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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

Form 10-K

(Mark One)

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

for the fiscal year ended December 31, 2015

OR

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

For the transition period from to

Commission file number: 001-35299

ALKERMES PUBLIC LIMITED COMPANY

(Exact name of registrant as specified in its charter)

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

+353-1-772-8000

(Registrant's telephone number, including area code)

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

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

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

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☒ 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 $9,530,707,684.

As of February 12, 2016, 150,741,617 ordinary shares were issued and outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the definitive proxy statement for our Annual General Meeting of Shareholders for the fiscal year ended December 31, 2015 are incorporated by reference into Part III of this report.

ALKERMES PLC AND SUBSIDIARIES
ANNUAL REPORT ON FORM 10-K
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CAUTIONARY NOTE CONCERNING FORWARD-LOOKING STATEMENTS

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

- our expectations regarding our financial performance, including revenues, expenses, gross margins, liquidity, capital expenditures and income taxes;
- our expectations regarding our products, including the development, regulatory (including expectations about regulatory filing, regulatory approval and regulatory timelines), therapeutic and commercial scope and potential of such products and the costs and expenses related thereto;
- our expectations regarding the initiation, timing and results of clinical trials of our products;
- our expectations regarding the competitive landscape, and changes therein, related to our products, including our development programs, and our industry generally;
- our expectations regarding the financial impact of currency exchange rate fluctuations and valuations;
- our expectations regarding future amortization of intangible assets;
- our expectations regarding our collaborations, licensing arrangements and other significant agreements with third parties relating to our products, including our development programs;
- our expectations regarding the impact of adoption of new accounting pronouncements;
- our expectations regarding near-term changes in the nature of our market risk exposures or in management's objectives and strategies with respect to managing such exposures;
- our ability to comply with restrictive covenants of our indebtedness and our ability to fund our debt service obligations;
- our expectations regarding future capital requirements and capital expenditures and our ability to finance our operations and capital requirements; and
- other factors discussed elsewhere in this Annual Report.

Actual results might differ materially from those expressed or implied by these forward-looking statements because these forward-looking statements are subject to risks, assumptions and uncertainties. You are cautioned not to place undue reliance on forward-looking statements, which speak only as of the date of this Annual Report. All subsequent written and oral forward-looking statements concerning the matters addressed in this Annual Report and attributable to us or any person acting on our behalf are expressly qualified in their entirety by the cautionary statements contained or referred to in this section. Except as required by applicable law or regulation, we do not undertake any obligation to update publicly or revise any forward-looking statements, whether as a result of new information, future events or otherwise. In light of these risks, assumptions and uncertainties, the forward-looking events discussed in this Annual Report might not occur. For more information regarding the risks and uncertainties of our business, see "Item 1A—Risk Factors" in this Annual Report.

Unless otherwise indicated, information contained in this Annual Report concerning the disorders targeted by our products and the markets in which we operate is based on information from various sources (including, without limitation, industry publications, medical and clinical journals and studies, surveys and forecasts and our internal research), on assumptions that we have made, which we believe are reasonable, based on those data and other similar sources and on our knowledge of the markets for our products. Our internal research has not been verified by any independent source, and we have not independently verified any third-party information. These projections, assumptions and estimates are necessarily subject to a high degree of uncertainty and risk due to a variety of factors, including those described in "Item 1A—Risk Factors." These and other factors could cause results to differ materially from those expressed in the estimates included in this Annual Report.

NOTE REGARDING COMPANY AND PRODUCT REFERENCES

Use of the terms such as "us," "we," "our," "Alkermes" or the "Company" in this Annual Report is meant to refer to Alkermes plc and its consolidated subsidiaries, except where the context makes clear that the time period being referenced is prior to September 16, 2011, in which case such terms shall refer to Alkermes, Inc. and its consolidated

subsidiaries. Prior to September 16, 2011, Alkermes, Inc. was an independent pharmaceutical company incorporated in the Commonwealth of Pennsylvania and traded on the NASDAQ Global Select Stock Market (the "NASDAQ") under the symbol "ALKS." Except as otherwise suggested by the context, (a) references to "products" or "our products" in this Annual Report include our marketed products, marketed products using our proprietary technologies, our product candidates and product candidates using our proprietary technologies, (b) references to the "biopharmaceutical industry" are used interchangeably with references to the "biotechnology and/or pharmaceutical industries" and (c) references to "licensees" are used interchangeably with references to "collaborative partners" and "partners."

NOTE REGARDING TRADEMARKS

We are the owner of various U.S. federal trademark registrations ("®") and other trademarks ("TM"), including ALKERMES®, ARISTADA®, CODAS®, IPDAS®, LinkeRx®, MXDAS®, NanoCrystal®, SECA™, SODAS®, VERELAN® and VIVITROL®.

The following are trademarks of the respective companies listed: ABILIFY® and ABILIFY MAINTENA®—Otsuka Pharmaceutical Co., Ltd.; AMPYRA®, FAMPYRA®—Acorda Therapeutics, Inc.; ANTABUSE®—Teva Women's Health, Inc.; AUBAGIO® and LEMTRADA®—Sanofi Societe Anonyme France; AVONEX®, PLEGRIDY®, TECFIDERA®, and TYSABRI®—Biogen MA Inc.; BETASERON®—Bayer Pharma AG; BUNAVAIL™—BioDelivery Sciences; BYDUREON® and BYETTA®—Amylin Pharmaceuticals, LLC; CAMPRAL®—Merck Sante; COPAXONE®—Teva Pharmaceutical Industries Ltd.; FOCALIN XR®, EXTAVIA®, GILENYA® and RITALIN LA®—Novartis AG; INVEGA® SUSTENNA®, RISPERDAL® CONSTA® INVEGA TRINZA™ and XEPLION®—Johnson & Johnson (or its affiliates); NOVANTRONE® and REBIF®—Ares Trading S.A.; SUBOXONE® and SUBUTEX®—Indivior plc; TRICOR®—Fournier Industrie et Sante Corporation; VICTOZA®—Novo Nordisk A/S LLC; ZOHYDRO™—Zogenix, Inc.; ZUBSOLV®—Orexo US, Inc.; and TRULICITY®, ZYPREXA® and ZYPREXA® RELPREVV®—Eli Lilly and Company. Other trademarks, trade names and service marks appearing in this Annual Report are the property of their respective owners. Solely for convenience, the trademarks and trade names in this Annual Report are referred to without the ® and ™ symbols, but such references should not be construed as any indicator that their respective owners will not assert, to the fullest extent under applicable law, their rights thereto.

NOTE REGARDING FISCAL YEAR

On May 21, 2013, our Audit and Risk Committee, with such authority delegated to it by our Board of Directors, approved a change to our fiscal year-end from March 31 to December 31. This Annual Report reflects our financial results for the twelve-month period from January 1, 2015 through December 31, 2015. The period ended December 31, 2014 reflects our financial results for the twelve-month period from January 1, 2014 through December 31, 2014. The period ended December 31, 2013 reflects our financial results for the nine-month period from April 1, 2013 through December 31, 2013.

PART I

Item 1. *Business*

The following discussion contains forward-looking statements. Actual results may differ significantly from those expressed or implied in the forward-looking statements. See "Cautionary Note Concerning Forward-Looking Statements" on pages 3 and 4 of this Annual Report. Factors that might cause future results to differ materially from those expressed or implied in the forward-looking statements include, but are not limited to, those discussed in "Item 1A—Risk Factors" and elsewhere in this Annual Report.

Overview

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

Products

Marketed Products

The key marketed products discussed below are expected to generate significant revenues for us. They possess long patent lives and, we believe, are singular or competitively advantaged products in their class. Refer to the "Patents and Proprietary Rights" section of this Annual Report for information with respect to the intellectual property protection for these marketed products. Summary information about these key marketed products is set forth in the table below:

Product	Indication(s)	Licensee	Territory
Proprietary Products			
ARISTADA	Schizophrenia	None	United States ("U.S.")
VIVITROL	Alcohol dependence, Opioid dependence	None	U.S.
		Cilag GmbH International ("Cilag")	Russia and Commonwealth of Independent States ("CIS")
Products Using Our Proprietary Technologies			
RISPERDAL CONSTA	Schizophrenia and Bipolar I disorder	Janssen Pharmaceutica Inc. ("Janssen, Inc.") and Janssen Pharmaceutica International, a division of Cilag International AG ("Janssen International")	Worldwide
INVEGA SUSTENNA / XEPLION & INVEGA TRINZA	Schizophrenia	Janssen Pharmaceutica N.V. (together with Janssen, Inc. Janssen International and their affiliates "Janssen")	U.S.
	Schizoaffective disorder		Rest of World ("ROW")
AMPYRA / FAMPYRA	Treatment to improve walking in patients with multiple sclerosis ("MS"), as demonstrated by an increase in walking speed	Acorda Therapeutics, Inc. ("Acorda")	U.S.
		Biogen International GmbH ("Biogen"), under sublicense from Acorda	ROW
BYDUREON	Type 2 diabetes	AstraZeneca plc ("AstraZeneca")	Worldwide

Proprietary Products

We developed and commercialize in the U.S. products designed to address the unmet needs of patients suffering from addiction and schizophrenia.

ARISTADA

ARISTADA (aripiprazole lauroxil) is an extended-release injectable suspension for the treatment of schizophrenia, which was approved by the U.S. Food and Drug Administration ("FDA"), and commercially launched by us, in October 2015. ARISTADA is the first of our products to utilize our proprietary LinkeRx technology. ARISTADA is a prodrug; once in the body, ARISTADA is likely converted by enzyme-mediated hydrolysis to N-hydroxymethyl aripiprazole, which is then hydrolyzed to aripiprazole. ARISTADA is the first atypical antipsychotic with once-monthly and six-week dosing options for delivering and maintaining therapeutic levels of medication in the body through an intramuscular injection. ARISTADA possesses three dosing options (441 mg, 662 mg and 882 mg) packaged in a ready-to-use, pre-filled product format. We developed, manufacture and commercialize ARISTADA in the U.S.

What is schizophrenia?

Schizophrenia is a chronic, severe and disabling brain disorder. The disease is marked by positive symptoms (hallucinations and delusions) and negative symptoms (depression, blunted emotions and social withdrawal), as well as by disorganized thinking. An estimated 2.4 million Americans over the age of 18 have schizophrenia in a given year, with men and women affected equally. Worldwide, it is estimated that one person in every 100 develops schizophrenia. Studies have demonstrated that as many as 75% of patients with schizophrenia have difficulty taking their oral medication on a regular basis, which can lead to worsening of symptoms.

VIVITROL

VIVITROL (naltrexone for extended-release injectable suspension) is the only once-monthly, non-addictive, injectable medication approved in the U.S., Russia and certain of the CIS for the treatment of alcohol dependence and for the prevention of relapse to opioid dependence, following opioid detoxification. VIVITROL uses our polymer-based microsphere injectable extended-release technology to deliver and maintain therapeutic medication levels in the body through one injection every four weeks. We developed, manufacture and commercialize VIVITROL in the U.S., and Cilag commercializes VIVITROL in Russia and certain countries of the CIS.

What are opioid dependence and alcohol dependence?

Opioid dependence is a serious and chronic brain disease characterized by compulsive, prolonged self-administration of opioid substances that are not used for a medical purpose. According to the 2014 U.S. National Survey on Drug Use and Health, an estimated 2.3 million people aged 18 or older were dependent on pain relievers or heroin in the U.S.

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

Products Using Our Proprietary Technologies

We have granted licenses under our proprietary technologies to enable third parties to develop, commercialize and, in some cases, manufacture products for which we receive royalties and/or manufacturing revenues. Such arrangements include the following:

INVEGA SUSTENNA/XEPLION, INVEGA TRINZA and RISPERDAL CONSTA

INVEGA SUSTENNA/XEPLION (paliperidone palmitate) and INVEGA TRINZA (paliperidone palmitate) and RISPERDAL CONSTA (risperidone long-acting injection) are long-acting atypical antipsychotics that incorporate our proprietary technologies and are owned and commercialized worldwide by Janssen.

INVEGA SUSTENNA is approved in the U.S. for the treatment of schizophrenia and for the treatment of schizoaffective disorder as either a monotherapy or adjunctive therapy. Paliperidone palmitate extended-release injectable suspension is approved in the European Union ("EU") and other countries outside of the U.S. for the treatment of schizophrenia and is marketed and sold under the trade name XEPLION. INVEGA SUSTENNA/XEPLION uses our nanoparticle injectable extended-release technology to increase the rate of dissolution and enable the formulation of an aqueous suspension for once-monthly intramuscular administration. INVEGA SUSTENNA/XEPLION is manufactured by Janssen.

INVEGA TRINZA is an atypical antipsychotic injection for the treatment of schizophrenia used in people who have been treated with INVEGA SUSTENNA for at least four months. INVEGA TRINZA, the first schizophrenia treatment to be taken once every three months, became commercially available in the U.S. in June 2015. INVEGA TRINZA uses our proprietary technology and is manufactured by Janssen.

RISPERDAL CONSTA is approved in the U.S. for the treatment of schizophrenia and as both monotherapy and adjunctive therapy to lithium or valproate in the maintenance treatment of bipolar I disorder. RISPERDAL CONSTA is approved in numerous countries outside of the U.S. for the treatment of schizophrenia and the maintenance treatment of bipolar I disorder. RISPERDAL CONSTA uses our polymer-based microsphere injectable extended-release technology to deliver and maintain therapeutic medication levels in the body through just one injection every two weeks. RISPERDAL CONSTA microspheres are exclusively manufactured by us.

Revenues from Janssen accounted for approximately 40%, 41% and 44% of our consolidated revenues for the fiscal years ended December 31, 2015 and 2014 and the nine months ended December 31, 2013, respectively. See “Collaborative Arrangements” later in Part I of this Annual Report for information about our relationship with Janssen.

What is schizophrenia?

Schizophrenia is a chronic, severe and disabling brain disorder. The disease is marked by positive symptoms (hallucinations and delusions) and negative symptoms (depression, blunted emotions and social withdrawal), as well as by disorganized thinking. An estimated 2.4 million Americans over the age of 18 have schizophrenia in a given year, with men and women affected equally. Worldwide, it is estimated that one person in every 100 develops schizophrenia. Studies have demonstrated that as many as 75% of patients with schizophrenia have difficulty taking their oral medication on a regular basis, which can lead to worsening of symptoms.

What is bipolar I disorder?

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

What is schizoaffective disorder?

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

about one in 100 people.

AMPYRA/FAMPYRA

AMPYRA (dalfampridine)/FAMPYRA (fampridine), to our knowledge, is the first treatment approved in the U.S. and in over 50 countries across Europe, Asia and the Americas to improve walking in adults with MS who have walking disability, as demonstrated by an increase in walking speed. Extended-release dalfampridine tablets are marketed and sold by Acorda in the U.S. under the trade name AMPYRA and by Biogen outside the U.S. under the trade name FAMPYRA. In July 2011, the European Medicines Agency ("EMA") conditionally approved FAMPYRA in the EU for the improvement of walking in adults with MS. This authorization was renewed as of August 2015. AMPYRA and FAMPYRA incorporate our oral controlled-release technology. AMPYRA and FAMPYRA are manufactured by us.

What is multiple sclerosis?

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

BYDUREON

BYDUREON (exenatide extended-release for injectable suspension) is approved in the U.S. and the EU for the treatment of type 2 diabetes. From August 2012 until February 2014, Bristol-Myers Squibb Company ("Bristol-Myers") and AstraZeneca co-developed and marketed BYDUREON through their diabetes collaboration. In February 2014, AstraZeneca assumed sole responsibility for the development and commercialization of BYDUREON. BYDUREON, a once-weekly formulation of exenatide, the active ingredient in BYETTA, uses our polymer-based microsphere injectable extended-release technology. BYDUREON is manufactured by AstraZeneca.

BYDUREON Pen 2 mg, a pre-filled, single-use pen injector that contains the same formulation and dose as the original BYDUREON single-dose tray, is available in the U.S., certain countries in the EU and Japan.

What is type 2 diabetes?

Diabetes is a disease in which the body does not produce or properly use insulin. Diabetes can result in serious health complications, including cardiovascular, kidney and nerve disease. Diabetes is believed to affect nearly 26 million people in the U.S. and an estimated 382 million adults worldwide. Approximately 90-95% of those affected have type 2 diabetes. An estimated 80% of people with type 2 diabetes are overweight or obese. Data indicate that weight loss (even a modest amount) supports patients in their efforts to achieve and sustain glycemic control.

Key Development Programs

Our research and development is focused on leveraging our formulation expertise and proprietary product platforms to develop novel, competitively advantaged medications designed to enhance patient outcomes in major CNS disorders, such as schizophrenia, addiction, depression and MS. As part of our ongoing research and development efforts, we have devoted, and will continue to devote, significant resources to conducting clinical studies to advance the development of new pharmaceutical products. The discussion below highlights our key current research and development programs. Drug development involves a high degree of risk and investment, and the status, timing and scope of our development programs are subject to change. Important factors that could adversely affect our drug development efforts are discussed in "Item 1A—Risk Factors." Refer to the "Patents and Proprietary Rights" section of this Annual Report for information

with respect to the intellectual property protection for our product candidates.

Product Candidate	Target Indication(s)	Status
ALKS 5461	Major Depressive Disorder ("MDD")	Phase 3
ALKS 3831	Schizophrenia	Phase 3
ALKS 8700	MS	Phase 3
ALKS 6428	VIVITROL Seven-Day Taper Kit	Phase 3
Aripiprazole Lauroxil Two-Month Dose	Schizophrenia	Completed Phase 1
ALKS 7119	Various CNS diseases	Phase 1
RDB 1450	Cancer Immunotherapy	Pre-clinical

ALKS 5461

ALKS 5461 is a proprietary, oral investigational medicine in development for the treatment of MDD in patients who have an inadequate response to standard antidepressant therapies. ALKS 5461 is composed of samidorphan in combination with buprenorphine. Samidorphan, formerly referred to as ALKS 33, is a proprietary oral opioid modulator characterized by limited hepatic metabolism and durable pharmacologic activity in modulating brain opioid receptors. ALKS 5461 acts as a balanced neuromodulator in the brain and represents a new approach with a novel mechanism of action for treating MDD. In October 2013, the FDA granted Fast Track status for ALKS 5461 for the adjunctive treatment of MDD in patients with inadequate response to standard antidepressant therapies.

In January 2015, we announced topline results from FORWARD-1, one of a series of supportive clinical studies in the FORWARD phase 3 pivotal program designed to evaluate the safety and tolerability of two titration schedules of ALKS 5461. Data from FORWARD-1 confirmed the safety and tolerability of ALKS 5461 in both titration schedules evaluated—one-week and two-week dose escalation schedules. These findings were consistent with the safety and tolerability profile seen in the phase 2 study of ALKS 5461 completed in 2013. In addition, the exploratory efficacy analyses showed that ALKS 5461 reduced depressive symptoms from baseline in patients who received either of the two titration schedules. These data supported the one-week titration schedule being utilized in the phase 3 efficacy studies in the FORWARD program. In December 2015, we also announced positive topline results from a human abuse potential study of ALKS 5461.

In January 2016, we announced the topline results of FORWARD-3 and FORWARD-4, two phase 3 clinical studies of ALKS 5461 in MDD. Neither of the two studies met the prespecified primary efficacy endpoint, which compared ALKS 5461 to placebo on the change from baseline on the Montgomery—Åsberg Depression Rating Scale (“MADRS”).

FORWARD-4 tested two dose levels of ALKS 5461 (2mg/2mg and 0.5mg/0.5mg) compared to placebo. There was a clear trend toward efficacy with the 2mg/2mg dose of ALKS 5461 on the primary endpoint, and post hoc analyses achieved statistical significance for the entire 2mg/2mg dose group on the MADRS endpoint. Based on these analyses, we believe that FORWARD-4 provides supportive evidence of the efficacy of ALKS 5461 in the treatment of MDD. FORWARD-3 tested ALKS 5461 (2mg/2mg) compared to placebo. Placebo response was greater than that observed in FORWARD-4 and no treatment effect of ALKS 5461 was observed.

FORWARD-5, the third pivotal efficacy study in the FORWARD program, is ongoing, testing two dose levels of ALKS 5461 (2mg/2mg and 1mg/1mg). FORWARD-5 shares common design features with FORWARD-4. Knowledge gained from FORWARD-3 and FORWARD-4 will be used to inform FORWARD-5.

In the case of a clear positive outcome for FORWARD-5, we will consult with the FDA to determine whether the evidence provided by it and the previously completed successful, randomized, placebo-controlled phase 2 study, together with supportive evidence from FORWARD-4, collectively could provide substantial evidence of efficacy for ALKS 5461 for the adjunctive treatment of MDD.

ALKS 3831

ALKS 3831 is a novel, proprietary oral investigational medicine designed as a broad-spectrum antipsychotic for the treatment of schizophrenia. ALKS 3831 is composed of samidorphan in combination with the established antipsychotic drug olanzapine, which is generally available under the name ZYPREXA. ALKS 3831 is designed to

provide the strong efficacy of olanzapine and a differentiated safety profile with favorable weight and metabolic properties and to have utility in the treatment of schizophrenia in patients with co-occurring alcohol use disorder.

In January 2015, we announced data from the first phase of a randomized, dose ranging, six-month phase 2 study of ALKS 3831 designed to assess the efficacy, safety and tolerability of ALKS 3831 in the treatment of schizophrenia and its attenuation of weight gain, compared to olanzapine. ALKS 3831 met the primary endpoint of the study, demonstrating equivalence to olanzapine in reduction from baseline in Positive and Negative Syndrome Scale ("PANSS") total scores at week 12. Results showed that ALKS 3831 also met the secondary endpoint of demonstrating a lower mean percent weight gain compared to olanzapine at week 12 in the full study population, and a lower mean percent weight gain compared to olanzapine at week 12 in a pre-specified subset of patients who gained weight during the one-week olanzapine lead-in.

In April 2015, we announced data from the completed, six-month, randomized, dose-ranging phase 2 study of ALKS 3831. Patients who received ALKS 3831 during the first phase of the study, which lasted for three months, continued to receive the same dose of ALKS 3831, and patients who had received olanzapine during the first phase were switched to ALKS 3831. Data from the completed study supported and extended the initial positive results showing ALKS 3831's favorable efficacy and mean weight gain profile and demonstrated for the first time that switching patients from olanzapine to ALKS 3831 resulted in a cessation of mean weight gain.

In December 2015, we announced the commencement of ENLIGHTEN-1, the first of two planned phase 3 studies from the ENLIGHTEN pivotal program for ALKS 3831. ENLIGHTEN-1 is a multicenter, randomized, double-blind phase 3 study to evaluate the antipsychotic efficacy of ALKS 3831 compared to placebo over four weeks in patients experiencing acute exacerbation of schizophrenia. In February 2016, we announced the initiation of ENLIGHTEN-2, a phase 3 study assessing weight gain with ALKS 3831 compared to olanzapine in patients with schizophrenia over a six month period. The ENLIGHTEN pivotal program will also include supportive studies to evaluate the pharmacokinetic and metabolic profile of ALKS 3831, as well as long-term safety. We expect to use safety and efficacy data from the ENLIGHTEN pivotal program to serve as the basis for a NDA to be submitted to the FDA, pending study results.

