusetts  
May 23, 2013

---

QuickLinks

[EXHIBIT 23.1](#)

[CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM](#)



**CERTIFICATIONS**

I, Richard F. Pops, certify that:

1. I have reviewed this annual 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 annual 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

---

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

May 23, 2013

---

QuickLinks

[EXHIBIT 31.1](#)

[CERTIFICATIONS](#)

**CERTIFICATIONS**

I, James M. Frates, certify that:

1. I have reviewed this annual 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 annual 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

---

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

May 23, 2013

---

QuickLinks

[EXHIBIT 31.2](#)

[CERTIFICATIONS](#)

**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 Annual Report of Alkermes plc (the "Company") on Form 10-K for the period ended March 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

---

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

/s/ JAMES M. FRATES

---

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

May 23, 2013

---

QuickLinks

[EXHIBIT 32.1](#)

[CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002](#)