ALKS 8700

ALKS 8700 is an oral, novel and proprietary monomethyl fumarate ("MMF") molecule in development for the treatment of MS. ALKS 8700 is designed to rapidly and efficiently convert to MMF in the body and to offer differentiated features as compared to the currently marketed dimethyl fumarate, TECFIDERA. In May 2015, we presented positive results from a phase 1, randomized, double-blind clinical study of ALKS 8700, designed to evaluate the safety, tolerability and single-dose pharmacokinetics of several oral formulations of ALKS 8700 compared to both placebo and active control groups. Data from the study showed that ALKS 8700 provided MMF exposures comparable to TECFIDERA, with less variability and favorable gastrointestinal tolerability. The most common adverse events were flushing and gastrointestinal-related.

Following a meeting with the FDA, we announced in October 2015 our plans to file a 505(b)(2) NDA using pharmacokinetic bridging data from studies comparing ALKS 8700 and TECFIDERA and a two-year, multicenter, open-label study designed to assess the safety of ALKS 8700, which we initiated in December 2015. Additionally, we plan to initiate a randomized, head-to-head phase 3 study of the gastrointestinal tolerability of ALKS 8700 compared to TECFIDERA in mid-2016.

In October 2015, we also announced data from a randomized, double-blind phase 1 comparative pharmacokinetic study evaluating plasma MMF levels achieved by the administration of single doses of ALKS 8700 and TECFIDERA. Initial data from this study showed that ALKS 8700 met the pharmacokinetic criteria for bioequivalence to TECFIDERA. The most common adverse events for ALKS 8700 in the study were flushing, dizziness and constipation. Based on these results, we have selected the ALKS 8700 dose to be used in the registration program. We will need to conduct additional preclinical studies and pharmacokinetic studies to further support pharmacokinetic comparability to TECFIDERA. We expect to complete ALKS 8700 registrational studies and file the NDA in 2018.

ALKS 6428

ALKS 6428 is an oral formulation of naltrexone designed to help physicians transition patients from physical dependence on opioids to antagonist therapy. This transition process includes doses of naltrexone in conjunction with buprenorphine during a seven-day treatment period. Upon successful completion of the transition process, physicians would then be able to administer VIVITROL. In September 2015, we initiated a phase 3 study evaluating the safety, tolerability and efficacy of ALKS 6428 in patients with opioid dependence.

Aripiprazole Lauroxil Two-Month Dose

Aripiprazole lauroxil is an injectable atypical antipsychotic, available as ARISTADA with once-monthly and six-week dosing options for the treatment of schizophrenia, in development with a two-month dosing interval. In February 2016, we announced positive topline results from a randomized, open-label, pharmacokinetic study evaluating a two-month dosing interval of aripiprazole lauroxil extended-release injectable suspension for the treatment of schizophrenia. Based on these phase 1 results, we plan to submit a supplemental New Drug Application ("NDA") to the FDA in the second half of 2016.

ALKS 7119

ALKS 7119 is a novel, proprietary investigational medicine that has a multivalent mechanism of action that acts on key receptors in the brain involved in several CNS diseases, including agitation in Alzheimer's disease, MDD and others. In January 2016, we announced the initiation of a phase 1, double-blind, placebo-controlled study designed to evaluate the safety and tolerability of single ascending doses of ALKS 7119 in healthy subjects. Results from this phase 1 study are expected in the second half of 2016.

RDB 1450

RDB 1450, formerly referred to as RDB 1419, is our selective effector cell activator ("SECA") that is designed to harness a patient's immune system to preferentially activate and increase the number of tumor killing immune cells. SECA proteins selectively target immune cells to avoid expansion of immune regulatory cells which interfere with the anti-tumor response. SECA molecules are engineered using our proprietary fusion protein technology platform to modulate the natural mechanism of action of a biologic product. Based on feedback from the FDA, we now plan to file an Investigational New Drug application with the FDA in the first quarter of 2016 and begin phase 1 clinical trials in the second quarter of 2016.

Product Candidates — Using our Proprietary Technologies

Acorda

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

Janssen

In August 2015, Janssen announced that it submitted an Extension Marketing Authorization Application to the EMA for the three-month formulation of paliperidone palmitate for the treatment of schizophrenia.

AstraZeneca

AstraZeneca is developing line extensions for BYDUREON for the treatment of type 2 diabetes, including weekly suspension formulations using our proprietary technology for extended-release microspheres.

Our Research and Development Expenditures

Please see "Management's Discussion and Analysis of Financial Condition and Results of Operations" for our research and development ("R&D") expenditures for the fiscal years ended December 31, 2015 and 2014 and the nine months ended December 31, 2013.

Collaborative Arrangements

We have entered into several collaborative arrangements to develop and commercialize products and, in so doing, to access technological, financial, marketing, manufacturing and other resources. Refer to the "Patents and Proprietary Rights" section of this Annual Report for information with respect to the intellectual property protection for these products.

Janssen

INVEGA SUSTENNA/XEPLION and INVEGA TRINZA

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 INVEGA TRINZA and related products.

Under our license agreement, we received milestone payments upon the achievement of certain development goals from Janssen; there are no further milestones to be earned under this agreement. We receive tiered royalty payments between 5% and 9% of INVEGA SUSTENNA/XEPLION and INVEGA TRINZA net sales in each country where the license is in effect, with the exact royalty percentage determined based on worldwide net sales. The tiered royalty payments consist of a patent royalty and a know-how royalty, both of which are determined on a county-by-country basis. The patent royalty, which equals 1.5% of net sales, is payable until the expiration of the last of the patents claiming the product in such country. The know-how royalty is a tiered royalty of 3.5%, 5.5% and 7.5% on aggregate worldwide net sales of below $250 million, between $250 million and $500 million, and greater than $500 million, respectively. The know-how royalty is payable for the later of 15 years from first commercial sale of a product in each individual country or March 31, 2019, subject in each case to the expiry of the license agreement. These royalty payments may be reduced in any country based on patent litigation or on competing products achieving certain minimum sales thresholds. The license agreement expires upon the later of (i) March 31, 2019 or (ii) the expiration of the last of the patents subject to the agreement. After expiration, Janssen retains a non-exclusive, royalty-free license to develop, manufacture and commercialize the products.

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

RISPERDAL CONSTA

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

Under license agreements, we granted Janssen and an affiliate of Janssen exclusive worldwide licenses to use and sell RISPERDAL CONSTA. Under our license agreements with Janssen, we receive royalty payments equal to 2.5% of Janssen's net sales of RISPERDAL CONSTA in each country where the license is in effect based on the quarter when the product is sold by Janssen. This royalty may be reduced in any country based on lack of patent coverage and significant competition from generic versions of the product. Janssen can terminate the license agreements upon 30 days' prior written notice to us. Either party may terminate the license agreements by written notice following a breach which continues for 90 days after the delivery of written notice thereof or upon the other party's insolvency. The licenses granted to Janssen expire on a country-by-country basis upon the later of (i) the expiration of the last patent claiming the product in such country or (ii) 15 years after the date of the first commercial sale of the product in such country, provided that in no event will the license granted to Janssen expire later than the twentieth anniversary of the first commercial sale of the product in such country, with the exception of certain countries where the fifteen-year limitation shall pertain regardless. After expiration, Janssen retains a non-exclusive, royalty-free license to manufacture, use and sell RISPERDAL CONSTA.

We exclusively manufacture RISPERDAL CONSTA for commercial sale. Under our manufacturing and supply agreement with Janssen, we record manufacturing revenues when product is shipped to Janssen, based on a

percentage of Janssen's net unit sales price for RISPERDAL CONSTA for the calendar year. This percentage is determined based on Janssen's unit demand for the calendar year and varies based on the volume of units shipped, with a minimum manufacturing fee of 7.5%. The manufacturing and supply agreement terminates on expiration of the license agreements. In addition, either party may terminate the manufacturing and supply agreement upon a material breach by the other party, which is not resolved within 60 days after receipt of a written notice specifying the material breach or upon written notice in the event of the other party's insolvency or bankruptcy. Janssen may terminate the agreement upon six months' written notice to us. In the event that Janssen terminates the manufacturing and supply agreement without terminating the license agreements, the royalty rate payable to us on Janssen's net sales of RISPERDAL CONSTA would increase from 2.5% to 5.0%.

Acorda

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

In June 2009, we entered into an amendment of the amended and restated license agreement and the supply agreement with Acorda and, pursuant to such amendment, consented to the sublicense by Acorda to Biogen of Acorda's rights to use and sell FAMPYRA in certain territories outside of the U.S. (to the extent that such rights were to be sublicensed to Biogen 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.

Acorda has the right to terminate the amended and restated license agreement upon 90 days' written notice. We have the right to terminate the amended and restated license agreement for countries in which Acorda fails to launch a product within a specified time after obtaining the necessary regulatory approval or fails to file regulatory approvals within a commercially reasonable time after completion of, and receipt of positive data from, all preclinical and clinical studies required for filing a marketing authorization application. Either party has the right to terminate the amended and restated license agreement by written notice following a material breach of the other party, which is not cured within a certain time period, or upon the other party's entry into bankruptcy or dissolution proceedings. If we terminate Acorda's license in any country, we are entitled to a license from Acorda of its patent rights and know-how relating to the product as well as the related data, information and regulatory files, and to market the product in the applicable country, subject to an initial payment equal to Acorda's cost of developing such data, information and regulatory files and to ongoing royalty payments to Acorda. Subject to the termination of the amended and restated license agreement, licenses granted under the license agreement terminate on a country-by-country basis on the later of (i) September 26, 2018 or (ii) the expiration of the last to expire of our patents or the existence of a threshold level of competition in the marketplace.

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

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

- initiation of a phase 3 clinical trial: $1.0 million;
- acceptance of an NDA by the FDA: $1.0 million;
- approval of the NDA by the FDA: $1.5 million; and

- the first commercial sale: $1.5 million.

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

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

AstraZeneca

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

Pursuant to the development and license agreement, AstraZeneca has an exclusive, worldwide license to our polymer-based microsphere technology for the development and commercialization of injectable extended-release formulations of exendins and other related compounds. We receive funding for research and development and will also receive royalty payments based on future product sales. Upon the achievement of certain development and commercialization goals, we received milestone payments consisting of cash and warrants for Amylin common stock; there are no further milestones to be earned under the agreement. In October 2005 and in July 2006, we amended the development and license agreement. Under the amended development and license agreement (i) we are responsible for formulation and are principally responsible for non-clinical development of any products that may be developed pursuant to the agreement and for manufacturing these products for use in early-phase clinical trials, and (ii) we transferred certain of our technology related to the manufacture of BYDUREON to Amylin and agreed to the manufacture of BYDUREON by Amylin. Under our amended development and license agreement, AstraZeneca is responsible for conducting clinical trials, securing regulatory approvals and commercializing exenatide products, including BYDUREON, on a worldwide basis.

Until December 31, 2021, we will receive royalties equal to 8% of net sales from the first 40 million units of BYDUREON sold in any particular calendar year and 5.5% of net sales from units sold beyond the first 40 million units for that calendar year. Thereafter, during the term of the development and license agreement, we will receive royalties equal to 5.5% of net sales of products sold. We were entitled to, and received, milestone payments related to the first commercial sale of BYDUREON in the EU and the first commercial sale of BYDUREON in the U.S.

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

terminate the development and license agreement for any reason upon 180 days' written notice to us. In addition, either party may terminate the development and license agreement upon a material default or breach by the other party that is not cured within 60 days after receipt of written notice specifying the default or breach. Alkermes may terminate the development and license agreement upon AstraZeneca's insolvency or bankruptcy.

Other Arrangements

Civitas Therapeutics, Inc.

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

We may terminate the asset purchase and license agreement for default in the event Civitas does not meet certain minimum development performance obligations. Either party may terminate the asset purchase and license agreement upon a material default or breach by the other party that is not cured within 45 days after receipt of written notice specifying the default or breach. Either party may also terminate the asset purchase and license agreement upon written notice in the event of the other party's insolvency or bankruptcy.

In October 2014, Civitas was acquired by Acorda for approximately $525.0 million, of which we received $29.6 million in exchange for our approximate 6% interest in Civitas. Also, in connection with Acorda's purchase of Civitas, we sold certain of our pulmonary manufacturing equipment to Acorda in exchange for $30.0 million. In November 2015, we assigned the lease to our pulmonary manufacturing facility located in Chelsea, Massachusetts to Civitas and terminated the sublease with Civitas related to this facility.

Recro Pharma, Inc.

On April 10, 2015, we completed the sale of our manufacturing facility in Gainesville, GA, the manufacturing and royalty revenue associated with products manufactured at that facility, and global rights to IV/IM and parenteral forms of Meloxicam (the "Disposition" or "Gainesville Transaction") to Recro Pharma, Inc., a Pennsylvania corporation listed on Nasdaq ("Recro") and Recro Pharma LLC (the "Acquisition Sub" and together with Recro, the "Purchasers") pursuant to a Purchase and Sale Agreement (the "Purchase Agreement") entered into on March 7, 2015 among us, Daravita Limited (an indirect wholly-owned subsidiary of the Company), and the Purchasers.

In accordance with the terms of the Purchase Agreement, at the closing of the Disposition, the Purchasers made an initial cash payment to us of $50 million, a $4 million payment relating to the net working capital, and issued us a seven-year warrant to purchase an aggregate of 350,000 shares of Recro common stock at a per share exercise price equal to $19.46, two times the closing price of Recro's common stock on the day prior to closing. We are also eligible to receive low double digit royalties on net sales of IV/IM and parenteral forms of Meloxicam and up to $120 million in milestone payments upon the achievement of certain regulatory and sales milestones related to IV/IM and parenteral forms of Meloxicam.

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 microsphere technology allows us to encapsulate small-molecule pharmaceuticals, peptides and proteins, in microspheres made of common medical polymers. The technology is

designed to enable novel formulations of pharmaceuticals by providing controlled, extended release of drugs over time. Drug release from the microsphere is controlled by diffusion of the drug through the microsphere and by biodegradation of the polymer. These processes can be modulated through a number of formulation and fabrication variables, including drug substance and microsphere particle sizing and choice of polymers and excipients.

LinkeRx Technology

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

NanoCrystal Technology

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

Oral Controlled Release Technology

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

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

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

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

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

Manufacturing and Product Supply

We own and occupy a R&D and manufacturing facility in Athlone, Ireland and a manufacturing facility in Wilmington, Ohio. We either purchase active drug product from third parties or receive it from our third-party licensees to formulate product using our technologies. The manufacture of our products for clinical trials and commercial use is subject to Current Good Manufacturing Practice ("cGMP") regulations and other regulatory agency regulations. Our manufacturing and development capabilities include formulation through process development, scale-up and full-scale commercial manufacturing and specialized capabilities for the development and manufacturing of controlled substances.

Although some materials for our products are currently available from a single source or a limited number of

qualified sources, we attempt to acquire an adequate inventory of such materials, establish alternative sources and/or negotiate long-term supply arrangements. We believe we do not have any significant issues in finding suppliers. However, we cannot be certain that we will continue to be able to obtain long-term supplies of our manufacturing materials.

Our third-party service providers involved in the manufacture of our products are subject to inspection by the FDA or comparable agencies in other jurisdictions. Any delay, interruption or other issues that arise in the acquisition of active pharmaceutical ingredients ("API"), manufacture, fill-finish, packaging, or storage of our marketed products or product candidates, including as a result of a failure of our facilities or the facilities or operations of third parties to pass any regulatory agency inspection, could significantly impair our ability to sell our products or advance our development efforts, as the case may be. For information about risks relating to the manufacture of our marketed products and product candidates, see "Item 1A—Risk Factors" and specifically those sections entitled "—We rely on third parties to provide services in connection with the manufacture and distribution of our products" and "—We are subject to risks related to the manufacture of our products."

Proprietary Products and Products using our Proprietary Technologies

We manufacture microspheres for RISPERDAL CONSTA and VIVITROL, polymer for BYDUREON, and ARISTADA in our Wilmington, Ohio facility. We are currently operating two RISPERDAL CONSTA lines, one VIVITROL line and one ARISTADA 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 and ARISTADA to a third-party contractor. Janssen is responsible for packaging operations for RISPERDAL CONSTA. Our Wilmington, Ohio facility has been inspected by U.S., European including the Medicines and Healthcare Products Regulatory Agency, Chinese, Japanese, Brazilian and Saudi Arabian regulatory authorities for compliance with required cGMP standards for continued commercial manufacturing.

We manufacture AMPYRA/FAMPYRA and other products in our Athlone, Ireland facility. This facility has been inspected by U.S., Irish, Brazilian, Turkish, Saudi Arabian, Korean and Belarusian 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 injectable extended-release products at our Wilmington, Ohio facility and NanoCrystal and OCR technology products at our Athlone, Ireland facility. We have also contracted with third-party manufacturers to formulate certain products for clinical use. We require that our contract manufacturers adhere to cGMP in the manufacture of products for clinical use.

Research & Development

We devote significant resources to R&D programs. We focus our R&D efforts on finding novel therapeutics in areas of high unmet medical need. Our R&D efforts include, but are not limited to, areas such as pharmaceutical formulation, analytical chemistry, process development, engineering, scale-up and drug optimization/delivery. Please see "Management's Discussion and Analysis of Financial Condition and Results of Operations" for our R&D expenditures for our years ended December 31, 2015 and 2014 and the nine months ended December 31, 2013.

Permits and Regulatory Approvals

We hold various licenses in respect of our manufacturing activities conducted in Wilmington, Ohio and Athlone, Ireland. The primary licenses held in this regard are FDA Registrations of Drug Establishment; and Drug Enforcement Administration of the U.S. Department of Justice ("DEA"). We also hold a Manufacturers Authorization (No. M1067), an Investigational Medicinal Products Manufacturers Authorization (No. IMP074) and Certificates of Good Manufacturing Practice Compliance of a Manufacturer (Ref. 2014/7828/IMP074 and 2014/7828/M1067) from the Health Products Regulatory Authority ("HPRA") in respect of our Athlone, Ireland facility, and a number of Controlled

Substance Licenses granted by the HPRA. Due to certain U.S. state law requirements, we also hold certain state licenses to cover distribution activities through certain states and not in respect of any manufacturing activities conducted in those states.

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

Marketing, Sales and Distribution

We are responsible for the marketing of VIVITROL and ARISTADA in the U.S. We focus our sales and marketing efforts on specialist physicians in private practice and in public treatment systems. We use customary pharmaceutical company practices to market our product and to educate physicians, such as sales representatives calling on individual physicians, advertisements, professional symposia, selling initiatives, public relations and other methods. We provide, or contract with third-party vendors to provide, customer service and other related programs for our products, such as product-specific websites, insurance research services and order, delivery and fulfillment services.

Our sales force for VIVITROL in the U.S. consists of approximately 70 individuals. VIVITROL is sold directly to pharmaceutical wholesalers, specialty pharmacies and a specialty distributor. Product sales of VIVITROL during the year ended December 31, 2015 to McKesson Corporation, CVS Caremark Corporation and Cardinal Health represented approximately 17%, 15% and 10%, respectively, of total VIVITROL sales.

Our sales force for ARISTADA in the U.S. consists of approximately 200 individuals. ARISTADA is primarily sold to pharmaceutical wholesalers.

ICS AmerisourceBergen, a division of AmerisourceBergen Corporation, provides warehousing, shipping and administrative services for VIVITROL and ARISTADA.

Under our license agreements with Janssen, AstraZeneca, Acorda and other licensees and sublicensees, 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 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 licensees, who control the commercialization of products from which we receive manufacturing and royalty revenues. These competitors are working to develop and market other systems, products and other methods of preventing or reducing disease, and new small-molecule and other classes of drugs that can be used with or without a drug delivery system.

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

There are other companies developing extended-release product platforms. In many cases, there are products on the market or in development that may be in direct competition with our products. In addition, we know of new chemical entities that are being developed that, if successful, could compete against our products. These chemical entities are being designed to work differently than our products and may turn out to be safer or to be more effective than our

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

With respect to our proprietary injectable product platform, we are aware that there are other companies developing extended-release delivery systems for pharmaceutical products. In the treatment of schizophrenia, ARISTADA, INVEGA SUSTENNA/XEPLION and INVEGA TRINZA and RISPERDAL CONSTA compete with each other and a number of other injectable products including ZYPREXA RELPREVV ((olanzapine) For Extended Release Injectable Suspension), which is marketed and sold by Lilly; ABILIFY MAINTENA, (aripiprazole for extended release injectable suspension), a once-monthly injectable formulation of ABILIFY (aripiprazole) developed by Otsuka Pharmaceutical Co., Ltd. ("Otsuka Pharm. Co."); oral compounds currently on the market; and generic versions of branded oral and injectable products. In the treatment of bipolar disorder, RISPERDAL CONSTA competes with antipsychotics such as ABILIFY, LATUDA, risperidone, olanzapine, ziprasidone and clozapine.

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

In the treatment of opioid dependence, VIVITROL competes with methadone, oral naltrexone, SUBOXONE (buprenorphine HCl/naloxone HCl dehydrate sublingual tablets), SUBOXONE (buprenorphine/naloxone) Sublingual Film, and SUBUTEX (buprenorphine HCl sublingual tablets), each of which is marketed and sold by Indivior plc, and BUNAVAIL buccal film (buprenorphine and naloxone) marketed by BioDelivery Sciences, and ZUBSOLV (buprenorphine and naloxone) marketed by Orexo US, Inc. It also competes with generic versions of SUBUTEX and SUBOXONE sublingual tablets. Other pharmaceutical companies are developing products that have shown promise in treating opioid dependence that, if approved by the FDA, would compete with VIVITROL.

BYDUREON competes with established diabetes 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 and TRULICITY ((dulaglutide) injection), which is marketed and sold by Lilly. Other pharmaceutical companies are developing product candidates for the treatment of type 2 diabetes that, if approved by the FDA, would compete with BYDUREON.

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

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

Patents and Proprietary Rights

Our success will be dependent, in part, on our ability to obtain and maintain patent protection for our products, including those marketed and sold by our licensees, to maintain trade secret protection and to operate without infringing upon the proprietary rights of others. We have a proprietary portfolio of patent rights and exclusive licenses to patents

and patent applications. In addition, our licensees may own issued patents that cover certain of our products. We have filed numerous patent applications in the U.S. and in other countries directed to compositions of matter as well as processes of preparation and methods of use, including patent applications relating to each of our delivery technologies. As of December 31, 2015, we owned more than 200 issued U.S. patents. In the future, we plan to file additional patent applications in the U.S. and in other countries directed to new or improved products and processes, and we intend to vigorously defend our patent positions.

ARISTADA

We have several U.S. patents and patent applications, and a number of corresponding foreign counterparts, related to ARISTADA. Our principal U.S. patents and expiration dates are:

- U.S. Patent No. 8,431,576, having claims to a class of compounds that includes aripiprazole lauroxil, expiring in 2030;
- U.S. Patent No. 8,796,276, having claims to methods of treating schizophrenia using a class of compounds that includes aripiprazole lauroxil, expiring in 2030;
- U.S. Patent No. 9,034,867, having claims to pharmaceutical compositions, expiring in 2032; and
- U.S. Patent No. 9,193,685, having claims to pharmaceutical compositions that confer long-term stability, expiring in 2033.

In addition to patent protection, in the U.S. ARISTADA is entitled to regulatory exclusivity afforded to new chemical entities until 2020.

VIVITROL, RISPERDAL CONSTA and BYDUREON

We have filed patent applications worldwide that cover our microsphere technology and have a significant number of patents and certain pending patent applications covering our microsphere technology, which, to some extent, cover VIVITROL, RISPERDAL CONSTA and BYDUREON. 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 the EU, respectively, and we own 20, 7, and 10 Orange-Book listed U.S. patents covering VIVITROL, RISPERDAL CONSTA and BYDUREON, respectively.

INVEGA SUSTENNA/XEPLION and INVEGA TRINZA

Our NanoCrystal technology patent portfolio contains a number of patents granted throughout the world, including the U.S. and countries outside of the U.S. We also have a number of pending patent applications covering our NanoCrystal technology which, to some extent, cover INVEGA SUSTENNA/XEPLION and INVEGA TRINZA. The latest of the patents covering INVEGA SUSTENNA/XEPLION expire in May 2019 in the U.S. and 2022 in the EU. The latest of the patents covering INVEGA TRINZA expire in November 2017 in the U.S. and 2022 in the EU. Additional pending applications may provide a longer period of patent coverage, if granted, and in certain countries, such as Australia and South Korea, patent coverage extends until 2023.

AMPYRA/FAMPYRA

Our OCR technology is protected by a patent estate including patents and patent applications filed worldwide. Some OCR patent families are product-specific (including some which are owned by our licensees), whereas others cover generic delivery platforms (e.g. different release profiles, taste masking). AMPYRA/FAMPYRA incorporates our OCR technology, and the latest of the patents covering AMPYRA/FAMPYRA expires in May 2027 in the U.S. and April 2025 in the EU. For a discussion of legal proceedings related to the patents covering AMPYRA, see “Item 3—Legal Proceedings.”

ALKS 5461, ALKS 3831 and ALKS 7119

We also have worldwide patent protection for our Key Development Programs. We own U.S. patents that cover a class of compounds that includes the opioid modulators in each of ALKS 5461, ALKS 3831 and ALKS 7119 and granted method of treatment claims that will cover ALKS 5461. Our principal U.S. patents and expiration dates for ALKS 5461, ALKS 3831, and ALKS 7119 are:

U.S. Patent No.	Product Candidate(s) Covered	Expiration Date
7,956,187	ALKS 5461 ALKS 3831 ALKS 7119	2021
8,252,929	ALKS 5461 ALKS 3831	2021
7,262,298	ALKS 5461 ALKS 3831	2025
8,680,112	ALKS 5461 ALKS 3831	2029
9,119,848	ALKS 5461 ALKS 3831	2031
9,126,977	ALKS 3831	2031
8,778,960	ALKS 3831	2032
9,211,293	ALKS 5461	2032
8,822,488	ALKS 5461	2032

ALKS 8700

We have U.S. patents and patent applications, and a number of corresponding foreign counterparts, related to ALKS 8700. Our U.S. patents and expiration dates for ALKS 8700 are:

- U.S. Patent No. 8,669,281, having claims to a composition of matter that covers ALKS 8700, expiring in 2033; and
- U.S. Patent No. 9,090,558, having claims to methods of treating MS, expiring in 2033.

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

We know of several U.S. patents issued to other parties that may relate to our products. The manufacture, use, offer for sale, sale or import of some of our products 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 products 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 licensees may not be able to manufacture, use, offer for sale, sell or import some of our products without first getting a license from the patent holder. The patent holder may not grant us a license on reasonable terms, or it may refuse to grant us a license at all. This could delay or prevent us from developing, manufacturing, selling or importing those of our products that would require the license.

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

We 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, 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. If any trade secret, know-how or other technology not protected by a patent were to be disclosed to, or independently developed by, a competitor, such event could materially adversely affect our business, results of operations, cash flows and financial condition. For more information, see "Item 1A—Risk Factors."

Our trademarks, including VIVITROL and ARISTADA, 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. Products using our proprietary technologies also use trademarks that are owned by our licensees, such as the marks INVEGA SUSTENNA, INVEGA TRINZA and RISPERDAL CONSTA, which are registered trademarks of Johnson & Johnson, BYDUREON, which is a registered trademark of Amylin, and AMPYRA and FAMPYRA, which are registered trademarks of Acorda. Trademark protection varies in accordance with local law, and continues in some countries as long as the mark is used and in other countries as long as the mark is registered. Trademark registrations generally are for fixed but renewable terms.

Revenues and Assets by Region

For the fiscal years ended December 31, 2015 and 2014 and the nine months ended December 31, 2013, our revenue and assets are presented below by geographic area:

(In thousands)	Year Ended December 31, 2015	Year Ended December 31, 2014	Nine Months Ended December 31, 2013
Revenue by region:			
U.S.	$ 448,639	$ 398,189	$ 269,005
Ireland	3,902	7,691	5,722
Rest of world	175,794	212,909	158,184
Assets by region:			
Current assets:			
U.S.	$ 360,154	$ 385,715	$ 382,571
Ireland	394,281	490,577	187,023
Rest of world	527	501	544
Long-term assets:			
U.S.:			
Intangible assets	$ —	$ —	$ —
Goodwill	—	3,677	3,677
Other	294,158	226,479	222,818
Ireland:			
Intangible assets	$ 379,186	$ 479,412	$ 537,565
Goodwill	92,873	90,535	89,063
Other	334,565	242,162	151,586

Regulatory

Regulation of Pharmaceutical Products

United States

Our current and contemplated activities, and the products and processes that result from such activities, are subject to substantial government regulation. Before new pharmaceutical products may be sold in the U.S., pre-clinical studies and clinical trials of the products must be conducted and the results submitted to the FDA for approval. Clinical trial programs must determine an appropriate dose and regimen, establish substantial evidence of effectiveness and define the conditions for safe use. This is a high-risk process that requires stepwise clinical studies in which the product candidate must successfully meet pre-specified endpoints.

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

organism, laboratory evaluation and characterization of the safety and efficacy of a drug and its formulation.

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

Clinical Trials: Clinical trials involve the administration of the drug to healthy human volunteers or to patients under the supervision of a qualified investigator pursuant to an FDA-reviewed protocol. Human clinical trials are typically conducted in three sequential phases, although the phases may overlap with one another and, depending upon the nature of the clinical program, a specific phase or phases may be skipped altogether. Clinical trials must be conducted under protocols that detail the objectives of the study, the parameters to be used to monitor safety, and the efficacy criteria, if any, to be evaluated. Each protocol must be submitted to the FDA as part of the IND.

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

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

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

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

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

For example, in October 2013, the FDA granted Fast Track status for ALKS 5461 for the adjunctive treatment of MDD in patients with inadequate response to standard antidepressant therapies. Fast Track is a process designed to expedite the review of such products by providing, among other things, more frequent meetings with the FDA to discuss the product's development plan, more frequent written correspondence from the FDA about trial design, eligibility for accelerated approval, and rolling review, which allows submission of individually completed sections of a NDA or BLA for FDA review before the entire filing is completed. Fast Track status does not ensure that a product will be developed more quickly or receive FDA approval.

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

educate health care providers of the drug's risks, limitations on who may prescribe or dispense the drug, or other measures that the FDA deems necessary to assure the safe use of the drug.

In reviewing a BLA or NDA, the FDA may grant marketing approval, or issue a complete response letter to communicate to the applicant the reasons the application cannot be approved in the current form and provide input on the changes that must be made before an application can be approved. Even if such additional information and data are submitted, the FDA may ultimately decide that the BLA or NDA does not satisfy the criteria for approval. The receipt of regulatory approval often takes a number of years, involves the expenditure of substantial resources and depends on a number of factors, including the severity of the disease in question, the availability of alternative treatments, potential safety signals observed in pre-clinical or clinical tests, and the risks and benefits demonstrated in clinical trials. It is impossible to predict with any certainty whether and when the FDA will grant marketing approval. Even if a product is approved, the approval may be subject to limitations based on the FDA's interpretation of the data. For example, the FDA may require, as a condition of approval, restricted distribution and use, enhanced labeling, special packaging or labeling, expedited reporting of certain adverse events, pre-approval of promotional materials or restrictions on direct-to-consumer advertising, any of which could negatively impact the commercial success of a drug. The FDA may require a sponsor to conduct additional post-marketing studies as a condition of approval to provide data on safety and effectiveness. In addition, prior to commercialization, controlled substances are subject to review and potential scheduling by the DEA.

The FDA tracks information on side effects and adverse events reported during clinical studies and after marketing approval. Non-compliance with safety reporting requirements may result in civil or criminal penalties. Side effects or adverse events that are identified during clinical trials can delay, impede or prevent marketing approval. Based on new safety information that emerges after approval, the FDA can mandate product labeling changes, impose a new REMS or the addition of elements to an existing REMS, require new post-marketing studies (including additional clinical trials), or suspend or withdraw approval of the product.

If we seek to make certain types of changes to an approved product, such as adding a new indication, making certain manufacturing changes, or changing manufacturers or suppliers of certain ingredients or components, the FDA will need to review and approve such changes in advance. In the case of a new indication, we are required to demonstrate with additional clinical data that the product is safe and effective for the new intended use. Such regulatory reviews can result in denial or modification of the planned changes, or requirements to conduct additional tests or evaluations that can substantially delay or increase the cost of the planned changes.

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

Controlled Substances Act: The DEA regulates pharmaceutical products that are controlled substances. Controlled substances are those drugs that appear on one of the five schedules promulgated and administered by the DEA under the Controlled Substances Act (the "CSA"). The CSA governs, among other things, the inventory, distribution, recordkeeping, handling, security and disposal of controlled substances. Pharmaceutical products that act on the CNS are often evaluated for abuse potential; a product that is then classified as controlled substance must undergo scheduling by the DEA, which is a separate process that may delay the commercial launch of a pharmaceutical product even after FDA approval of the NDA. Companies with a scheduled pharmaceutical product are subject to periodic and ongoing inspections by the DEA and similar state drug enforcement authorities to assess ongoing compliance with the DEA's regulations. Any failure to comply with these regulations could lead to a variety of sanctions, including the revocation, or a denial of renewal, of any DEA registration and injunctions, or civil or criminal penalties.

Outside the United States

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

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

Good Manufacturing Processes

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

Good Clinical Practices

The FDA, the EMA and other regulatory agencies promulgate regulations and standards, commonly referred to as Good Clinical Practices ("GCP"), for designing, conducting, monitoring, auditing and reporting the results of clinical trials to ensure that the data and results are accurate and that the trial participants are adequately protected. The FDA, the EMA and other regulatory agencies enforce GCP through periodic inspections of trial sponsors, principal investigators, trial sites, contract research organizations ("CROs") and institutional review boards. If our studies fail to comply with applicable GCP, the clinical data generated in our clinical trials may be deemed unreliable, and relevant regulatory agencies may require us to perform additional clinical trials before approving our marketing applications. Noncompliance can also result in civil or criminal sanctions. We rely on third parties, including CROs, to carry out many of our clinical trial-related activities. Failure of such third parties 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 an NDA for a product that contains an active ingredient, known as the active drug moiety, not found in any other approved product. The FDA is prohibited from accepting any abbreviated NDA ("ANDA") for a generic drug or 505(b)(2) application for five years from the date of approval of the NCE, or four years in the case of an ANDA or 505(b)(2) application containing a patent challenge. A 505(b)(2) application is an NDA wherein the applicant relies, in part, on data and the FDA's findings of safety and efficacy

from studies not conducted by or for it and for which the applicant has not obtained a right of reference. This exclusivity will not prevent the submission or approval of a full NDA (e.g., under 505(b)(1)), as opposed to an ANDA or 505(b)(2) application, for any drug, including, for example, a drug with the same active ingredient, dosage form, route of administration, strength and conditions of use.

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

The Hatch-Waxman Act requires NDA applicants and NDA holders to provide certain information about patents related to the drug for listing in the FDA's Approved Drugs Product List, commonly referred to as the Orange Book. ANDA and 505(b)(2) applicants must then certify regarding each of the patents listed with the FDA for the reference product. A certification that a listed patent is invalid or will not be infringed by the marketing of the applicant's product is called a "Paragraph IV certification." If the ANDA or 505(b)(2) applicant provides such a notification of patent invalidity or noninfringement, then the FDA may accept the ANDA or 505(b)(2) application four years after approval of the NDA for an NCE. If a Paragraph IV certification is filed and the ANDA or 505(b)(2) application has been accepted as a reviewable filing by the FDA, the ANDA or 505(b)(2) applicant must then, within 20 days, provide notice to the NDA holder and patent owner stating that the application has been submitted and providing the factual and legal basis for the applicant's opinion that the patent is invalid or not infringed. The NDA holder or patent owner may file suit against the ANDA or 505(b)(2) applicant for patent infringement. If this is done within 45 days of receiving notice of the Paragraph IV certification, a one-time, 30-month stay of the FDA's ability to approve the ANDA or 505(b)(2) application is triggered. The 30-month stay begins at the end of the NDA holder's data exclusivity period, or, if data exclusivity has expired, on the date that the patent holder is notified. The FDA may approve the proposed product before the expiration of the 30-month stay if a court finds the patent invalid or not infringed, or if the court shortens the period because the parties have failed to cooperate in expediting the litigation.

Sales and Marketing

We are subject to various U.S. federal and state laws pertaining to healthcare fraud and abuse, including anti-kickback laws and false claims laws. Anti-kickback laws make it illegal for a prescription drug manufacturer to solicit, offer, receive, or pay any remuneration in exchange for, or to induce, the referral of business, including the purchase or prescription of a particular drug. Due to the broad scope of the U.S. statutory provisions, the general absence of guidance in the form of regulations, and few court decisions addressing industry practices, it is possible that our practices might be challenged under anti-kickback or similar laws. False claims laws prohibit anyone from knowingly and willingly presenting, or causing to be presented, for payment to third-party payers (including Medicare and Medicaid) claims for reimbursed drugs or services that are false or fraudulent, claims for items or services not provided as claimed or claims for medically unnecessary items or services. Activities relating to the sale and marketing of our products may be subject to scrutiny under these laws. Violations of fraud and abuse laws may be punishable by criminal and/or civil sanctions, including fines and civil monetary penalties, as well as the possibility of exclusion from federal healthcare programs (including Medicare and Medicaid). In addition, federal and state authorities are paying increased attention to enforcement of these laws within the pharmaceutical industry and private individuals have been active in alleging violations of the laws and bringing suits on behalf of the government under the federal civil False Claims Act. If we were subject to allegations concerning, or were convicted of violating, these laws, our business could be harmed. See "Item 1A—Risk Factors" and specifically those sections entitled "—If we fail to comply with the extensive legal and regulatory requirements affecting the healthcare industry, we could face increased costs, penalties and a loss of business," "—Revenues generated by sales of our products depend on the availability of reimbursement from third-party payers, and a reduction in payment rate or reimbursement or an increase in our financial obligation to governmental payers could result in decreased sales of our products and decreased revenues" and "—The commercial use of our products may cause unintended side effects or adverse reactions, or incidents of misuse may occur, which could adversely affect our business and share price."

Laws and regulations have been enacted by the federal government and various states to regulate the sales and

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

Pricing and Reimbursement

United States

In the U.S., sales of our products, including those sold by our licensees, and our ability to generate revenues on such sales are dependent, in significant part, on the availability and level of reimbursement from third-party payers such as state and federal governments, including Medicare and Medicaid, managed care providers and private insurance plans. Third-party payers are increasingly challenging the prices charged for medical products and examining the medical necessity and cost-effectiveness of medical products, in addition to their safety and efficacy.

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

Medicare is a federal program that is administered by the federal government that covers individuals age 65 and over as well as those with certain disabilities. Medicare Part B pays physicians who administer our products under a payment methodology using average sales price ("ASP") information. Manufacturers, including us, are required to provide ASP information to the CMS on a quarterly basis. This information is used to compute Medicare payment rates, with rates for Medicare Part B drugs outside the hospital outpatient setting and in the hospital outpatient setting consisting of ASP plus a specified percentage. These rates are adjusted periodically. If a manufacturer is found to have made a misrepresentation in the reporting of ASP, the statute provides for civil monetary penalties for each misrepresentation for each day in which the misrepresentation was applied.

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

The availability of federal funds to pay for our products under the Medicaid Drug Rebate Program and

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

We also make our products available for purchase by authorized users of the Federal Supply Schedule ("FSS") of the General Services Administration pursuant to our FSS contract with the Department of Veterans Affairs. Under the Veterans Health Care Act of 1992 (the "VHC Act"), we are required to offer deeply discounted FSS contract pricing to four federal agencies: the Department of Veterans Affairs; the Department of Defense; the Coast Guard; and the PHS (including the Indian Health Service), in order for federal funding to be made available for reimbursement of any of our products by such federal agencies and certain federal grantees. Coverage under Medicaid, the Medicare Part B program and the PHS pharmaceutical pricing program is also conditioned upon FSS participation. FSS pricing is negotiated periodically with the Department of Veterans Affairs. FSS pricing is intended not to exceed the price that we charge our most-favored non-federal customer for a product. In addition, prices for drugs purchased by the Department of Veterans Affairs, Department of Defense (including drugs purchased by military personnel and dependents through the TriCare retail pharmacy program), Coast Guard and PHS are subject to a cap on pricing equal to 76% of the non-federal average 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.

In addition, on January 21, 2016, CMS released the final Medicaid covered outpatient drug regulation, which will be effective April 1, 2016. This regulation implements those changes made by the Affordable Care Act to the Medicaid drug rebate statute in 2010 and addresses a number of other issues with respect to the Medicaid program, including, but not limited to, the eligibility and calculation methodologies for AMP and best price, and the expansion of Medicaid rebate liability to include Medicaid managed care organizations.

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

Outside the United States

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

Other Regulations

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

records that accurately and fairly reflect their transactions and to devise and maintain an adequate system of internal accounting controls.

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

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

Other Laws: We are subject to a variety of financial disclosure, securities trading regulations and governmental regulations as an Irish-incorporated public company in the U.S., including laws relating to the oversight activities of the Securities and Exchange Commission ("SEC"), the Irish Companies Act 2014, and the regulations of the NASDAQ, on which our shares are traded. We are also subject to various laws, regulations and recommendations relating to safe working conditions, laboratory practices, the experimental use of animals, and the purchase, storage, movement, import and export and use and disposal of hazardous or potentially hazardous substances used in connection with our research work.

Employees

As of February 12, 2016, we had approximately 1,500 full-time employees. A significant number of our management and professional employees have prior experience with pharmaceutical, biotechnology or medical product companies. We believe that we have been successful in attracting skilled and experienced scientific and senior management personnel; however, competition for such personnel is intense. None of our employees is covered by a collective bargaining agreement. We consider our relations with our employees to be good.

Available Information

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

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

Our principal executive offices are located at Connaught House, 1 Burlington Road, Dublin 4, Ireland. Our telephone number is +353-1-772-8000 and our website address is www.alkermes.com. 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.

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

Investing in our company involves a high degree of risk. In deciding whether to invest in our ordinary shares, you should consider carefully the risks described below in addition to the financial and other information contained in this Annual Report, including the matters addressed under the caption "Cautionary Note Concerning Forward-Looking Statements" above. If any events described by the following risks actually occur, they could materially adversely affect our business, financial condition, cash flows or operating results. This could cause the market price of our ordinary shares to decline, and could cause you to lose all or a part of your investment. Except as otherwise suggested by the context, references to "products" or "our products" include our marketed products, marketed products using our proprietary technologies, product candidates and product candidates using our proprietary technologies.

We rely heavily on our licensees in the commercialization and continued development of products from which we receive revenue; and if our licensees are not effective, our revenues could be materially adversely affected.

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

The revenues that we receive from manufacturing fees and royalties depend primarily upon the success of our licensees, and particularly Janssen, Acorda, Biogen, and AstraZeneca, in commercializing products from which we receive revenue. Janssen is responsible for the commercialization of RISPERDAL CONSTA, INVEGA SUSTENNA/XEPLION, and INVEGA TRINZA, and VIVITROL in Russia and the CIS. Acorda and Biogen are responsible for commercializing AMPYRA/FAMPYRA. AstraZeneca is responsible for commercializing BYDUREON. We have no involvement in the commercialization efforts for such products. Our revenues may fall below our expectations, the expectations of our partners or those of investors, which could have a material adverse effect on our results of operations and the price of our ordinary shares. Such revenues will depend on numerous factors, many of which are outside our control.

Our licensees may also choose to use their own or other technology to develop an alternative product and withdraw their support of our product, or to compete with our jointly developed product. In addition, a proprietary product we have developed competes directly with products we developed with our licensees from which we receive revenue. Disputes may also arise between us and a licensee and may involve the ownership of technology developed under a license or other issues arising out of collaborative agreements. Such a dispute could delay the related program or result in expensive arbitration or litigation, which may not be resolved in our favor.

In addition, most of our licensees can terminate their agreements with us without cause, and we cannot guarantee that any of these relationships will continue. Failure to make or maintain these arrangements or a delay in, or failure of, a licensee'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.

We receive substantial revenues from certain products.

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

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

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

- perception of physicians and other members of the healthcare community as to our products' safety and efficacy relative to that of competing products;

- the cost-effectiveness of our products;
- patient and physician satisfaction with our products;
- the successful manufacture of our products on a timely basis;
- the cost and availability of raw materials necessary for the manufacture of our products;
- the size of the markets for our products;
- reimbursement policies of government and third-party payers;
- unfavorable publicity concerning our products, similar classes of drugs or the industry generally;
- the introduction, availability and acceptance of competing treatments, including treatments marketed and sold by our licensees;
- the reaction of companies that market competitive products;
- adverse event information relating to our products or to similar classes of drugs;
- changes to the product labels of our products, or of products within the same drug classes, to add significant warnings or restrictions on use;
- our continued ability to access third parties to vial, package and/or distribute our products on acceptable terms;
- the unfavorable outcome of litigation, including so-called "Paragraph IV" litigation and other patent litigation, related to any of our products;
- regulatory developments related to the manufacture or continued use of our products, including the issuance of a REMS by the FDA;
- the extent and effectiveness of the sales and marketing and distribution support our products receive, including from our licensees;
- our licensees' decisions as to the timing of product launches, pricing and discounting;
- disputes with our licensees relating to the marketing and sale of products from which we receive revenue;
- 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 licensees' orders, the timing of shipments, and our ability to manufacture products successfully, including our yield and our production schedule. The unit costs to manufacture our products may be higher than anticipated if certain volume levels are not achieved. In addition, we may not be able to supply the products in a timely manner or at all.

We have limited experience in the commercialization of products.

VIVITROL is the first commercial product for which we have had sole responsibility for commercialization in the U.S., including sales, marketing, distribution and reimbursement-related activities. In October 2015, ARISTADA was approved by the FDA and commercially launched by us. ARISTADA is the second commercial product that we developed, manufacture, and are currently commercializing and is the newest entrant into a highly competitive marketplace for the treatment of schizophrenia.

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, to secure reimbursement for our products 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 our sales efforts are not effective or if the costs of developing sales and marketing capabilities exceed their cost-effectiveness, we may not be able to successfully commercialize VIVITROL and ARISTADA and such events could materially adversely affect our business, financial condition, cash flows and results of operations.

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

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

able to resolve any such problems in a timely fashion, if at all.

We rely solely on our manufacturing facility in Wilmington, Ohio for the manufacture of RISPERDAL CONSTA, VIVITROL, ARISTADA, 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.

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 products, or suspension of the sale of our products, 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 licensees, 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, storage and product distribution services, customer service activities and product returns processing. These third parties must comply with federal, state and local regulations applicable to their business, including FDA and, as applicable, DEA regulations. Although we actively manage these third-party relationships to ensure continuity, quality and compliance with regulations, 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 both ARISTADA and 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. We endeavor to qualify and register new vendors and to develop contingency plans so that production is not impacted by issues associated with single-source providers. Nonetheless, our business could be materially and adversely affected by issues associated with single-source providers.

We are also dependent in certain cases on third parties to manufacture products. Where the manufacturing rights to the products in which our technologies are applied are granted to, or retained by, our third-party licensee (for example, in the cases of INVEGA SUSTENNA/XEPLION, INVEGA TRINZA and BYDUREON) or approved sub-licensee, we have no control over the manufacturing, supply or distribution of the product. Supply or manufacturing issues encountered by such licensees or sublicenses could materially and adversely affect sales of products from which we receive revenue, our business, financial condition, cash flows and results of operations.

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

We and our third-party providers are generally required to comply with cGMP regulations and other applicable

foreign standards in the manufacture of our products. In addition, in the U.S., the DEA and state-level agencies heavily regulate the manufacturing, holding, processing, security, recordkeeping and distribution of substances, including controlled substances. Our products that are scheduled by the DEA as controlled substances make us subject to the DEA's regulations. We are subject to unannounced inspections by the FDA, the DEA and comparable state and foreign agencies in other jurisdictions to confirm compliance with all applicable laws. Any changes of suppliers or modifications of methods of manufacturing require amending our application to the FDA or other regulatory agencies, and ultimate amendment acceptance by such agencies, prior to release of product to the applicable marketplace. Our inability or the inability of our third-party service providers to demonstrate ongoing cGMP or other regulatory compliance could require us to withdraw or recall products and interrupt commercial supply of our products. Any delay, interruption or other issues that may arise in the manufacture, formulation, packaging or storage of our products as a result of a failure of our facilities or the facilities or operations of third parties to pass any regulatory agency inspection could significantly impair our ability to develop and commercialize our products. This could increase our costs, cause us to lose revenue or market share and damage our reputation.

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

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

In both U.S. and non-U.S. markets, sales of our products depend, in part, on the availability of reimbursement from third-party payers such as state and federal governments, including Medicare and Medicaid in the U.S. and similar programs in other countries, managed care providers and private insurance plans. Deterioration in the timeliness, certainty and amount of reimbursement for our products, including the existence of barriers to coverage of our products (such as prior authorization, criteria for use or other requirements), limitations by healthcare providers on how much, or under what circumstances, they will prescribe or administer our products or unwillingness by patients to pay any required co-payments, could reduce the use of, and revenues generated from, our products and could have a material adverse effect on our business, financial condition, cash flows and results of operations. In addition, when a new product is approved, the availability of government and private reimbursement for that product is uncertain, as is the amount for which that product will be reimbursed. We cannot predict the availability or amount of reimbursement for our products.

In the U.S., federal and state legislatures, health agencies and third-party payers continue to focus on containing the cost of healthcare, including by comparing the effectiveness, benefits and costs of similar treatments. Any adverse findings for our products from such comparisons 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. Managed care organizations continue to seek price discounts and, in some cases, to impose restrictions on the coverage of particular drugs. Government efforts to reduce Medicaid expenses may lead to increased use of managed care organizations by Medicaid programs. This may result in managed care organizations influencing prescription decisions for a larger segment of the population and a corresponding constraint on prices and reimbursement for our products.

The government-sponsored healthcare systems in Europe and many other countries are the primary payers for healthcare expenditures, including payment for drugs and biologics. We expect that countries may take actions to reduce expenditure on drugs and biologics, including mandatory price reductions, patient access restrictions, suspensions of price increases, increased mandatory discounts or rebates, preference for generic products, reduction in the amount of reimbursement and greater importation of drugs from lower-cost countries. These cost-control measures likely would reduce our revenues. In addition, certain countries set prices by reference to the prices in other countries where our products are marketed. Thus, the inability to secure adequate prices in a particular country may not only limit the marketing of products within that country, but may also adversely affect the ability to obtain acceptable prices in other markets.

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, technologies and developing technologies, including those that are the subject of licenses with our licensees;
- 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 or withstand challenge by the time such products are commercialized.

Although we believe that we make reasonable efforts to protect our intellectual property rights and to ensure that our proprietary technology does not infringe the rights of other parties, we cannot ascertain the existence of all potentially conflicting claims. Therefore, there is a risk that third parties may make claims of infringement against our products or technologies. We know of several patents issued in the U.S. to third parties that may relate to our products. 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 products if such patents are issued in their present form. If patents are issued that cover our products, we may not be able to manufacture, use, offer for sale, sell or import such products without first getting a license from the patent holder. The patent holder may not grant us a license on reasonable terms, or it may refuse to grant us a license at all. This could delay or prevent us from developing, manufacturing, selling or importing those of our products that would require the license. 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 biopharmaceutical companies involve complex legal and factual questions, enforceability of patents cannot be predicted with certainty. The ultimate degree of patent protection that will be afforded to products and processes, including ours, in the U.S. and in other important markets, remains uncertain and is dependent upon the scope of protection decided upon by the patent offices, courts and lawmakers in these countries. 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 licensees, licensees, employees and consultants. Any of these parties may breach the agreements and disclose our confidential information, or our competitors might learn of the information in some other way. To the extent that our employees, consultants or contractors use intellectual property owned by others in their work for us, disputes may arise as to the rights in related or resulting know-how and inventions. If any trade secret, know-how or other technology not protected by a patent were to be disclosed to, or independently developed by, a competitor, such event could materially adversely affect our business, financial condition, cash flows and results of operations.

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

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

In part as a result of this uncertainty, there has been, and we expect that there may continue to be, significant litigation in the pharmaceutical industry regarding patents and other intellectual property rights. A patent holder might file an infringement action against us claiming that the manufacture, use, offer for sale, sale or import of our products infringed one or more of its patents. 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 (see "—We face claims against our intellectual property rights and competition from generic drug manufacturers." for additional information regarding litigation with generic drug manufacturers). We expect that litigation may be necessary in some instances to determine the validity and scope of certain of our proprietary rights. Competitors may sue us as a way of delaying the introduction of our products.

Litigation and administrative proceedings concerning patents and other intellectual property rights may be expensive, protracted with no certainty of success, and distracting to management. Ultimately, the outcome of such litigation could adversely affect our business and the validity and scope of our patent or other proprietary rights or hinder our ability to manufacture and market our products.

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

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

Our existing indebtedness is secured by a first priority lien on substantially all of the combined company assets and properties of Alkermes plc and most of its subsidiaries, which serve as guarantors. The agreements governing the Term Loan Facility include a number of restrictive covenants that, among other things, subject to certain exceptions and baskets, impose operating and financial restrictions on us. Our level of indebtedness and the terms of these financing arrangements could adversely affect our business by, among other things:

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

Our failure to comply with these restrictions or to make these payments could lead to an event of default that could result in an acceleration of the indebtedness. Our future operating results may not be sufficient to ensure compliance with these covenants or to remedy any such default. In the event of an acceleration of this indebtedness, we may not have, or be able to obtain, sufficient funds to make any accelerated payments.

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

As is typical in the pharmaceutical industry, we utilize pharmaceutical wholesalers in connection with the distribution of the products that we market and sell. A significant amount of our product is sold to end-users through the three largest wholesalers in the U.S. market, Cardinal Health Inc., AmerisourceBergen Corp., and McKesson Corp. If we are unable to maintain our business relationships with these major pharmaceutical wholesalers on commercially

acceptable terms, if the buying patterns of these wholesalers fluctuate due to seasonality or if wholesaler buying decisions or other factors outside of our control change, such events could materially adversely affect our business, financial condition, cash flows and results of operations.

Our business may suffer if we are unable to develop new products.

Our long-term viability and growth will depend upon the successful development of new products from our research and development activities and we expect the development of products for our own account to consume substantial resources. Since we fund the development of our proprietary products, there is a risk that we may not be able to continue to fund all such development efforts to completion or to provide the support necessary to perform the clinical trials, obtain regulatory approvals, obtain a final DEA scheduling designation (to the extent our products are controlled substances) or market any approved products on a worldwide basis. 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 licensees.

If our delivery technologies or product development efforts fail to result in the successful development and commercialization of products, if our licensees decide not to pursue development and/or commercialization of our products or if new products do not perform as anticipated, such events could materially adversely affect our business, financial condition, cash flows and results of operations. For factors that may affect the market acceptance of our products approved for sale (see "—We face claims against our intellectual property rights and competition from generic drug manufacturers." for additional information relating to competition from generic drug manufacturers).

Clinical trials for our products are expensive, may take several years to complete, and their outcome is uncertain.

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 products are safe and effective for use in humans. Conducting clinical trials is a lengthy, time-consuming and expensive process. We have incurred, and we will continue to incur, substantial expense for pre-clinical testing and clinical trials.

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

- the potential delay by a collaborative partner in beginning a clinical trial;
- the failure of third-party CROs and other third-party service providers and independent clinical investigators to manage and conduct the trials, to perform their oversight of the trials or to meet expected deadlines;
- the inability to recruit clinical trial participants at the expected rate;
- the failure of clinical trials to demonstrate a product's safety or efficacy;
- the inability to follow patients adequately after treatment;
- unforeseen safety issues;
- the inability to manufacture or obtain sufficient quantities of materials used for clinical trials; and
- unforeseen governmental or regulatory issues, including those by the FDA, DEA and other regulatory agencies.

In addition, we are currently conducting and enrolling patients in clinical studies in a number of countries where our experience is more limited. For example, the phase 3 extension study of ALKS 5461 is being conducted in many countries around the world, including in Eastern Europe and Asia. We depend on independent clinical investigators, CROs and other third-party service providers and our collaborators in the conduct of clinical trials for our products 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 outcome of our clinical trials is uncertain. The results from pre-clinical testing and early clinical trials often

have not predicted results of later clinical trials. A number of products have shown promising results in early clinical trials but subsequently failed to establish sufficient safety and efficacy data to obtain necessary regulatory approvals.

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 products may be delayed or prevented, and such events could materially adversely affect our business, financial condition, cash flows and results of operations.

The FDA or other regulatory agencies may not approve our products or may delay approval.

We must obtain government approvals before marketing or selling our products in the U.S. and in jurisdictions outside the U.S. The FDA, DEA (to the extent a product is a controlled substance), and comparable regulatory agencies in other countries, impose substantial and rigorous requirements for the development, production and commercial introduction of drug products. These include pre-clinical, laboratory and clinical testing procedures, sampling activities, clinical trials and other costly and time-consuming procedures. Satisfaction of the requirements of the FDA and of other regulatory agencies typically takes a significant number of years and can vary substantially based upon the type, complexity and novelty of the product.

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. 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.

This product approval 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 may not demonstrate safety and efficacy for each target indication in accordance with regulatory agency standards;
- data from pre-clinical testing and clinical trials may be interpreted by the FDA or other regulatory agencies in different ways than we or our partners interpret it;
- the FDA or other regulatory agencies might not approve our or our partners' manufacturing processes or facilities;
- the FDA or other regulatory agencies may not approve accelerated development timelines for our product;
- 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.

Failure to obtain regulatory approval for products will prevent their commercialization. Any delay in obtaining regulatory approval for products could adversely affect our ability to successfully commercialize such products. In addition, share prices have declined significantly in certain instances where companies have failed to obtain FDA approval of a product or where 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 products, our share price could decline significantly.

The FDA or other regulatory agencies may impose limitations on any product approval.

Even if regulatory approval to market a drug product is granted by the FDA and other regulatory agencies, 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 post-approval requirements and the FDA, as a result, requires us to change sections of the label for our products.

Further, even if the FDA provides regulatory approval, controlled substances will not become commercially available until after the DEA provides its final schedule designation, which may take longer and may be more restrictive than we expect or change after its initial designation. We currently expect ALKS 5461 and ALKS 3831 to require such DEA final schedule designation prior to commercialization. Restrictive designation could adversely affect our ability to commercialize such products and could adversely affect our business and share price.

Citizen Petitions and other actions filed with, or litigation against, the FDA or other regulatory agencies or litigation against Alkermes may negatively impact the approval of our products and our business.

As described under Part I, Item 3—Legal Proceedings in this Annual Report, on July 13, 2015, Otsuka Pharmaceutical Development & Commercialization, Inc. ("Otsuka PD&C") filed a Citizen Petition with the FDA which requested that the FDA refuse to approve the NDA for ARISTADA or delay approval of such NDA until the exclusivity rights covering long-acting aripiprazole expire in December 2017. The FDA approved ARISTADA on October 5, 2015 and, concurrent with such approval, denied Otsuka PD&C's Citizen Petition. On October 15, 2015, Otsuka Pharm. Co., Otsuka PD&C, and Otsuka America Pharmaceutical, Inc. (collectively, "Otsuka") filed an action for declaratory and injunctive relief against the FDA requesting, among other things, that the court vacate FDA's approval of the ARISTADA NDA. We have successfully intervened in, and received the court's approval to become a party to, this action. The action is currently pending before the court; oral arguments were held on January 7, 2016.

If Otsuka's action is successful, the Court could remand the ARISTADA NDA to the FDA for further action, vacate the FDA's approval of the ARISTADA NDA, declare that Otsuka's exclusivity rights preclude FDA from granting approval of the NDA for ARISTADA until December 2017, grant injunctive relief and require that we remove ARISTADA from the market, and/or require that the FDA impose limitations on the approval of the ARISTADA NDA. These outcomes and others could adversely affect our ability to generate revenues from the commercialization and sale of ARISTADA, and our share price.

In addition, in the past, following periods of volatility in the market price of a company's securities, securities class action litigation has often been instituted against companies. This type of litigation, if instituted, could result in substantial costs and a diversion of management's attention and resources, which could harm our business.

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 licensees and third-party providers, are subject to comprehensive government regulation. Government regulation by various national, state and local agencies, which includes detailed inspection of, and controls over, research and laboratory procedures, clinical investigations, product approvals and manufacturing, marketing and promotion, adverse event reporting, sampling, distribution, recordkeeping, storage, and disposal practices, and achieving compliance with these regulations, substantially increases the time, difficulty and costs incurred in obtaining and maintaining the approval to market newly developed and existing products. Government regulatory actions can result in delay in the release of products, seizure or recall of products, suspension or revocation of the authority necessary for their production and sale, and other civil or criminal sanctions, including fines and penalties. Pharmaceutical and biotechnology companies also have been the target of government 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 and violations related to environmental matters. In addition, we may be the subject of securities law claims and derivative actions.

While we have implemented numerous risk mitigation measures, we cannot guarantee that we, our employees, our licensees, our consultants or our contractors are, or will be, in compliance with all potentially applicable U.S. federal and

state regulations and/or laws or all potentially applicable regulations and/or laws outside the U.S. and interpretations of the applicability of these laws to marketing practices. If we or our agents fail to comply with any of those regulations and/or laws, a range of actions could result, including the termination of clinical trials, the failure to approve a product, 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.

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. The enactment in the U.S. of healthcare reform, the promulgation of regulations, new legislation and legislation on comparative effectiveness research are examples of previously enacted and possible future changes in laws that could adversely affect our business.

We face competition in the biopharmaceutical industry.

We face intense competition in the development, manufacture, marketing and commercialization of our products from many and varied sources, such as academic institutions, government agencies, research institutions, pharmaceutical and biotechnology companies, including other companies with similar technologies, and manufacturers of generic drugs (see "—We face claims against our intellectual property rights and competition from generic drug manufacturers." for additional information relating to competition from generic drug manufacturers). Some of these competitors are also our licensees, who control the commercialization of products from which we receive manufacturing and royalty revenues. These competitors are working to develop and market other systems, products, and other methods of preventing or reducing disease, and new small-molecule and other classes of drugs that can be used with or without a drug delivery system.

The pharmaceutical and biotechnology 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 products or product platforms obsolete or noncompetitive before we recover expenses incurred in connection with their development or realize any revenues from any marketed product.

There are other companies developing extended-release product platforms. In many cases, there are products on the market or in development that may be in direct competition with our products. In addition, we know of new chemical entities that are being developed that, if successful, could compete against our products. These chemical entities are being designed to work differently than our products and may turn out to be safer or to be more effective than our products. 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 products. Our licensees could choose a competing technology to use with their drugs instead of one of our product platforms and could develop products that compete with our products.

With respect to our proprietary injectable product platform, we are aware that there are other companies developing extended-release delivery systems for pharmaceutical products. In the treatment of schizophrenia, ARISTADA, RISPERDAL CONSTA and INVEGA SUSTENNA/XEPLION, and INVEGA TRINZA compete with each other and a number of other injectable products including ZYPREXA RELPREVV ((olanzapine) For Extended Release Injectable Suspension), which is marketed and sold by Lilly; ABILIFY MAINTENA (aripiprazole for extended release injectable suspension), a once-monthly injectable formulation of ABILIFY (aripiprazole) developed by Otsuka Pharm. Co.; oral compounds currently on the market; and generic versions of branded oral and injectable products. In the treatment of bipolar disorder, RISPERDAL CONSTA competes with antipsychotics such as ABILIFY, LATUDA, risperidone, olanzapine, ziprasidone and clozapine.

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

In the treatment of opioid dependence, VIVITROL competes with methadone, oral naltrexone, SUBOXONE

(buprenorphine HCl/naloxone HCl dehydrate sublingual tablets), SUBOXONE (buprenorphine/naloxone) Sublingual Film, and SUBUTEX (buprenorphine HCl sublingual tablets), each of which is marketed and sold by Indivior plc, and BUNAVAIL buccal film (buprenorphine and naloxone) marketed by BioDelivery Sciences, and ZUBSOLV (buprenorphine and naloxone) marketed by Orexo US, Inc. It also competes with generic versions of SUBUTEX and SUBOXONE sublingual tablets. Other pharmaceutical companies are developing products that have shown promise in treating opioid dependence that, if approved by the FDA, would compete with VIVITROL.

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

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

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

Our inability to compete successfully in the pharmaceutical and biotechnology industries could materially adversely affect our business, results of operations, cash flows and financial condition.

We face claims against our intellectual property rights and competition from generic drug manufacturers.

In the U.S., generic manufacturers of innovator drug products may file ANDAs and, in doing so, certify that their products do not infringe the innovator's patents and/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 have received notices of ANDA filings for AMPYRA asserting that a generic form of AMPYRA would not infringe AMPYRA's Orange-Book listed patents and/or those patents are invalid. We are currently engaged in Paragraph IV litigation disputing such claims, which is scheduled to go to trial in September 2016. This litigation may be costly and time consuming. For a discussion of legal proceedings related to the patents covering AMPYRA, see "Item 3—Legal Proceedings."

Although we intend to vigorously enforce our intellectual property rights, there can be no assurance that we will prevail in our defense of our patent rights. Our existing patents could be invalidated, found unenforceable or found not to cover generic forms of our products. If an ANDA filer were to receive FDA approval to sell a generic version of our products and/or prevail in any patent litigation, our products would become subject to increased competition and our revenue could be adversely affected.

The commercial use of our products may cause unintended side effects or adverse reactions, or incidents of misuse may occur, which could adversely affect our business and share price.

We cannot predict whether the commercial use of our products will produce undesirable or unintended side effects that have not been evident in the use of, or in clinical trials conducted for, such products to date. The administration of drugs in humans carries the inherent risk of product liability claims whether or not the drugs are actually the cause of an

injury. Our products 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 products have been administered to patients for a prolonged period of time. 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, REMS programs, and requirements for additional labeling), all of which could have a material adverse effect on our business, financial condition, cash flows and results of operations. In addition, the reporting of adverse safety events involving our products and public rumors about such events could cause our product sales or share price to decline or experience periods of volatility.

Our business involves environmental, health and safety risks.

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

We may not become profitable on a sustained basis.

At December 31, 2015, our accumulated deficit was $739.5 million, which was primarily the result of net losses incurred from 1987, the year Alkermes, Inc., was founded, through December 31, 2015 as we invest in our R&D pipeline, partially offset by net income over certain of our recent fiscal periods. There can be no assurance we will achieve sustained profitability.

A major component of our revenue is dependent on our licensees' and our ability to commercialize, and our and our partners' ability to manufacture economically, our marketed products. In the fourth quarter of 2015, we completed the two-year restructuring plan of our Athlone, Ireland manufacturing facility, pursuant to which we terminated manufacturing services for certain products that were no longer expected to be economically practicable to produce.

Our ability to achieve sustained profitability in the future depends, in part, on our or our licensees', as applicable, ability to:

- successfully commercialize VIVITROL and ARISTADA in the U.S.;
- obtain and maintain regulatory approval for products both in the U.S. and in other countries;
- efficiently manufacture our products;
- support the commercialization of products by our licensees;
- enter into agreements to develop and commercialize our products;
- develop, have manufactured or expand our capacity to manufacture and market our products;
- obtain adequate reimbursement coverage for our products from insurance companies, government programs and other third-party payers;
- obtain additional research and development funding for our proprietary products; 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 products, including clinical trials;
- the time and expense that will be required to pursue FDA and/or non-U.S. regulatory approvals for our products and whether such approvals are obtained;
- the time that will be required for the DEA to provide its final scheduling designation for our products that are controlled substances;
- the time and expense required to prosecute, enforce and/or challenge patent and other intellectual property

rights;
- the cost of building, operating and maintaining manufacturing and research facilities;
- the cost of third-party manufacture;
- the number of products we pursue, particularly proprietary products;
- how competing technological and market developments affect our products;
- 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 is intense.

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

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

We may require additional funds in the future to execute on our business strategy, and we may seek funds through various sources, including debt and equity offerings, corporate collaborations, bank borrowings, arrangements relating to assets, sale of royalty streams we receive on our products or other financing methods or structures. The source, timing and availability of any financings will depend on market conditions, interest rates and other factors. If we issue additional equity securities or securities convertible into equity securities to raise funds, our shareholders will suffer dilution of their investment, and it may adversely affect the market price of our ordinary shares. In addition, as a condition to providing additional funds to us, future investors or lenders may demand, and may be granted, rights superior to those of existing shareholders. If we issue additional debt securities in the future, our existing debt service obligations will increase further. If we are unable to generate sufficient cash to meet these obligations and need to use existing cash or liquidate investments in order to fund our debt service obligations or to repay our debt, we may be forced to delay or terminate clinical trials or curtail operations. We cannot be certain, however, that additional financing will be available from any of these sources when needed or, if available, will be on acceptable terms, if at all, particularly if the credit and financial markets are constrained at the time we require funding. If we fail to obtain additional capital when we need it, we may not be able to execute our business strategy successfully and may have to give up rights to our product platforms, products or grant licenses on terms that may not be favorable to us.

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

As a result of adverse 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 licensees, and we sell our products to our licensees through contracts that may not be secured by collateral or other security. Accordingly, we bear the risk if our partners are unable to pay amounts due to us thereunder. Due to volatility in the financial markets, there may be a disruption or delay in the performance of our third-party contractors, suppliers or licensees. If such third parties are unable to pay amounts owed to us or satisfy their commitments to us, or if there are reductions in the availability or extent of reimbursement available to us, our business, financial condition, cash flows and results of operations would be adversely affected.

Currency exchange rates may affect revenues and expenses.

We conduct a large portion of our business in international markets. For example, we derive a majority of our RISPERDAL CONSTA revenues and all of our FAMPYRA and XEPLION revenues from sales in countries other than the U.S., and these sales are denominated in non-U.S. dollar ("USD") currencies. We also incur substantial operating costs in Ireland and face exposure to changes in the exchange ratio of the USD and the Euro arising from expenses and payables at our Irish operations that are settled in Euro. The impact of changes in the exchange ratio of the USD and the Euro on our USD-denominated revenues earned in countries other than the U.S. is partially offset by the opposite impact of changes in the exchange ratio of the USD and the Euro on operating expenses and payables incurred at our Irish operations that are settled in Euro. Refer to "Item 7A. Quantitative and Qualitative Disclosure about Market Risk" for

additional information relating to our foreign currency exchange rate risk.

We may not be able to retain our key personnel.

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

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

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

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

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

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

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

At December 31, 2015, we have $379.2 million of amortizable intangible assets and $92.9 million of goodwill. Under accounting principles generally accepted in the U.S. (“GAAP”), we must assess, at least annually and potentially more frequently, whether the value of goodwill and other indefinite- lived intangible assets have been impaired. Amortizing intangible assets will be assessed for impairment in the event of an impairment indicator. Any reduction or impairment of the value of goodwill or other intangible assets will result in a charge against earnings, which could materially adversely affect our results of operations and shareholders’ equity in future periods.

Our effective tax rate may increase.

As a global biopharmaceutical company, we are subject to taxation in a number of different jurisdictions. As a result, our effective tax rate is derived from a combination of applicable tax rates in the various places that we operate. In preparing our financial statements, we estimate the amount of tax that will become payable in each of these places. Our effective tax rate may fluctuate depending on a number of factors, including, but not limited to, the distribution of our profits or losses between the jurisdictions where we operate and differences in interpretation of tax laws. In addition, the tax laws of any jurisdiction in which we operate may change in the future, which could impact our effective tax rate. Tax authorities in the jurisdictions in which we operate may audit us. If we are unsuccessful in defending any tax positions adopted in our submitted tax returns, we may be required to pay taxes for prior periods, interest, fines or penalties, and may be obligated to pay increased taxes in the future, any of which could have a material adverse effect on our business, financial condition, cash flows, results of operations and growth prospects.

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

For U.S. federal income tax purposes, a corporation is generally considered tax resident in the place of its incorporation. Because we are incorporated in Ireland, we should be deemed an Irish corporation under these general rules. However, Section 7874 of the Internal Revenue Code of 1986, as amended (the "Code") generally provides that a corporation organized outside the U.S. that acquires substantially all of the assets of a corporation organized in the U.S. will be treated as a U.S. corporation (and, therefore, a U.S. tax resident) for U.S. federal income tax purposes if shareholders of the acquired U.S. corporation own at least 80% (of either the voting power or the value) of the stock of the acquiring foreign corporation after the acquisition by reason of holding stock in the domestic corporation, and the "expanded affiliated group" (as defined in Section 7874) that includes the acquiring corporation does not have substantial business activities in the country in which it is organized.

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

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

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

- responding to proxy contests and other actions by activist shareholders can be costly and time-consuming, disrupting operations and diverting the attention of management and employees, and can lead to

uncertainty;

- perceived uncertainties as to future direction may result in the loss of potential acquisitions, collaborations or in-licensing opportunities, and may make it more difficult to attract and retain qualified personnel and business partners; and
- if individuals are elected to our board of directors with a specific agenda, it may adversely affect our ability to effectively implement our strategic plan in a timely manner and create additional value for our shareholders.

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

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

Any change of control, or change in management, of our licensees may result in a reprioritization of our product within such licensee's portfolio, or such licensee may fail to maintain the financial or other resources necessary to continue the development and/or commercialization of such product.

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

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

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

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

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

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

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

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

None.

Item 2. ***Properties***

We lease approximately 14,600 square feet of corporate office space in Dublin, Ireland, which houses our corporate headquarters. This lease expires in 2022 and includes a tenant option to terminate in 2017. We lease approximately 175,000 square feet of space in Waltham, Massachusetts, which houses corporate offices, administrative areas and laboratories. This lease expires in 2021 and includes a tenant option to extend the term for up to two five-year periods. We lease approximately 3,800 square feet of office space in Washington, DC. This lease expires in 2020.

We own a R&D and manufacturing facility in Athlone, Ireland (approximately 400,000 square feet) and a manufacturing facility in Wilmington, Ohio (approximately 280,000 square feet).

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***

ARISTADA

On July 13, 2015, Otsuka PD&C filed a Citizen Petition with the FDA which requested that the FDA refuse to approve the NDA for ARISTADA or delay approval of such NDA until the exclusivity rights covering long-acting aripiprazole expire in December 2017. The FDA approved ARISTADA on October 5, 2015 and, concurrent with such approval, denied Otsuka PD&C's Citizen Petition.

On October 15, 2015, Otsuka filed an action for declaratory and injunctive relief with the United States District Court for the District of Columbia (the "Court") against Sylvia Mathews Burwell, Secretary, U.S. Department of Health and Human Services; Dr. Stephen Ostroff, Acting Commissioner, FDA; and the FDA, requesting that (a) the Court expedite the legal proceedings; (b) the Court declare that the FDA's denial of Otsuka's claimed exclusivity rights and approval of the ARISTADA NDA were arbitrary, capricious, an abuse of discretion, and otherwise not in accordance with law; (c) the Court vacate FDA's approval of the ARISTADA NDA and vacate any FDA decisions or actions underlying or supporting or predicated upon that approval; (d) the Court declare that Otsuka's claimed exclusivity rights preclude FDA from granting approval of the Alkermes NDA until the expiration of such exclusivity rights in December 2017; and (e) the Court grant any and all other, further, and additional relief, including all necessary and appropriate protective preliminary, interim, or permanent relief, as the nature of the cause may require, including all necessary and appropriate declarations of rights and injunctive relief. We believe Otsuka's action is without merit and will vigorously defend ARISTADA against such action. We successfully intervened in, and received the Court's approval to become a party to, this action. The Court held a hearing on the case in January 2016. The action is currently pending before the Court. For information about risks relating to this action, see "Item 1A—Risk Factors" of this Annual Report and specifically the section entitled "Citizen Petitions and other actions filed with, or litigation against, the FDA or other regulatory agencies or litigation against Alkermes may negatively impact the approval of our products and our business."

AMPYRA

Ampyra ANDA Litigation

Ten separate Paragraph IV Certification Notices have been submitted to us and/or our partner Acorda from Accord Healthcare, Inc.; Actavis Laboratories FL, Inc. ("Actavis"); Alkem Laboratories Ltd.; Apotex, Inc.; Aurobindo Pharma Ltd. ("Aurobindo"); Mylan Pharmaceuticals, Inc. ("Mylan"); Par Pharmaceutical, Inc. ("Par"); Roxane Laboratories, Inc.; Sun Pharmaceutical Industries Limited and Sun Pharmaceuticals Industries Inc. (collectively, "Sun"); and Teva Pharmaceuticals USA, Inc., advising that each of these companies had submitted an ANDA to the FDA seeking marketing approval for generic versions of Ampyra (dalfampridine) Extended Release Tablets, 10 mg. The ANDA filers have challenged the validity of the Orange Book-listed patents for Ampyra, and they have also asserted that their generic

versions do not infringe certain claims of these patents. In response, we and/or Acorda filed lawsuits against the ANDA filers in the U.S. District Court for the District of Delaware (the "Delaware Court") asserting infringement of U.S. Patent Nos. 5,540,938 (which we own), 8,007,826, 8,354,437, 8,440,703, and 8,663,685 (which are owned by Acorda). Requested judicial remedies include recovery of litigation costs and injunctive relief. Lawsuits with eight of the ANDA filers have been consolidated into a single case. The Delaware Court has scheduled a Markman hearing on March 7, 2016, and has set a five-day bench trial starting on September 19, 2016. Mylan is challenging the jurisdiction of the Delaware Court with respect to the Delaware action. Due to Mylan's motion to dismiss, we, together with Acorda, also filed another patent infringement suit against Mylan in the U.S. District Court for the Northern District of West Virginia asserting the same U.S. patents and requesting the same judicial relief as in the Delaware action. On January 4, 2016, the Federal Circuit Court of Appeals held oral arguments on Mylan's appeal of the Delaware Court's jurisdictional decision. All lawsuits were filed within 45 days from the date of receipt of each of the Paragraph IV Certification Notices. As a result, a 30-month statutory stay of approval period applies to each of the ANDAs under the Hatch-Waxman Act. The 30-month stay starts from January 22, 2015, which is the end of the new chemical entity exclusivity period for Ampyra. This stay restricts the FDA from approving the ANDAs until July 2017 at the earliest, unless a Federal district court issues a decision adverse to all of the asserted Orange Book-listed patents prior to that date.

In the fourth quarter of 2015, we and/or Acorda entered into a settlement agreement with each of Actavis, Aurobindo, Par and Sun (collectively, the "Settling ANDA Filers") to resolve the patent litigation that we and/or Acorda brought against the Settling ANDA Filers in the Delaware Court as described above. As a result of the settlement agreements, the Settling ANDA Filers will be permitted to market a generic version of Ampyra in the U.S. at a specified date in 2027, or potentially earlier under certain circumstances. The parties have submitted their respective settlement agreements to the Federal Trade Commission and the Department of Justice, as required by federal law. The settlements with the Settling ANDA Filers do not resolve pending patent litigation that we and Acorda brought against the other ANDA filers, as described in this Annual Report.

We intend to vigorously enforce our intellectual property rights. For information about risks relating to the Ampyra Paragraph IV litigations and other proceedings see "Item 1A—Risk Factors" in this Annual Report and specifically the section entitled "We face claims against our intellectual property rights and competition from generic drug manufacturers."

Ampyra IPR Proceedings

A hedge fund (acting with affiliated entities and individuals and proceeding under the name of the Coalition for Affordable Drugs) has filed inter partes review petitions with the U.S. Patent and Trademark Office, challenging U.S. Patent Nos. 8,007,826, 8,354,437, 8,440,703, and 8,663,685 (which are owned by Acorda). The challenged patents are four of the five Ampyra Orange-Book listed patents. The 30-month statutory stay period based on patent infringement suits filed by us and Acorda against ANDA filers is not impacted by these filings, and remains in effect.

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 under the symbol "ALKS." Set forth below for the indicated periods are the high and low closing sales prices for our ordinary shares.

	Year Ended December 31, 2015		Year Ended December 31, 2014	
	High	Low	High	Low
1st Quarter	$ 73.64	$ 58.24	$ 53.82	$ 40.07
2nd Quarter	67.00	55.37	50.94	41.10
3rd Quarter	72.79	55.08	51.75	41.54
4th Quarter	80.14	57.89	58.88	40.23

There were 170 shareholders of record for our ordinary shares on February 12, 2016. In addition, the last reported sale price of our ordinary shares as reported on the NASDAQ on February 12, 2016 was $32.45.

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 2016 Annual General Meeting of Shareholders.

Repurchase of equity securities

On September 16, 2011, our board of directors authorized the continuation of the Alkermes, Inc. program to repurchase up to $215.0 million of our ordinary shares at the discretion of management from time to time in the open market or through privately negotiated transactions. We did not purchase any shares under this program during the year ended December 31, 2015. As of December 31, 2015, we had purchased a total of 8,866,342 shares at a cost of $114.0 million. Our Term Loan Facility includes restrictive covenants that impose certain limitations on our ability to repurchase our ordinary shares.

Irish taxes applicable to U.S. holders

The following is a general summary of the main Irish tax considerations applicable to the purchase, ownership and disposition of our ordinary shares by U.S. holders. It is based on existing Irish law and practices in effect on January 31, 2016, and on discussions and correspondence with the Irish Revenue Commissioners. Legislative, administrative or judicial changes may modify the tax consequences described below.

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

Withholding tax on dividends

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

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

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

Income tax on dividends

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

Irish tax on capital gains

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

Capital acquisitions tax

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

CAT is levied at a rate of 33% above certain tax-free thresholds. The appropriate tax-free threshold is dependent upon (i) the relationship between the donor and the recipient, and (ii) the aggregation of the values of previous gifts and inheritances received by the recipient from persons within the same category of relationship for CAT purposes. Gifts and inheritances passing between spouses are exempt from CAT. Our shareholders should consult their own tax advisers as to whether CAT is creditable or deductible in computing any domestic tax liabilities.

Stamp duty

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

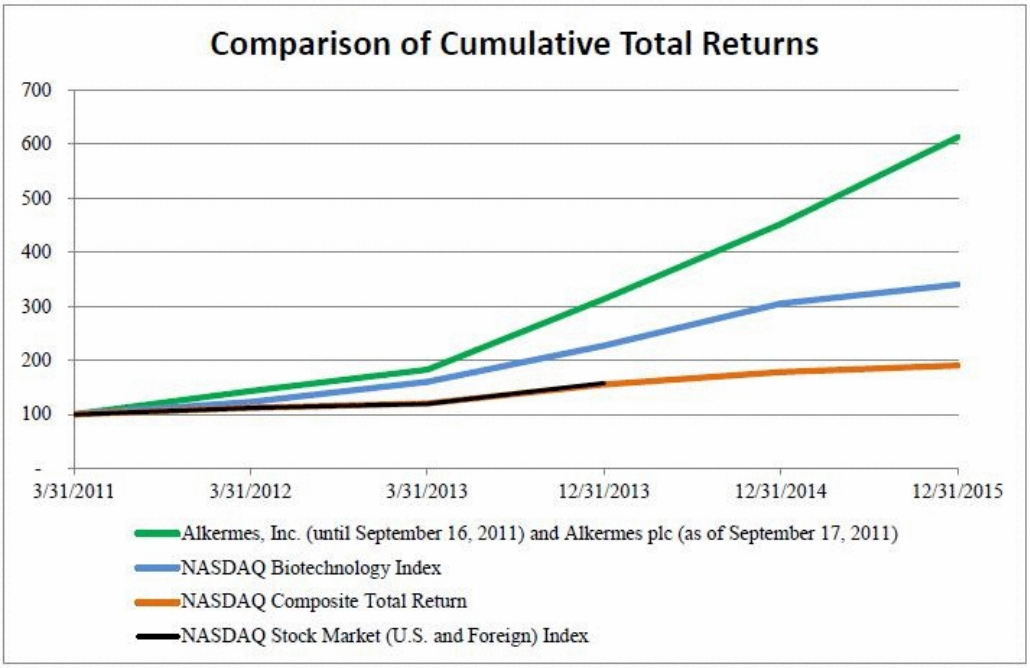
A shareholder who holds ordinary shares outside of DTC may transfer those ordinary shares into DTC without giving rise to Irish stamp duty provided that the shareholder would be the beneficial owner of the related book-entry interest in those ordinary shares recorded in the systems of DTC, and in exactly the same proportions, as a result of the transfer and at the time of the transfer into DTC there is no sale of those book-entry interests to a third party being contemplated by the shareholder. Similarly, a shareholder who holds ordinary shares through DTC may transfer those

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

Stock Performance Graph

The information contained in the performance graph shall not be deemed to be "soliciting material" or to be "filed" with the SEC, and such information shall not be incorporated by reference into any future filing under the Securities Act of 1933, as amended or the Securities Exchange Act of 1934, as amended (the "Exchange Act"), except to the extent that we specifically incorporate it by reference into such filing.

The following graph compares the cumulative total shareholder return on our ordinary shares since March 31, 2011 through December 31, 2015 with the NASDAQ Composite Total Return Index and the NASDAQ Biotechnology Index. As a result of a change in the total return data made available to us through our vendor provider, our performance graphs going forward will use the NASDAQ Composite Total Return Index in lieu of the NASDAQ US & Foreign Index. Please note that information for the NASDAQ US & Foreign Index is provided only from March 31, 2011 through December 31, 2013, the last day this data was made available by our third-party index provider. The NASDAQ Biotechnology Index was not affected by this change. It is important to note that information set forth in the graph below with respect to the time period prior to September 16, 2011 refers to the common stock performance of Alkermes, Inc., while that information with respect to the time period after September 16, 2011 refers to the ordinary share performance of Alkermes plc. The comparison assumes $100 was invested on March 31, 2011 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.



	Year Ended March 31,			Nine Months Ended December 31,	Year Ended December 31,	
	2011	2012	2013	2013	2014	2015
Alkermes	100	143	183	314	452	613
NASDAQ Composite Total Return	100	112	120	155	178	191
NASDAQ Biotechnology Index	100	123	160	228	305	340
NASDAQ Stock Market (U.S. and Foreign) Index	100	112	120	158	—	—

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

The selected historical financial data set forth below at December 31, 2015 and 2014 and for the years ended December 31, 2015 and 2014 and the nine months ended December 31, 2013 are derived from our audited consolidated financial statements, which are included elsewhere in this Annual Report. The selected historical financial data set forth below at December 31, 2013, March 31, 2013 and March 31, 2012 and for the years ended March 31, 2013 and 2012 are derived from audited consolidated financial statements, which are not included in this Annual Report. The selected historical financial data for the period prior to September 16, 2011 is that of Alkermes, Inc., while the selected historical financial data for the period after September 16, 2011 is that of Alkermes plc. The Company has elected not to recast prior period amounts to conform to the change in its fiscal year.

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

	Year Ended December 31,		Nine Months Ended December 31,	Year Ended March 31,	
	2015	2014	2013	2013	2012[1]
	(In thousands, except per share data)				
Consolidated Statements of Operations Data:					
REVENUES:					
Manufacturing and royalty revenues	$ 475,288	$ 516,876	$ 371,039	$ 510,900	$ 326,444
Product sales, net	149,028	94,160	57,215	58,107	41,184
Research and development revenue	4,019	7,753	4,657	6,541	22,349
Total revenues	628,335	618,789	432,911	575,548	389,977
EXPENSES:					
Cost of goods manufactured and sold	138,989	175,832	134,306	170,466	127,578
Research and development	344,404	272,043	128,125	140,013	141,893
Selling, general and administrative[2]	311,558	199,905	116,558	125,758	137,632
Amortization of acquired intangible assets	57,685	58,153	38,428	41,852	25,355
Restructuring[3]	—	—	—	12,300	—
Impairment of long-lived assets[4]	—	—	—	3,346	45,800
Total expenses	852,636	705,933	417,417	493,735	478,258
OPERATING (LOSS) INCOME	(224,301)	(87,144)	15,494	81,813	(88,281)
OTHER INCOME (EXPENSE), NET[5]	296	73,115	(10,097)	(46,372)	(26,111)
(LOSS) INCOME BEFORE INCOME TAXES	(224,005)	(14,029)	5,397	35,441	(114,392)
PROVISION (BENEFIT) FOR INCOME TAXES	3,158	16,032	(12,252)	10,458	(714)
NET (LOSS) INCOME	$ (227,163)	$ (30,061)	$ 17,649	$ 24,983	$ (113,678)
(LOSS) EARNINGS PER COMMON SHARE:					
BASIC	$ (1.52)	$ (0.21)	$ 0.13	$ 0.19	$ (0.99)
DILUTED	$ (1.52)	$ (0.21)	$ 0.12	$ 0.18	$ (0.99)
WEIGHTED AVERAGE NUMBER OF COMMON SHARES OUTSTANDING:					
BASIC	149,206	145,274	135,960	131,713	114,702
DILUTED	149,206	145,274	144,961	137,100	114,702
Consolidated Balance Sheet Data:					
Cash, cash equivalents and investments	$ 798,849	$ 801,646	$ 449,995	$ 304,179	$ 246,138
Total assets[6]	1,855,744	1,919,058	1,574,848	1,467,121	1,425,786
Long-term debt[6]	349,944	355,756	361,553	365,837	435,029
Shareholders' equity	1,314,275	1,396,837	1,065,186	952,374	853,852

(1) On September 16, 2011, the businesses of Alkermes, Inc., and EDT were combined under Alkermes plc. We paid Elan $500.0 million in cash and issued Elan 31.9 million ordinary shares of Alkermes plc, which had a fair value of approximately $525.1 million on the closing date, for the EDT business. Alkermes, Inc.'s results are included for all periods being presented, whereas the results of the acquiree, EDT, are included only after the date of acquisition, September 16, 2011, through March 31, 2012.

(2) Includes $29.1 million of expenses in the year ended March 31, 2012, related to the acquisition of EDT, which consists primarily of banking, legal and accounting expenses.

(3) Represents a one-time charge in connection with the restructuring plan related to our Athlone, Ireland manufacturing facility recorded in the year ended March 31, 2013. The charge consists of severance payments and other employee-related expenses.

(4) Includes an impairment charge of $3.3 million related to the impairment of certain of our equipment located at our Wilmington, Ohio manufacturing facility in the year ended March 31, 2013, and an impairment charge of $45.8 million related to the impairment of certain of our in-process R&D ("IPR&D") in the year ended March 31, 2012.

(5) Includes $9.6 million Gain on the Gainesville Transaction in the year ended December 31, 2015.

(6) In 2015, the Company retrospectively adopted the Financial Accounting Standards Board's guidance, simplifying the presentation of debt issuance costs. As a result, deferred financing costs of $2.2 million, $2.7 million, $3.2 million and $9.4 million that were classified within "Other long-term assets" at December 31, 2014, December 31, 2013, March 31, 2013 and March 31, 2012, respectively, were reclassified to "Long-term debt" to conform to the current period presentation.

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 "Cautionary Note Concerning Forward-Looking Statements" on pages 3 and 4 of this Annual Report. Factors that might cause future results to differ materially from those projected in the forward-looking statements also include, but are not limited to, those discussed in "Item 1A—Risk Factors" and elsewhere in this Annual Report.

On May 21, 2013, our Audit and Risk Committee, with such authority delegated to it by our board of directors, approved a change to our fiscal year-end from March 31 to December 31. This Annual Report reflects our financial results for the twelve month period from January 1, 2015 through December 31, 2015. The period ended December 31, 2014 reflects our financial results for the twelve-month period from January 1, 2014 through December 31, 2014. The period ended December 31, 2013 reflects our financial results for the nine-month period from April 1, 2013 through December 31, 2013.

Overview

Alkermes is a fully integrated, global biopharmaceutical company that applies its scientific expertise and proprietary technologies to research, develop and commercialize, both with partners and on its own, pharmaceutical products that are designed to address unmet medical needs of patients in major therapeutic areas. We have a diversified portfolio of commercial drug products and a clinical pipeline of product candidates that address CNS disorders such as schizophrenia, depression, addiction and multiple sclerosis.

We earn revenue on net sales of VIVITROL and ARISTADA, which are proprietary products that we manufacture, market and sell in the U.S and manufacturing and/or royalty revenues on net sales of products commercialized by our partners. Our key marketed products are expected to generate significant revenues for us in the near- and medium-term, as they possess long remaining patent lives and we believe are singular or competitively advantaged products in their classes and are generally in the launch phases of their commercial lives. These key marketed products consist of our antipsychotic franchise, INVEGA SUSTENNA/XEPLION and INVEGA TRINZA and RISPERDAL CONSTA; AMPYRA/FAMPYRA; BYDUREON; VIVITROL; and ARISTADA. Revenues from these products accounted for 88% of our total revenues during the year ended December 31, 2015, as compared to 74% and 68% during the years ended December 31, 2014 and 2013, respectively.

During the year ended December 31, 2015 we incurred an operating loss of $224.3 million which was primarily due to the significant investments we made in our R&D pipeline and the increase in our commercial operations group in anticipation of the launch of ARISTADA. In addition, in April 2015, we sold our Gainesville, GA manufacturing facility and the related manufacturing and royalty revenue associated with certain products manufactured at this facility including RITALIN LA, FOCALIN XR, VERELAN, ZOHYDRO ER, and BIDIL, and the rights to IV/IM and parenteral forms of Meloxicam. This facility generated revenues of $19.7 million, $73.0 million and $50.2 million and income before income taxes of $4.5 million, $22.8 million and $16.2 million in the years ended December 31, 2015 and 2014 and the nine months ended December 31, 2013, respectively.

Our revenues in 2015, when compared to 2014, increased by $9.5 million, however, after taking into account the loss of revenues from our Gainesville facility, our revenues increased by $62.8 million, with VIVITROL accounting for $50.3 million of this increase. R&D expense increased by $72.4 million from 2014, driven by our advancing development pipeline as we continued with the pivotal clinical development programs for ALKS 5461; moved ALKS 3831 into a pivotal development program in the fourth quarter of 2015 following the positive results from our dose-ranging phase 2 study announced in April 2015; and initiated phase 3 studies of ALKS 6428 and ALKS 8700 in September 2015 and December 2015, respectively. Our increases in selling, general and administrative ("SG&A") expense was primarily due to the preparations for the launch of ARISTADA in October 2015 following approval by the FDA.

Results of Operations

Years Ended December 31, 2015, 2014 and 2013

Manufacturing and Royalty Revenues

Manufacturing revenues are earned from the sale of products under arrangements with our licensees when product is shipped to them at an agreed upon price. Royalties are generally earned on our licensees' sales of products that incorporate our technologies and are recognized in the period the products are sold by our licensees. The following table compares manufacturing and royalty revenues earned in the years ended December 31, 2015, 2014 and 2013:

	Year Ended December 31,			Change Favorable/(Unfavorable)	
(In millions)	2015	2014	2013 (unaudited)	2015 - 2014	2014 - 2013
Manufacturing and royalty revenues:					
Continuing products:					
INVEGA SUSTENNA/XEPLION & INVEGA TRINZA	$ 149.7	$ 127.8	$ 97.7	$ 21.9	$ 30.1
AMPYRA/FAMPYRA	104.7	80.9	75.7	23.8	5.2
RISPERDAL CONSTA	100.7	120.6	137.9	(19.9)	(17.3)
BYDUREON	46.1	36.6	24.8	9.5	11.8
Other	55.3	80.6	114.7	(25.3)	(34.1)
	456.5	446.5	450.8	10.0	(4.3)
Divested products:					
RITALIN LA & FOCALIN XR	9.3	40.7	41.6	(31.4)	(0.9)
Other	9.5	29.7	25.6	(20.2)	4.1
	18.8	70.4	67.2	(51.6)	3.2
Manufacturing and royalty revenues	$ 475.3	$ 516.9	$ 518.0	$ (41.6)	$ (1.1)

Our partnered, long-acting antipsychotic franchise consists of INVEGA SUSTENNA/XEPLION and, upon its launch in June 2015, INVEGA TRINZA as well as RISPERDAL CONSTA. Under our INVEGA SUSTENNA/XEPLION and INVEGA TRINZA agreement with Janssen, we earn royalties on end-market net sales of INVEGA SUSTENNA/XEPLION and INVEGA TRINZA 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%. Under our RISPERDAL CONSTA supply and license agreements with Janssen, we earn manufacturing revenues at 7.5% of Janssen's unit net sales price of RISPERDAL CONSTA and royalty revenues at 2.5% of end-market sales.

The increase in INVEGA SUSTENNA/XEPLION and INVEGA TRINZA royalty revenues in each period was due to an increase in Janssen's end-market sales of INVEGA SUSTENNA/XEPLION and INVEGA TRINZA. Janssen's end-market sales of INVEGA SUSTENNA/XEPLION and INVEGA TRINZA were $1,830.0 million, $1,588.0 million and $1,248.0 million, during the years ended December 31, 2015, 2014 and 2013, respectively. Partially offsetting the increase in INVEGA SUSTENNA/XEPLION and INVEGA TRINZA end-market sales by Janssen in 2015, as compared to 2014, was an 8% decrease in revenue due to the strengthening of the U.S. dollar in relation to the currencies in which XEPLION was sold.

The decrease in RISPERDAL CONSTA revenue in each period was primarily due to a decline in Janssen's end-market net sales of RISPERDAL CONSTA. Janssen's end-market sales of RISPERDAL CONSTA were $970.0 million, $1,190.0 million and $1,318.0 million, during the years ended December 31, 2015, 2014 and 2013, respectively. The decline in Janssen's end-market sales led to a decrease in our royalty revenues of 18% in 2015, as compared to 2014 and 10% in 2014, as compared to 2013. Contributing to the decrease in RISPERDAL CONSTA end-market sales by Janssen in 2015, as compared to 2014, was a 9% decrease in revenue due to the strengthening of the U.S. dollar in relation to the currencies in which RISPERDAL CONSTA was sold.

The manufacturing revenue we earned on shipments of RISPERDAL CONSTA to Janssen also declined by 16% in 2015, as compared to 2014 and by 13% in 2014, as compared to 2013. The decrease in manufacturing revenue in 2015, as compared to 2014, was primarily due to a 17% decrease in the number of units shipped to Janssen. The decrease in manufacturing revenue in 2014, as compared to 2013, was primarily due to a 39% decrease in the number of units shipped to Janssen for resale in U.S., partially offset by an 8% increase in price and a 5% increase in the number of units shipped to Janssen for resale in countries other than the U.S., partially offset by a 4% decrease in price.

We expect revenues from our long-acting, atypical antipsychotic franchise to continue to grow as INVEGA SUSTENNA/XEPLION and INVEGA TRINZA 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 INVEGA SUSTENNA/XEPLION and INVEGA TRINZA and RISPERDAL CONSTA. Increased competition may lead to reduced unit sales of INVEGA SUSTENNA/XEPLION and INVEGA TRINZA and RISPERDAL CONSTA, as well as increasing pricing pressure. INVEGA SUSTENNA/XEPLION is covered by a patent until 2022 in the EU and 2019 in the U.S.; INVEGA TRINZA is covered by a patent until 2022 in the EU and 2017 in the U.S.; and RISPERDAL CONSTA is covered by a patent until 2021 in the EU and 2023 in the U.S. and, as such, we do not anticipate any generic versions in the near-term for either of these products.

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

The increase in AMPYRA/FAMPYRA revenues in 2015, as compared to 2014, was due to a 31% increase in manufacturing revenue and a 28% increase in royalty revenue. The increase in manufacturing revenue was primarily due to a 20% increase in product shipped to Acorda and Biogen and an 8% increase in price. The increase in royalty revenue was due to an increase in the end-market sales of AMPYRA/FAMPYRA as end-market sales of the product were $520.7 million, $446.4 million and $376.5 million in the years ended December 31, 2015, 2014 and 2013, respectively. The increase in AMPYRA/FAMPYRA revenues in 2014, as compared to 2013, was due to a 9% increase in royalty revenues, due primarily to the increase in end-market sales as previously noted, and a 4% increase in manufacturing revenues.

We expect AMPYRA/FAMPYRA sales to continue to grow as Acorda continues to penetrate the U.S. market with AMPYRA and Biogen continues to launch FAMPYRA in the rest of the world. AMPYRA is covered by a patent until 2027 in the U.S. and FAMPYRA is covered by a patent until 2025 in the EU. A number of companies, including us, are working to develop products to treat multiple sclerosis that may compete with AMPYRA/FAMPYRA, which may negatively impact future sales of the products. For a discussion of legal proceedings related to the patents covering AMPYRA, see “Item 3—Legal Proceedings.”

Under our BYDUREON license agreement with AstraZeneca, we earned royalties on end-market sales of BYDUREON of 8% in the years ended December 31, 2015, 2014 and 2013. The increase in BYDUREON royalty revenues in each period presented was due to an increase in end-market sales of BYDUREON. AstraZeneca’s end-market sales of BYDUREON was $580.0 million, $457.3 million and $311.5 million in 2015, 2014 and 2013, respectively. BYDUREON is covered by a patent until 2025 in the U.S. and until 2024 in the EU, and as such, we do not anticipate any generic versions of this product in the near-term.

Included in other manufacturing and royalty revenues in 2015, 2014 and 2013 was $9.5 million, $29.7 million and $25.6 million, respectively, of revenue associated with certain products manufactured at our Gainesville facility, including VERELAN, ZOHYDRO ER, and BIDIL, which were sold in April 2015. RITALIN LA and FOCALIN XR were also manufactured at our Gainesville facility. Included in revenue from 2013 was $30.0 million of IP license revenue unrelated to key development programs.

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 and, following its approval by the FDA in October 2015, ARISTADA, in the U.S. to wholesalers, specialty distributors and specialty pharmacies. The following table presents the

adjustments to arrive at product sales, net for sales of VIVITROL and ARISTADA in the U.S. during the years ended December 31, 2015, 2014 and 2013:

	Year Ended December 31,					
(In millions)	2015	% of Sales	2014	% of Sales	2013 (unaudited)	% of Sales
Product sales, gross	$ 227.0	100.0 %	$ 137.1	100.0 %	$ 99.4	100.0 %
Adjustments to product sales, gross:						
Medicaid rebates	(32.2)	(14.2)%	(11.1)	(8.1)%	(7.0)	(7.0)%
Chargebacks	(17.8)	(7.8)%	(9.3)	(6.8)%	(6.5)	(6.5)%
Product discounts	(13.2)	(5.8)%	(7.2)	(5.3)%	(4.5)	(4.5)%
Co-pay assistance	(6.5)	(2.9)%	(6.1)	(4.4)%	(4.6)	(4.6)%
Product returns	(2.2)	(1.0)%	(3.0)	(2.2)%	(1.1)	(1.1)%
Other	(6.1)	(2.7)%	(6.2)	(4.5)%	(3.9)	(3.9)%
Total adjustments	(78.0)	(34.4)%	(42.9)	(31.3)%	(27.6)	(27.8)%
Product sales, net	$ 149.0	65.6 %	$ 94.2	68.7 %	$ 71.8	72.2 %

The 66% increase in product sales, gross in 2015, as compared to 2014, was due to a 61% increase in VIVITROL gross sales and the launch of ARISTADA to the market in October 2015. The 61% increase in VIVITROL gross sales was primarily due to a 46% increase in the number of VIVITROL units sold and an 11% increase in the price of VIVITROL. The increase in product sales, gross in 2014, as compared to 2013, was due to a 32% increase in the number of VIVITROL units sold and a 5% increase in price. The increase in Medicaid rebates as a percentage of sales in 2015, as compared to 2014, and in 2014, as compared to 2013, was primarily due to an increase in the amount of VIVITROL sold under the Medicaid Drug Rebate Program.

We expect our product sales, net will continue to grow as VIVITROL continues to penetrate the opioid dependence market in the U.S., and as ARISTADA sales increase following its approval by the FDA in October 2015.

A number of companies, including us, are working to develop products to treat addiction, including alcohol and opioid dependence that may compete with and negatively impact future sales of VIVITROL. Increased competition may lead to reduced unit sales of VIVITROL, as well as increasing pricing pressure. VIVITROL is covered by a patent that will expire in the U.S. in 2029 and in Europe in 2021 and, as such, we do not anticipate any generic versions of this product in the near-term. A number of companies, including us, currently market and/or are working to develop products to treat schizophrenia that may compete with and negatively impact future sales of ARISTADA. Increased competition may lead to reduced unit sales of ARISTADA, as well as increasing pricing pressure. ARISTADA is covered by a patent that will expire in the U.S. in 2033, and, as such, we do not anticipate any generic versions of this product in the near-term.

Costs and Expenses

Cost of Goods Manufactured and Sold

	Year Ended December 31,			Change Favorable/(Unfavorable)	
(In millions)	2015	2014	2013 (unaudited)	2015 - 2014	2014 - 2013
Cost of goods manufactured and sold	$ 139.0	$ 175.8	$ 182.3	$ 36.8	$ 6.5

The decrease in cost of goods manufactured and sold in 2015, as compared to 2014, was primarily due to the Gainesville Transaction. During the years ended December 31, 2015 and 2014, the Gainesville facility had cost of goods manufactured of $10.2 million and $37.1 million, respectively. Also, in connection with the restructuring plan related to our Athlone, Ireland manufacturing facility initiated in April 2013, our cost of goods manufactured at our Athlone facility decreased by $14.3 million, with the most significant savings being occupancy and depreciation expense of $9.2 million and employee-related expenses of $4.1 million. These decreases were partially offset by an increase in cost of goods manufactured and sold related to our Ohio manufacturing facility of $4.4 million, which was primarily due to the increase in sales of VIVITROL and the launch of ARISTADA in October 2015, partially offset by a decrease in cost of goods manufactured for RISPERDAL CONSTA due to a decrease in the number of units shipped to Janssen.

The decrease in cost of goods manufactured and sold in 2014, as compared to 2013, was primarily due to an $8.5 million decrease in cost of goods manufactured for RISPERDAL CONSTA, which was primarily due to a 5% decrease in the number of units shipped to Janssen. This decrease was partially offset by a $3.2 million increase in the cost of goods sold for VIVITROL due to VIVITROL's increased sales.

Research and Development Expenses

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

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

	Year Ended December 31,			Change Favorable/(Unfavorable)	
(In millions)	2015	2014	2013 (unaudited)	2015 - 2014	2014 - 2013
External R&D Expenses:					
Key development programs:					
ALKS 5461	$ 108.4	$ 77.1	$ 8.4	$ (31.3)	$ (68.7)
ARISTADA	38.1	30.9	45.1	(7.2)	14.2
ALKS 3831	26.1	28.8	7.6	2.7	(21.2)
ALKS 8700	17.9	10.1	2.6	(7.8)	(7.5)
ALKS 6428	7.0	—	—	(7.0)	—
Other development programs	19.5	25.0	18.3	5.5	(6.7)
Total external R&D expenses	217.0	171.9	82.0	(45.1)	(89.9)
Internal R&D expenses:					
Employee-related	97.5	75.7	57.9	(21.8)	(17.8)
Occupancy	8.1	6.9	11.1	(1.2)	4.2
Depreciation	6.2	8.2	7.6	2.0	(0.6)
Other	15.6	9.3	5.3	(6.3)	(4.0)
Total internal R&D expenses	127.4	100.1	81.9	(27.3)	(18.2)
Research and development expenses	$ 344.4	$ 272.0	$ 163.9	$ (72.4)	$ (108.1)

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

The fluctuations in the expenses from period to period in our key development programs are primarily due to the timing and level of study activity. We initiated the pivotal clinical development program for ALKS 5461 in March 2014. Data from the first study, FORWARD-1, was announced in December 2015 and data from FORWARD-3 and FORWARD-4 was announced in January 2016. There is one additional on-going study, FORWARD-5, from which data is due later in 2016. ARISTADA was approved by the FDA in October 2015 following an NDA filing in August 2014 based on the positive phase 3 results announced in April 2014. Also, in December 2014, we initiated a phase 1 clinical study of extended dosing intervals of ARISTADA in patients with schizophrenia. We completed a phase 2 study of ALKS 3831, initiated in 2013, to assess the safety, tolerability and impact of ALKS 3831 on weight gain and other metabolic factors in patients with schizophrenia and announced the results from this study in 2015. In December 2015, we announced that we advanced ALKS 3831 into a pivotal development program, referred to as ENLIGHTEN. We initiated a phase 1 study of ALKS 8700 in 2014 and announced data from the study in 2015. In December 2015, we announced that we had advanced ALKS 8700 into a pivotal development program. In September 2015, we initiated a phase 3 program for ALKS 6428. For additional detail on the status of our key development programs, refer to "Key Development Programs" within Part 1, Item 1, "Business" in this Annual Report. Expenses incurred under the ALKS 7119 and RDB 1450 development programs in 2015, 2014 and 2013 were not material.

The increase in employee-related expenses was primarily due to an increase in headcount and share-based compensation expense. Our R&D related headcount increased by 20% and 23% in 2015, as compared to 2014, and in 2014 as compared to 2013, respectively. The increase in share-based compensation expense in 2015, as compared to 2014, and in 2014, as compared to 2013, was primarily due to recent equity grants being awarded with higher grant-date fair values than older grants due to the increase in our stock price.

Selling, General and Administrative Expenses

(In millions)	Year Ended December 31, 2015	2014	2013 (unaudited)	Change Favorable/(Unfavorable) 2015 - 2014	2014 - 2013
Selling, general and administrative expense	$ 311.6	$ 199.9	$ 151.2	$ (111.7)	$ (48.7)

The increase in SG&A expense in 2015, as compared to 2014, was primarily due to the preparation of the launch of ARISTADA in October 2015, which consisted of an $82.9 million increase in employee-related expenses and a $24.3 million increase in marketing and professional services expenses. The increase in employee-related expenses was primarily due to a 92% increase in SG&A-related headcount and a $26.4 million increase in share-based compensation expense due to the increase in the amount of equity awards granted, the vesting of performance-based restricted stock units in October 2015 that were tied to the approval of ARISTADA and that recent equity grants being awarded with higher grant-date fair values than older grants due to the increase in our stock price. The increase in marketing and professional services expenses were primarily due to pre-launch activities for ARISTADA.

The increase in SG&A expenses in 2014, as compared to 2013, was primarily due to a $23.9 million increase in employee-related expenses and a $20.9 million increase in marketing and professional services expenses. The increase in employee-related expenses was primarily due to a 21% increase in SG&A-related headcount and an $11.3 million increase in share-based compensation expense due to equity grants being awarded with higher grant-date fair values than older grants due to the increase in our stock price. The increase in marketing and professional services expenses were primarily due to activity around a label update for VIVITROL and pre-launch activities for ARISTADA.

Amortization of Acquired Intangible Assets

(In millions)	Year Ended December 31, 2015	2014	2013 (unaudited)	Change Favorable/(Unfavorable) 2015 - 2014	2014 - 2013
Amortization of acquired intangible assets	$ 57.7	$ 58.2	$ 48.8	$ 0.5	$ (9.4)

Our amortizable intangible assets consist of technology and collaborative arrangements acquired as part of the acquisition of EDT in September 2011, which are being amortized over 12 to 13 years. We amortize our amortizable intangible assets using the economic use method, which reflects the pattern that the economic benefits of the intangible assets are consumed as revenue is generated from the underlying patent or contract.

As part of the Gainesville Transaction, we sold certain of the intellectual property we acquired from EDT that had an original cost of $57.8 million. Based on our most recent analysis, amortization of intangible assets included within our consolidated balance sheet at December 31, 2015 is expected to be approximately $60.0 million, $60.0 million, $60.0 million, $55.0 million and $50.0 million in the years ending December 31, 2016 through 2020, respectively.

Other Income (Expense), Net

(In millions)	Year Ended December 31, 2015	2014	2013 (unaudited)	Change Favorable/(Unfavorable) 2015 - 2014	2014 - 2013
Interest income	$ 3.3	$ 2.0	$ 0.9	$ 1.3	$ 1.1
Interest expense	(13.2)	(13.4)	(21.9)	0.2	8.5
Gain on the Gainesville Transaction	9.6	—	—	9.6	—
Decrease in the fair value of contingent consideration	(2.3)	—	—	(2.3)	—
Gain on sale of property, plant and equipment	2.9	41.9	—	(39.0)	41.9
Gain on sale of investment in Civitas Therapeutics, Inc.	—	29.6	—	(29.6)	29.6
Gain on sale of investment in Acceleron Pharma Inc.	—	15.3	—	(15.3)	15.3
Other income (expense), net	—	(2.3)	(0.2)	2.3	(2.1)
Total other income (expense), net	$ 0.3	$ 73.1	$ (21.2)	$ (72.8)	$ 94.3

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

In April 2015, we completed the Gainesville Transaction which included the sale of: our manufacturing facility in Gainesville, GA; the related manufacturing and royalty revenue associated with certain products manufactured at this facility including RITALIN LA, FOCALIN XR, VERELAN, ZOHYDRO ER, and BIDIL; and the IV/IM and parenteral

formulations of Meloxicam, a nonsteroidal anti-inflammatory drug, which has completed multiple phase 2 trials for the management of moderate-to-severe acute pain. We acquired these assets in 2011 as part of our business combination with EDT.

The proceeds from the Gainesville Transaction consisted of $54.0 million in cash, $2.1 million in warrants to acquire Recro common stock and $57.6 million in contingent consideration tied to low double digit royalties on net sales of IV/IM and parenteral forms of Meloxicam, and up to $120.0 million in milestone payments upon the achievement of certain regulatory and sales milestones related to IV/IM and parenteral forms of Meloxicam. We determined the fair value of the contingent consideration through three valuation approaches, which are described in greater detail in Note 3, *Divestiture*, in the "Notes to Consolidated Financial Statements" in this Annual Report.

We will, at each reporting date, update our assessment of the fair value of this contingent consideration and reflect any changes to the fair value within the consolidated statements of operations and comprehensive (loss) income until the milestones and/or royalties included in the contingent consideration have been settled. During the year ended December 31, 2015, we determined that the fair value of the contingent consideration decreased by $2.3 million, which was primarily due to a delay in the timing of future clinical events.

Gain on the sale of property, plant and equipment in 2014 consists of the following two transactions: in April 2014, we sold certain of our land, buildings and equipment at our Athlone, Ireland facility that had a carrying value of $2.2 million, in exchange for $17.5 million and recorded a gain of $12.3 million, as $3.0 million of the sale proceeds were placed in escrow pending the completion of certain additional services we were obligated to perform, which were completed in December 2015. In October 2014, we sold certain of our commercial-scale pulmonary manufacturing equipment which had a carrying value of $0.4 million, to Acorda in exchange for $30.0 million.

In October 2014, in connection with the acquisition of Civitas by Acorda, we received $27.2 million and $2.4 million was placed in escrow, for our approximate 6% equity interest in Civitas. We received the amounts held in escrow in October 2015. During the second quarter of 2014, we sold our investment in Acceleron Pharma Inc., which consisted of equity securities, for a gain of $15.3 million.

Provision (Benefit) for Income Taxes

	Year Ended December 31,			Change Favorable/(Unfavorable)	
(In millions)	2015	2014	2013 (unaudited)	2015 - 2014	2014 - 2013
Provision (benefit) for income taxes	$ 3.2	$ 16.0	$ (7.4)	$ 12.8	$ (23.4)

The income tax provision for the years ended December 31, 2015 and 2014 was primarily due to U.S. federal and state taxes on income earned in the U.S. The income tax benefit in the year ended December 31, 2013 was primarily due to the release of the valuation allowance held against U.S. deferred tax assets, partially offset by federal and state taxes on income earned in the U.S.

No provision for income tax has been provided on undistributed earnings of our foreign subsidiaries because such earnings may be repatriated to Ireland without incurring any tax liability. Cumulative unremitted earnings of overseas subsidiaries totaled approximately $107.0 million at December 31, 2015.

At December 31, 2015, we maintained a valuation allowance of $2.6 million against certain U.S. state deferred tax assets and $104.2 million against certain Irish deferred tax assets as we determined that it is more-likely-than-not that these net deferred tax assets will not be realized. If we demonstrate consistent profitability in the future, the evaluation of the recoverability of these deferred tax assets may change and the remaining valuation allowance may be released in part or in whole.

As of December 31, 2015, we had $881.0 million of Irish NOL carryforwards, $5.5 million of U.S. federal NOL carryforwards and $7.2 million of U.S. state NOL carryforwards, $44.8 million of federal R&D credits, $9.8 million of alternative minimum tax credits and $5.9 million of U.S. state tax credits which either expire on various dates through 2035 or can be carried forward indefinitely. These loss carryforwards and credits are available to reduce certain future Irish and U.S. taxable income and tax, respectively, if any. These loss carryforwards are subject to review and possible adjustment by the appropriate taxing authorities. These loss carryforwards, which may be utilized in any future period, may be subject to limitations based upon changes in the ownership of our stock. We have performed a review of

ownership changes in accordance with the Code and have determined that it is more-likely-than-not that, as a result of the Business Combination, we experienced a change of ownership. As a consequence, a portion of our U.S. federal NOL carryforwards and tax credit carryforwards are subject to an annual limitation of $127.0 million.

Nine Months Ended December 31, 2013 and 2012

Manufacturing and Royalty Revenues

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

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

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

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

The increase in BYDUREON royalty revenues was due to an increase in end-market sales of BYDUREON from $145.7 million during the nine months ended December 31, 2012 to $242.1 million during the nine months ended December 31, 2013.

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

Product Sales, Net

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

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

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

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

Costs and Expenses

Cost of Goods Manufactured and Sold

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

The increase in cost of goods manufactured and sold was primarily due to a $6.2 million increase in cost of goods manufactured for RISPERDAL CONSTA and a $4.5 million increase in depreciation at our Athlone, Ireland manufacturing facility. The increase in RISPERDAL CONSTA cost of goods manufactured was primarily due to the 9% increase in the number of units shipped to Janssen. The increase in depreciation expense at our Athlone, Ireland manufacturing facility was due to $5.4 million of accelerated depreciation on certain of our manufacturing assets that will have no future use at the completion of our restructuring plan in the year ended December 31, 2015.

Research and Development Expenses

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

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

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

Selling, General and Administrative Expenses

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

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

Amortization of Acquired Intangible Assets

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

Our amortizable intangible assets consist of technology and collaborative arrangements acquired as part of the acquisition of EDT in 2011 which are being amortized over 12 to 13 years. We amortize our amortizable intangible assets using the economic use method, which reflects the pattern that the economic benefits of the intangible assets are consumed as revenue is generated from the underlying patent or contract.

Other Expense, Net

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

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

(Benefit) Provision for Income Taxes

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

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

Liquidity and Capital Resources

Our financial condition is summarized as follows:

(In millions)	December 31, 2015 U.S.	December 31, 2015 Ireland	December 31, 2015 Total	December 31, 2014 U.S.	December 31, 2014 Ireland	December 31, 2014 Total
Cash and cash equivalents	$ 70.8	$ 110.3	$ 181.1	$ 69.6	$ 154.4	$ 224.0
Investments—short-term	202.4	151.2	353.6	182.7	224.4	407.1
Investments—long-term	129.1	135.0	264.1	68.7	101.8	170.5
Total cash and investments	$ 402.3	$ 396.5	$ 798.8	$ 321.0	$ 480.6	$ 801.6
Outstanding borrowings—current and long-term	$ 349.9	$ —	$ 349.9	$ 355.8	$ —	$ 355.8

At December 31, 2015, our investments consisted of the following:

(In millions)	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Investments—short-term	$ 354.0	$ 0.1	$ (0.4)	$ 353.7
Investments—long-term available-for-sale	261.6	—	(1.0)	260.6
Investments—long-term held-to-maturity	3.4	—	—	3.4
Total	$ 619.0	$ 0.1	$ (1.4)	$ 617.7

Sources and Uses of Cash

We used $40.4 million and generated cash from operations of $11.1 million and $92.2 million during the years ended December 31, 2015 and 2014 and the nine months ended December 31, 2013, respectively. We expect that our existing cash and investments will be sufficient to finance our anticipated working capital and other cash requirements, such as capital expenditures and principal and interest payments on our long-term debt for at least the next twelve months.

Our investment objectives are, first, to preserve liquidity and conserve capital and, second, to generate investment income. We mitigate credit risk in our cash reserves by maintaining a well-diversified portfolio that limits the amount of investment exposure as to institution, maturity and investment type. Our available-for-sale investments consist primarily of short- and long-term U.S. government and agency debt securities and corporate debt securities. We classify

available-for-sale investments in an unrealized loss position, which do not mature within 12 months, as long-term investments. We have the intent and ability to hold these investments until recovery, which may be at maturity, and it is more-likely-than-not that we would not be required to sell these securities before recovery of their amortized cost. At December 31, 2015, we performed an analysis of our investments with unrealized losses for impairment and determined that they were temporarily impaired.

Information about our cash flows, by category, is presented in the accompanying consolidated statements of cash flows. The following table summarizes our cash flows for the years ended December 31, 2015 and 2014 and the nine months ended December 31, 2013:

(In millions)	Year Ended December 31, 2015	Year Ended December 31, 2014	Nine Months Ended December 31, 2013
Cash and cash equivalents, beginning of period	$ 224.1	$ 167.6	$ 97.0
Cash (used in) provided by operating activities	(40.4)	11.1	92.2
Cash used in investing activities	(43.5)	(263.4)	(65.4)
Cash provided by financing activities	40.9	308.8	43.8
Cash and cash equivalents, end of period	$ 181.1	$ 224.1	$ 167.6

Operating Activities

The $51.5 million increase in cash used in operating activities in 2015, as compared to 2014, was primarily due to a $53.4 million increase in the amount of cash paid to our employees and a $18.5 million increase in the amount of cash paid to our suppliers, partially offset by a $10.9 million increase in the amount of cash we collected from our customers. The increase in the amount of cash paid to our employees is primarily due to the increase in our headcount and the increase in the amount of cash paid to our suppliers is due to the increase in R&D and commercial activity, as previously discussed.

The decrease in cash provided by operating activities in 2014, as compared to 2013, was also primarily due to the increased spending on our R&D pipeline and commercial activities, as previously discussed.

Investing Activities

Cash used in investing activities decreased by $219.9 million in 2015, as compared to 2014, which was primarily due to a decrease in the net purchases of investments of $260.2 million. The net purchases of investments in 2014 were greater than that in 2015 and 2013 due to certain significant transactions occurring in 2014 including: the receipt of $250.0 million in gross proceeds from the sale of 5.9 million of our ordinary shares to the Invesco Funds in January 2014; the receipt of $17.5 million from the sale of certain of our land, buildings and equipment located at our Athlone, Ireland facility in April 2014; and the receipt of $57.2 million from Civitas, $30.0 million of which was from the sale of certain commercial-scale pulmonary manufacturing equipment and $27.2 million for our approximate 6% equity interest in Civitas when they were acquired by Acorda in October 2015. We used the majority of the proceeds from these transactions to purchase available-for-sale investments.

As discussed previously, in 2015 we received $50.0 million in net proceeds from the Gainesville Transaction. Also, in 2015, we increased our capital spending when compared to 2014, and in 2014 when compared to 2013, primarily for the construction of facilities and equipment at our Wilmington, Ohio and Athlone, Ireland locations for the manufacture of products currently in development and existing proprietary products.

We expect to spend approximately $45.0 million during the year ended December 31, 2016 for capital expenditures. Amounts included as construction in progress at December 31, 2015 primarily include capital expenditures at our manufacturing facility in Wilmington, 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 decrease in cash provided by financing activities in 2015, as compared to 2014, was primarily due to the Invesco transaction, as noted above. We also spent $13.1 million more in employee taxes related to the net share settlement of equity awards in 2015, as compared to 2014, but received $3.8 million less in proceeds from the exercise of stock options by our employees.

The increase in cash provided by financing activities in 2014, as compared to 2013, was primarily due to the Invesco transaction and a $21.0 million increase in excess tax benefit from share-based compensation.

Borrowings

At December 31, 2015, our borrowings consisted of $353.1 million outstanding under our Term Loan Facility. Please refer to Note 10, *Long-Term Debt*, in the accompanying "Notes to Consolidated Financial Statements" for a discussion of our outstanding term loans.

Contractual Obligations

The following table summarizes our obligations to make future payments under our current contracts at December 31, 2015:

Contractual Obligations	Total	Less Than One Year (2016)	One to Three Years (2017 - 2018)	Three to Five Years (2019 - 2020)	More than Five Years (After 2020)
			(In thousands)		
Term Loan Facility—Principal	$353,063	$ 65,813	$ 6,000	$ 281,250	$ —
Term Loan Facility—Interest	38,881	11,594	19,924	7,363	—
Operating lease obligations	26,870	5,708	11,629	8,600	933
Purchase obligations	398,950	398,950	—	—	—
Total contractual cash obligations	$817,764	$482,065	$ 37,553	$ 297,213	$ 933

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 0.43%, which was the approximate one-month LIBOR rate at December 31, 2015. This table excludes any liabilities pertaining to uncertain tax positions as we cannot make a reliable estimate of the period of cash settlement with the respective taxing authorities.

At December 31, 2015, we had $3.8 million of net liabilities associated with uncertain tax positions. We do not anticipate that the amount of existing unrecognized tax benefits will significantly increase or decrease within the next 12 months.

In September 2006, we entered into a license agreement with the Rensselaer Polytechnic Institute ("RPI"), which granted us exclusive rights to a family of opioid receptor compounds discovered at RPI. Under the terms of the agreement, RPI granted us an exclusive worldwide license to certain patents and patent applications relating to its compounds designed to modulate opioid receptors. We are responsible for the continued research and development of any resulting product candidates. We are obligated to pay annual fees of up to $0.2 million, and tiered royalty payments of between 1% and 4% of annual net sales in the event any products developed under the agreement are commercialized. In addition, we are obligated to make milestone payments in the aggregate of up to $7.0 million upon certain agreed-upon development events. All amounts paid to RPI to date under this license agreement have been expensed and are included in R&D expenses.

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

Off-Balance Sheet Arrangements

At December 31, 2015, we were not a party to any off-balance sheet arrangements that have, or are reasonably likely to have, a current or future effect on our financial condition, results of operations, liquidity, capital expenditures or capital resources.

Critical Accounting Estimates

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

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

Manufacturing and Royalty Revenue

Our manufacturing and royalty revenues are earned under the terms of collaboration agreements with pharmaceutical companies, the most significant of which include Janssen for INVEGA SUSTENNA/XEPLION and INVEGA TRINZA, as well as RISPERDAL CONSTA, Acorda for AMPYRA/FAMPYRA and AstraZeneca for BYDUREON. Manufacturing revenues are recognized when persuasive evidence of an arrangement exists, delivery has occurred and title to the product and associated risk of loss has passed to the customer, the sales price is fixed or determinable and collectability is reasonably assured.

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

Royalty revenues are related to the sale of products by our collaborative partners that incorporate our technologies. Royalties, with the exception of AMPYRA, are earned under the terms of a license agreement in the period the products are sold by our collaborative partner, and the royalty earned can be reliably measured and collectability is reasonably assured. Sales information is provided to us by our collaborative partners and may require estimates to be made. Differences between actual royalty revenues and estimated royalty revenues are reconciled and adjusted for in the period in which they become known, which is generally the following quarter. The difference between actual and estimated royalty revenues has not been material. Royalties on AMPYRA are earned in the period product is shipped to Acorda. We also earn royalties on shipments of AMPYRA to Acorda manufactured by third-party manufacturers.

Product Sales, Net

We recognize revenue from product sales of VIVITROL and ARISTADA 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 and ARISTADA to pharmaceutical wholesalers, specialty distributors and specialty pharmacies.

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 product sales net of the following significant categories of product sales allowances:

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

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

- *Product Discounts*—cash consideration, including sales incentives, given by us under distribution service agreements with a number of wholesaler, distributor and specialty pharmacy customers that provide them with the opportunity to earn discounts in exchange for the performance of certain services. To date, actual product discounts have not differed materially from our estimates;

- *Co-pay Assistance*— the Company has a program whereby a patient can receive monetary assistance each month toward their product co-payment, co-insurance or deductible, provided the patient meets certain eligibility criteria. Reserves are recorded upon the product sale. To date, actual co-pay assistance has not differed materially from the Company's estimates; and

- *Product Returns*—we record an estimate for product returns at the time our customer takes title to our product. We estimate the liability based on our historical return levels and specifically identified anticipated returns due to known business conditions and product expiry dates. Once product is returned, it is destroyed. At December 31, 2015, our product return reserve was estimated to be approximately 1.5% of our product sales.

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

(In millions)	Medicaid Rebates	Chargebacks	Product Discounts	Co-Pay Assistance	Product Returns	Other	Total
Balance, December 31, 2013	$ 2.7	$ —	$ 0.8	$ 0.2	$ 3.8	$ —	$ 7.5
Provision:							
Current period	11.0	9.3	7.4	5.8	3.0	4.7	41.2
Prior period	0.1	—	(0.2)	0.3	—	1.5	1.7
Total	11.1	9.3	7.2	6.1	3.0	6.2	42.9
Actual:							
Current period	(7.2)	(9.2)	(7.0)	(6.3)	—	(3.4)	(33.1)
Prior period	(2.9)	—	(0.1)	—	(1.3)	(0.9)	(5.2)
Total	(10.1)	(9.2)	(7.1)	(6.3)	(1.3)	(4.3)	(38.3)
Balance, December 31, 2014	$ 3.7	$ 0.1	$ 0.9	$ —	$ 5.5	$ 1.9	$ 12.1
Provision:							
Current period	31.4	17.8	13.2	7.2	3.3	6.1	79.0
Prior period	0.8	—	—	(0.7)	(1.1)	—	(1.0)
Total	32.2	17.8	13.2	6.5	2.2	6.1	78.0
Actual:							
Current period	(14.2)	(17.3)	(10.7)	(6.7)	(0.9)	(4.4)	(54.2)
Prior period	(4.5)	—	(0.5)	—	(0.1)	(0.2)	(5.3)
Total	(18.7)	(17.3)	(11.2)	(6.7)	(1.0)	(4.6)	(59.5)
Balance, December 31, 2015	$ 17.2	0.6	2.9	(0.2)	6.7	3.4	30.6

Investments

We hold investments in U.S. government and agency obligations, debt securities issued by foreign agencies and backed by foreign governments and corporate debt securities. In accordance with the accounting standard for fair value measurements, we have classified our financial assets as Level 1, 2 or 3 within the fair value hierarchy. Fair values determined by Level 1 inputs utilize quoted prices in active markets for identical assets that we have the ability to access. Fair values determined by Level 2 inputs utilize data points that are observable such as quoted prices, interest rates and yield curves. Fair values determined by Level 3 inputs utilize unobservable data points for the asset.

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.

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 shares 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 years ended December 31, 2015 and 2014 and the nine months ended December 31, 2013, the ranges in weighted-average assumptions were as follows:

	Year Ended December 31, 2015	Year Ended December 31, 2014	Nine Months Ended December 31, 2013
Expected option term	5 - 7 years	5 - 7 years	5 - 7 years
Expected stock volatility	38 % - 46 %	39 % - 46 %	45 % - 48 %
Risk-free interest rate	1.29 % - 2.02 %	1.46 % - 2.24 %	0.75 % - 2.15 %
Expected annual dividend yield	—	—	—

In addition to the above, we apply judgment in developing estimates of award forfeitures. For the year ended December 31, 2015, we used an estimated forfeiture rate of zero for our non-employee directors, 1.75% for members of senior management and 8.25% for all other employees.

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

Amortization and Impairment of Long-Lived Assets

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

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

Our amortizable intangible assets include technology and collaborative arrangements that were acquired as part of the Business Combination. These intangible assets are being amortized as revenue is generated from these products, which we refer to as the economic benefit amortization model. This amortization methodology involves calculating a ratio of actual current period sales to total anticipated sales for the life of the product and applying this ratio to the carrying amount of the intangible asset.

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

Based on our most recent analysis, amortization of intangible assets included within our consolidated balance sheet at December 31, 2015, is expected to be approximately $60.0 million, $60.0 million, $60.0 million, $55.0 million and $50.0 million in the years ending December 31, 2016 through 2020, 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 for our reporting units annually, as of October 31, and whenever events or changes in circumstances indicate its carrying value may not be recoverable. 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, 2015, we have one operating segment and two reporting units. Our goodwill, which solely relates to Business Combination, has been assigned to one reporting unit which consists of the former EDT business.

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

The first step of the quantitative two-step 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 considered the Gainesville Transaction to be a change in circumstance requiring an analysis as to the recoverability of our goodwill. Accordingly, we performed a goodwill assessment when we determined that the Gainesville assets were considered "held-for-sale" and upon closing of the Gainesville Transaction, and we determined that the fair value of the reporting unit was substantially in excess of its carrying value at both dates. For our annual impairment analysis at October 31, 2015, we elected to first assess qualitative factors to determine whether it was necessary to perform the two step impairment test. Based on the weight of all available evidence, including the significance in which the fair value of our reporting unit was in excess of its carrying value at the closing of the Gainesville Transaction and the increase in its fair value from the date of the Gainesville Transaction to October 31, 2015, we determined that the fair value of the reporting unit more likely than not exceeded its carrying value.

Contingent Consideration

We record contingent consideration we receive at fair value on the acquisition date. We estimate the fair value of contingent consideration through valuation models that incorporate probability-adjusted assumptions related to the achievement of milestones and thus likelihood of receiving related payments. We revalue our contingent consideration each reporting period, with changes in the fair value of contingent consideration recognized within the consolidated statements of operations and comprehensive (loss) income. Changes in the fair value of contingent consideration can result from changes to one or multiple inputs, including adjustments to the discount rates, changes in the amount or timing of cash flows, changes in the assumed achievement or timing of any development or sales-based milestones and changes in the assumed probability associated with regulatory approval.

The period over which we discount contingent consideration is based on the current development stage of the product candidates, the specific development plan for that product candidate adjusted for the probability of completing the development step, and the date on which contingent payments would be triggered. In estimating the probability of success, we utilize data regarding similar milestone events from several sources, including industry studies and our own experience. These fair value measurements are based on significant inputs not observable in the market. Significant judgment was employed in determining the appropriateness of these assumptions at the acquisition date and for each

subsequent period. Accordingly, changes in assumptions described above could have a material impact on the increase or decrease in the fair value of contingent consideration recorded in any given period.

In accordance with the accounting standard for fair value measurements, our contingent consideration has been classified as a Level 3 asset as its fair value is based on significant inputs not observable in the market. The contingent consideration consists of three distinct earn-out scenarios and the fair value was determined as follows:

- We are entitled to receive payments based on the achievement of regulatory milestone events. The fair value of the two regulatory milestones were estimated based on applying the likelihood of achieving the regulatory milestone and applying a discount rate from the expected time the milestone occurs to the balance sheet date. We expect the regulatory milestone events to occur within the next two and three years, respectively, and used a discount rate of 4.0% and 5.3%, respectively, for each of these events;

- We are entitled to receive future royalties on net sales of IV/IM and parenteral forms of Meloxicam. To estimate the fair value of the future royalties, we assessed the likelihood of IV/IM and parenteral forms of Meloxicam being approved for sale and estimated the expected future sales given approval and IP protection. We then discounted these expected payments using a discount rate of 17.0%, which we believe captures a market participant's view of the risk associated with the expected payments;

- We are entitled to receive payments upon achieving certain sales milestones on future sales of IV/IM and parenteral forms of Meloxicam. The sales milestones were determined through the use of a real options approach, where net sales are simulated in a risk-neutral world. To employ this methodology, we used a risk-adjusted expected growth rate based on its assessments of expected growth in net sales of the approved IV/IM and parenteral forms of Meloxicam, adjusted by an appropriate factor capturing their respective correlation with the market. A resulting expected (probability-weighted) milestone payment was then discounted at a cost of debt plus a risk adjustment, which ranged from 13.2% to 15.4%.

Significant judgment was employed in determining the appropriateness of these assumptions at the acquisition date and for each subsequent period. Accordingly, changes in assumptions described above could have a material impact on the increase or decrease in the fair value of contingent consideration we record in any given period.

Valuation of Deferred Tax Assets

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

- future reversals of existing taxable temporary differences;
- future taxable income exclusive of reversing temporary differences and carryforwards;
- taxable income in prior carryback years; and
- tax-planning strategies.

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

- nature, frequency and severity of recent losses;
- duration of statutory carryforward periods;
- historical experience with tax attributes expiring unused; and
- near- and medium-term financial outlook.

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

The evaluation of deferred tax assets requires judgment in assessing the likely future tax consequences of events that have been recognized in our financial statements or tax returns and future profitability. Our accounting for deferred tax

consequences represents our best estimate of those future events. Changes in our current estimates, due to unanticipated events or otherwise, could have a material effect on our financial condition and results of operations.

Recent Accounting Pronouncements

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

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

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

We do not believe that inflation and changing prices have had a material impact on our results of operations, and as approximately 57% of our investments are in debt securities issued by the U.S. government or its agencies, our exposure to liquidity and credit risk is not believed to be significant.

At December 31, 2015, our borrowings consisted of $353.1 million outstanding under our Term Loan Facility. Term Loan B-1 bears interest at three-month LIBOR plus 2.75% with a LIBOR floor of 0.75%. As the three-month LIBOR rate was 0.61% at December 31, 2015, and the LIBOR floor under Term Loan B-1 is 0.75%, we do not expect changes in the three-month LIBOR to have a material effect on our financial statements through December 31, 2016. Term Loan B-2 bears interest at one-month LIBOR plus 2.75% with no LIBOR floor. At December 31, 2015, the one-month LIBOR rate was 0.43%. A 10% increase in the one-month LIBOR rate would have increased our interest expense in the year ended December 31, 2015 by an immaterial amount.

Currency Exchange Rate Risk

Manufacturing and royalty revenues we receive on certain of our products and services are a percentage of the net sales made by our licensees and a portion of these sales are made in countries outside the U.S. and are denominated in currencies in which the product is sold, which is predominantly the Euro. The manufacturing and royalty payments on these non-U.S. sales are calculated initially in the currency in which the sale is made and are then converted into USD to determine the amount that our partners pay us for manufacturing and royalty revenues. Fluctuations in the exchange ratio of the USD and these non-U.S. currencies will have the effect of increasing or decreasing our revenues even if there is a constant amount of sales in non-U.S. currencies. For example, if the USD weakens against a non-U.S. currency, then our revenues will increase given a constant amount of sales in such non-U.S. currency. For the year ended December 31, 2015, an average 10% strengthening of the USD relative to the currencies in which these products are sold would have resulted in revenues being reduced by approximately $17.3 million.

We incur significant operating costs in Ireland and face exposure to changes in the exchange ratio of the USD and the Euro arising from expenses and payables at our Irish operations that are settled in Euro. The impact of changes in the exchange ratio of the USD and the Euro on our USD denominated revenues earned in countries other than the U.S. is largely offset by the opposite impact of changes in the exchange ratio of the USD and the Euro on operating expenses and payables incurred at our Irish operations that are settled in Euro. For the year ended December 31, 2015, an average 10% weakening in the USD relative to the Euro would have resulted in an increase to our expenses denominated in Euro of approximately $6.7 million.

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

Selected Quarterly Financial Data (unaudited)

(In thousands, except per share data)	First Quarter	Second Quarter	Third Quarter	Fourth Quarter	Total
Year Ended December 31, 2015					
REVENUES:					
Manufacturing and royalty revenues	$128,744	$113,162	$114,072	$119,310	$ 475,288
Product sales, net	31,137	37,172	37,903	42,816	149,028
Research and development revenue	1,333	1,036	678	972	4,019
Total revenues	161,214	151,370	152,653	163,098	628,335
EXPENSES:					
Cost of goods manufactured and sold	39,974	30,418	33,806	34,791	138,989
Research and development	70,278	87,882	92,558	93,686	344,404
Selling, general and administrative	63,050	71,539	89,497	87,472	311,558
Amortization of acquired intangible assets	15,220	14,052	14,207	14,206	57,685
Total expenses	188,522	203,891	230,068	230,155	852,636
OPERATING LOSS	(27,308)	(52,521)	(77,415)	(67,057)	(224,301)
OTHER (EXPENSE) INCOME, NET[1]	(2,839)	9,476	(605)	(5,736)	296
LOSS BEFORE INCOME TAXES	(30,147)	(43,045)	(78,020)	(72,793)	(224,005)
INCOME TAX PROVISION (BENEFIT)	510	3,064	2,995	(3,411)	3,158
NET LOSS	$ (30,657)	$ (46,109)	$ (81,015)	$ (69,382)	$(227,163)
LOSS PER SHARE—BASIC AND DILUTED	$ (0.21)	$ (0.31)	$ (0.54)	$ (0.46)	$ (1.52)

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

(1) In April 2015, we entered into the Gainesville Transaction and recorded a Gain on the Gainesville Transaction of $9.9 million in the second quarter of 2015. In the fourth quarter, we reduced the Gain on the Gainesville Transaction to $9.6 million due to an increase in transaction costs.

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

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

Not applicable.

Item 9A. Controls and Procedures

Disclosure Controls and Procedures and Internal Control Over Financial Reporting

Controls and Procedures

Our management has evaluated, with the participation of our principal executive officer and principal financial officer, the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act), as of December 31, 2015. Based upon that evaluation, our principal executive officer and principal financial officer concluded that, as of the end of the period covered by this report, our disclosure controls and procedures were effective to provide reasonable assurance that (a) the information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms, and (b) such information is accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate to allow timely decisions regarding required disclosure. In designing and evaluating our disclosure controls and procedures, our management recognized that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives, and our management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting during the quarter ended December 31, 2015 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Management's Annual Report on Internal Control over Financial Reporting

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

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

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

Our management assessed the effectiveness of our internal control over financial reporting as of December 31, 2015. In making this assessment, management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission ("COSO") in its 2013 Internal Control—Integrated Framework.

Based on this assessment, our management has concluded that, as of December 31, 2015, our internal control over financial reporting was effective.

The effectiveness of our internal control over financial reporting as of December 31, 2015 has been audited by PricewaterhouseCoopers LLP, an independent registered public accounting firm, as stated in their report, which is included herein.

Item 9B. Other Information

The Company's policy governing transactions in its securities by its directors, officers and employees permits its officers, directors and employees to enter into trading plans in accordance with Rule 10b5-1 under the Exchange Act. During the quarter ended December 31, 2015, Dr. Elliot W. Ehrich and Messrs. Iain M. Brown, James M. Frates, Michael J. Landine, Richard F. Pops and Mark Stejbach, each an executive officer of the Company, entered into trading plans in accordance with Rule 10b5-1, and the Company's policy governing transactions in its securities by its directors, officers and employees. The Company undertakes no obligation to update or revise the information provided herein, including for revision or termination of an established trading plan.

PART III

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

The information required by this item is incorporated herein by reference to the Proxy Statement for our 2016 Annual General Meeting of Shareholders.

Item 11. ***Executive Compensation***

The information required by this item is incorporated herein by reference to the Proxy Statement for our 2016 Annual General Meeting of Shareholders.

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

The information required by this item is incorporated herein by reference to the Proxy Statement for our 2016 Annual General Meeting of Shareholders.

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

The information required by this item is incorporated herein by reference to the Proxy Statement for our 2016 Annual General Meeting of Shareholders.

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

The information required by this item is incorporated herein by reference to the Proxy Statement for our 2016 Annual General Meeting of Shareholders.

PART IV

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

(a)(1) Consolidated Financial Statements—The consolidated financial statements of Alkermes plc, required by this item, are submitted in a separate section beginning on page F-1 of this Annual Report.

(2) Financial Statement Schedules—All schedules have been omitted because the absence of conditions under which they are required or because the required information is included in the consolidated financial statements or notes thereto.

(3) See the Exhibit Index immediately following the signature page of this Annual Report. The exhibits listed on the Exhibit Index are filed or furnished as part of this Annual Report or are incorporated into this Annual Report by reference.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

ALKERMES PLC

By: /s/ Richard F. Pops
Richard F. Pops
Chairman and Chief Executive Officer

February 25, 2016

POWER OF ATTORNEY

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

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

Signature	Title	Date
/s/ Richard F. Pops Richard F. Pops	Chairman and Chief Executive Officer (Principal Executive Officer)	February 25, 2016
/s/ James M. Frates James M. Frates	Senior Vice President and Chief Financial Officer (Principal Financial Officer)	February 25, 2016
/s/ Iain M. Brown Iain M. Brown	Vice President and Chief Accounting Officer (Principal Accounting Officer)	February 25, 2016
/s/ David W. Anstice David W. Anstice	Director	February 25, 2016
/s/ Floyd E. Bloom Floyd E. Bloom	Director	February 25, 2016
/s/ Robert A. Breyer Robert A. Breyer	Director	February 25, 2016
/s/ Wendy L. Dixon Wendy L. Dixon	Director	February 25, 2016
/s/ Paul J. Mitchell Paul J. Mitchell	Director	February 25, 2016
/s/ Nancy J. Wysenski Nancy J. Wysenski	Director	February 25, 2016

EXHIBIT INDEX

Exhibit No.	Description of Exhibit	Incorporated by reference herein	
		Form	Date
2.1 *	Purchase and Sale Agreement, dated March 7, 2015, by and among Alkermes Pharma Ireland Limited, Daravita Limited, Eagle Holdings USA, Inc., Recro Pharma, Inc., and Recro Pharma LLC.	Exhibit 2.1 of the Alkermes plc Current Report on Form 8-K/A (File No. 001-35299)	April 16, 2015
3.1	Amended and Restated Memorandum and Articles of Association of Alkermes plc.	Exhibit 3.1 to the Alkermes plc Current Report on Form 8-K (File No. 001-35299)	September 16, 2011
10.1	Lease Agreement between Alkermes, Inc. and PDM Unit 850, LLC, dated as of April 22, 2009.	Exhibit 10.5 to the Alkermes, Inc. Annual Report on Form 10-K (File No. 001-14131)	May 28, 2009
10.1.1	First Amendment to Lease Agreement between Alkermes, Inc. and PDM Unit 850, LLC, dated as of June 18, 2009.	Exhibit 10.2 to the Alkermes, Inc. Quarterly Report on Form 10-Q (File No. 001-14131)	August 6, 2009
10.1.2	Second Amendment to Lease Agreement between Alkermes, Inc. and PDM Unit 850, LLC, dated as of November 12, 2013.	Exhibit 10.74 of the Alkermes plc Transition Report on Form 10-KT (File No. 001-35299)	February 27, 2014
10.1.3	Third Amendment to Lease Agreement between Alkermes, Inc. and PDM 850 Unit, LLC, dated as of May 15, 2014.	Exhibit 10.2 of the Alkermes plc Quarterly Report on Form 10-Q (File No. 001-35299)	July 31, 2014
10.1.4	Fourth Amendment to Lease Agreement between Alkermes, Inc. and Gl TC 850 Winter Street, LLC, dated as of December 30, 2014.	Exhibit 10.7 to the Alkermes plc Quarterly Report on Form 10-Q (File No. 001-35299)	July 30, 2015
10.2 #	License Agreement, dated as of February 13, 1996, between Medisorb Technologies International L.P. and Janssen Pharmaceutica Inc. (United States) (assigned to Alkermes, Inc. in July 2006).		
10.2.1 *	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).	Exhibit 10.5 to the Alkermes, Inc. Quarterly Report on Form 10-Q (File No. 001-14131)	February 8, 2005

Exhibit No.	Description of Exhibit	Incorporated by reference herein	
		Form	Date
10.2.2 *	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.	Exhibit 10.3 of the Alkermes plc Quarterly Report on Form 10-Q (File No. 001-35299)	November 1, 2012
10.3 #	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).		
10.4 #	Manufacturing and Supply Agreement, dated August 6, 1997, by and among JPI Pharmaceutica International, Janssen Pharmaceutica, Inc. and Alkermes Controlled Therapeutics Inc. II (assigned to Alkermes, Inc. in July 2006).		
10.4.1 *	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).	Exhibit 10.4 to the Alkermes, Inc. Quarterly Report on Form 10-Q (File No. 001-14131)	February 8, 2005
10.4.2 #	Addendum to the Manufacturing and Supply Agreement by and among JPI Pharmaceutica International, Janssen Pharmaceutica Inc. and Alkermes Controlled Therapeutics Inc. II, dated August 1, 2001.		
10.4.3 #	Letter Agreement and Exhibits to Manufacturing and Supply Agreement, dated February 1, 2002, by and among among JPI Pharmaceutica International, Janssen Pharmaceutica Inc. and Alkermes Controlled Therapeutics Inc. II (assigned to Alkermes, Inc. in July 2006).		
10.4.4 *	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).	Exhibit 10.6 to the Alkermes plc Quarterly Report on Form 10-Q (File No. 011-35299)	July 30, 2015

Exhibit No.	Description of Exhibit	Incorporated by reference herein	
		Form	Date
10.4.5 *	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).	Exhibit 10.9 to the Alkermes, Inc. Quarterly Report on Form 10-Q (File No. 001-14131)	February 8, 2005
10.5 *	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).	Exhibit 10.28 to the Alkermes, Inc. Annual Report on Form 10-K (File No. 001-14131)	May 20, 2011
10.6 *	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).	Exhibit 10.6 to the Alkermes, Inc. Quarterly Report on Form 10-Q (File No. 001-14131)	February 8, 2005
10.6.1 *	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).	Exhibit 10.7 to the Alkermes, Inc. Quarterly Report on Form 10-Q (File No. 001-14131)	February 8, 2005
10.7	Amended and Restated License Agreement, dated September 26, 2003, by and between Acorda Therapeutics, Inc. and Elan Corporation, plc.	Exhibit 10.14 of the Acorda Therapeutics, Inc. Quarterly Report on Form 10-Q/A (File No.000-50513; film No. 11821367)	July 20, 2011
10.7.1 *	Supply Agreement, dated September 26, 2003, by and between Acorda Therapeutics, Inc. and Elan Corporation, plc.	Exhibit 10.22 of the Alkermes plc Annual Report on Form 10-K (File No. 001-35299)	May 23, 2013
10.7.2	Amendment No. 1 to the Amended and Restated License Agreement, to the Supply Agreement and the Sublicense Consent Between Elan Pharma International Limited, Acorda Therapeutics, Inc. and Biogen Idec International GmbH dated June 30, 2009.	Exhibit 10.56 to Acorda Therapeutics, Inc.'s Quarterly Report on Form 10-Q (File No.000-50513; film No. 09999376)	August 10, 2009
10.7.3	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.	Exhibit 10.46 of the Acorda Therapeutics, Inc. Annual Report on Form 10-K (File No.000-50513; film no. 13653677)	February 28, 2013

Exhibit No.	Description of Exhibit	Incorporated by reference herein	
		Form	Date
10.7.4	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.	Exhibit 10.1 of the Acorda Therapeutics, Inc. Quarterly Report on Form 10-Q (File No. 000-50513; film No. 13831684)	May 10, 2013
10.7.5*	Development and Supplemental Agreement between Elan Pharma International Limited and Acorda Therapeutics, Inc. dated January 14, 2011.	Exhibit 10.21 of the Alkermes plc Annual Report on Form 10-K (File No. 001-35299)	May 23, 2013
10.8 *	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.	Exhibit 10.23 of the Alkermes plc Annual Report on Form 10-(File No. 001-35299)	May 23, 2013
10.8.1	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.	Exhibit 10.24 of the Alkermes plc Annual Report on Form 10-K (File No. 001-35299)	May 23, 2013
10.8.2 *	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.	Exhibit 10.25 of the Alkermes plc Annual Report on Form 10-K (File No. 001-35299)	May 23, 2013
10.9	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.	Exhibit 10.1 of the Alkermes plc Current Report on Form 8-K (File No. 011-35299)	September 25, 2012
10.9.1	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.	Exhibit 10.1 of the Alkermes plc Current Report on Form 8-K (File No. 011-35299)	February 19, 2013
10.9.2	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.	Exhibit 10.52 of the Alkermes plc Annual Report on Form 10-K (File No. 011-35299)	May 23, 2013

Exhibit No.	Description of Exhibit	Incorporated by reference herein	
		Form	Date
10.10 †	Employment agreement, dated as of December 12, 2007, by and between Richard F. Pops and Alkermes, Inc.	Exhibit 10.1 to the Alkermes, Inc. Quarterly Report on Form 10-Q (File No. 001-14131)	February 11, 2008
10.10.1 †	Amendment to Employment Agreement, dated as of October 7, 2008, by and between Alkermes, Inc. and Richard F. Pops.	Exhibit 10.5 to the Alkermes, Inc. Current Report on Form 8-K (File No. 001-14131)	October 7, 2008
10.10.2 †	Amendment No. 2 to Employment Agreement by and between Alkermes, Inc. and Richard F. Pops, dated September 10, 2009.	Exhibit 10.2 to the Alkermes, Inc. Current Report on Form 8-K (File No. 001-14131)	September 11, 2009
10.11 †	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.	Exhibit 10.3 to the Alkermes, Inc. Quarterly Report on Form 10-Q (File No. 001-14131)	February 11, 2008
10.11.1 †	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.	Exhibit 10.7 to the Alkermes, Inc. Current Report on Form 8-K (File No. 001-14131)	October 7, 2008
10.12 †	Form of Covenant Not to Compete, of various dates, by and between Alkermes, Inc. and each of Kathryn L. Biberstein and James M. Frates.	Exhibit 10.15 to the Alkermes, Inc. Annual Report on Form 10-K (File No. 001-14131)	May 30, 2008
10.13 †	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.	Exhibit 10.15(a) to the Alkermes, Inc. Annual Report on Form 10-K (File No. 001-14131)	May 30, 2008
10.14 †	Shane Cooke Offer Letter, dated as of September 15, 2011.	Exhibit 10.5 to the Alkermes plc Current Report on Form 8-K (File No. 011-35299)	September 20, 2011
10.14.1 †	Employment Agreement by and between Alkermes Pharma Ireland Limited and Shane Cooke, dated as of September 16, 2011.	Exhibit 10.6 to the Alkermes plc Current Report on Form 8-K (File No. 011-35299)	September 20, 2011
10.15 †	Offer Letter between Alkermes, Inc. and Mark P. Stejbach, effective as of February 15, 2012.	Exhibit 10.2 to the Alkermes plc Current Report on Form 8-K (File No. 011-35299)	March 5, 2012
10.15.1 †	Employment Agreement by and between Alkermes, Inc. and Mark P. Stejbach, dated as of February 29, 2012.	Exhibit 10.1 to the Alkermes plc Current Report on Form 8-K (File No. 011-35299)	March 5, 2012
10.15.2 †	Amendment to Employment Agreement, dated as of July 21, 2015, by and between Mark P. Stejbach and Alkermes, Inc.	Exhibit 10.2 to the Alkermes plc Quarterly Report on Form 10-Q (File No. 011-35299)	July 30, 2015

Exhibit No.	Description of Exhibit	Incorporated by reference herein	
		Form	Date
10.16 †	Employment agreement, dated as of July 30, 2012, by and between Rebecca J. Peterson and Alkermes, Inc.	Exhibit 10.1 of the Alkermes plc Quarterly Report on Form 10-Q (File No. 011-35299)	November 1, 2012
10.16.1 †	Amendment to Employment Agreement, dated as of July 22, 2015, by and between Rebecca J. Peterson and Alkermes, Inc.	Exhibit 10.8 to the Alkermes plc Quarterly Report on Form 10-Q (File No. 011-35299)	July 30, 2015
10.16.2 †#	Separation Agreement, dated as of October 21, 2015, by and between Rebecca J. Peterson and Alkermes, Inc.		
10.17 †	Employment Agreement, dated as of September 30, 2008, by and between Iain M. Brown and Alkermes, Inc.	Exhibit 10.1 to the Alkermes plc Quarterly Report on Form 10-Q (File No. 011-35299)	July 30, 2015
10.17.1 †	Amendment to Employment Agreement, dated as of July 28, 2015, by and between Iain M. Brown and Alkermes, Inc.	Exhibit 10.9 to the Alkermes plc Quarterly Report on Form 10-Q (File No. 011-35299)	July 30, 2015
10.18 †	James L. Botkin Offer Letter, dated as of September 15, 2011	Exhibit 10.7 to the Alkermes plc Current Report on Form 8-K (File No. 011-35299)	September 20, 2011
10.18.1 †	Employment Agreement by and between Alkermes Gainesville LLC and James L. Botkin, dated as of September 16, 2011.	Exhibit 10.8 to the Alkermes plc Current Report on Form 8-K (File No. 011-35299)	September 20, 2011
10.19 †	Form of Indemnification Agreement by and between Alkermes, Inc. and each of its directors and executive officers.	Exhibit 10.1 to the Alkermes, Inc. Current Report on Form 8-K (File No. 001-14131)	March 25, 2010
10.20 †	Form of Deed of Indemnification for Alkermes plc Officers.	Exhibit 10.1 to the Alkermes plc Current Report on Form 8-K (File No. 011-35299)	September 20, 2011
10.21 †	Form of Deed of Indemnification for Alkermes plc Directors/Secretary.	Exhibit 10.2 to the Alkermes plc Current Report on Form 8-K (File No. 011-35299)	September 20, 2011
10.22 †	Form of Deed of Indemnification for Alkermes, Inc. and Subsidiaries Directors/Secretary.	Exhibit 10.3 to the Alkermes plc Current Report on Form 8-K (File No. 011-35299)	September 20, 2011
10.23 †	Alkermes, Inc. Amended and Restated 1999 Stock Option Plan.	Appendix A to the Alkermes, Inc. Definitive Proxy Statement on Form DEF 14/A (File No. 001-14131)	July 27, 2007

Exhibit No.	Description of Exhibit	Incorporated by reference herein	
		Form	Date
10.23.1 †	Form of Incentive Stock Option Certificate pursuant to the 1999 Stock Option Plan, as amended.	Exhibit 10.35 to the Alkermes, Inc. Annual Report on Form 10-K (File No. 001-14131)	June 14, 2006
10.23.2 †	Form of Non-Qualified Stock Option Certificate pursuant to the 1999 Stock Option Plan, as amended.	Exhibit 10.36 to the Alkermes, Inc. Annual Report on Form 10-K (File No. 001-14131)	June 14, 2006
10.24 †	2006 Stock Option Plan for Non-Employee Directors.	Exhibit 10.4 to the Alkermes, Inc. Quarterly Report on Form 10-Q (File No. 001-14131)	November 9, 2006
10.24.1 †	Amendment to 2006 Stock Option Plan for Non-Employee Directors.	Appendix C to the Alkermes, Inc. Definitive Proxy Statement on Form DEF 14/A (File No. 001-14131)	July 27, 2007
10.25†	Alkermes plc Amended and Restated 2008 Stock Option and Incentive Plan, as amended. (Incorporated by reference to Exhibit 10.1 to the Alkermes plc Quarterly Report on Form 10-Q for the quarter ended March 31, 2015.)	Exhibit 10.1 to the Alkermes plc Quarterly Report on Form 10-Q for the quarter ended March 31, 2015 (File No. 001-35299)	April 30, 2015
10.25.1 †	Alkermes, Inc. 2008 Stock Option and Incentive Plan, Stock Option Award Certificate (Incentive Stock Option), as amended.	Exhibit 10.27(a) to the Alkermes, Inc. Annual Report on Form 10-K (File No. 001-14131)	May 21, 2010
10.25.2 †	Alkermes, Inc. 2008 Stock Option and Incentive Plan, Stock Option Award Certificate (Non-Qualified Option), as amended.	Exhibit 10.27(b) to the Alkermes, Inc. Annual Report on Form 10-K (File No. 001-14131)	May 21, 2010
10.25.3 †	Alkermes, Inc. 2008 Stock Option and Incentive Plan, Stock Option Award Certificate (Non-Employee Director).	Exhibit 10.4 to the Alkermes, Inc. Current Report on Form 8-K (File No. 001-14131)	October 7, 2008
10.25.4 †	Alkermes, Inc. 2008 Stock Option and Incentive Plan, Restricted Stock Unit Award Certificate (Time Vesting Only).	Exhibit 10.1 to the Alkermes, Inc. Current Report on Form 8-K (File No. 001-14131)	May 22, 2009
10.25.5 †	Alkermes, Inc. 2008 Stock Option and Incentive Plan, Restricted Stock Unit Award Certificate (Performance Vesting Only).	Exhibit 10.2 to the Alkermes, Inc. Current Report on Form 8-K (File No. 001-14131)	May 22, 2009
10.26 †	Alkermes plc 2011 Stock Option and Incentive Plan, as amended.	Exhibit 10.2 to the Alkermes plc Quarterly Report on Form 10-Q (File No. 001-35299)	April 30, 2015

Exhibit No.	Description of Exhibit	Incorporated by reference herein	
		Form	Date
10.26.1 #†	Alkermes plc 2011 Stock Option and Incentive Plan, Stock Option Award Certificate (Incentive Stock Option – U.S.), as amended.		
10.26.2 #†	Alkermes plc 2011 Stock Option and Incentive Plan, Stock Option Award Certificate (Time Vesting Non-Qualified Option – U.S.), as amended.		
10.26.3 #†	Alkermes plc 2011 Stock Option and Incentive Plan, Stock Option Award Certificate (Performance Vesting Non-Qualified Option – U.S.).		
10.26.4 †	Alkermes plc 2011 Stock Option and Incentive Plan, Restricted Stock Unit Award Certificate (Time Vesting Only – U.S.), as amended.	Exhibit 10.75 of the Alkermes plc Transition Report on Form 10-KT (File No. 011-35299)	February 27, 2014
10.26.5 #†	Alkermes plc 2011 Stock Option and Incentive Plan, Restricted Stock Unit Award Certificate (Performance Vesting Only – U.S.), as amended.		
10.26.6 †	Alkermes plc 2011 Stock Option and Incentive Plan, Restricted Stock Unit Award Certificate (Time Vesting Only - Irish), as amended.	Exhibit 10.77 of the Alkermes plc Transition Report on Form 10-KT (File No. 011-35299)	February 27, 2014
10.26.7 #†	Alkermes plc 2011 Stock Option and Incentive Plan, Restricted Stock Unit Award Certificate (Performance Vesting Only - Irish).		
10.26.8 †	Alkermes plc 2011 Stock Option and Incentive Plan, Stock Option Award Certificate (Non-Employee Director).	Exhibit 10.79 of the Alkermes plc Transition Report on Form 10-KT (File No. 011-35299)	February 27, 2014
10.26.9 #†	Alkermes plc 2011 Stock Option and Incentive Plan, Stock Option Award Certificate (Time Vesting Non-Qualified Option – Irish).		
10.26.10 #†	Alkermes plc 2011 Stock Option and Incentive Plan, Stock Option Award Certificate (Performance Vesting Non-Qualified Option – Irish).		
21.1 #	List of subsidiaries		
23.1 #	Consent of PricewaterhouseCoopers LLP, an independent registered public accounting firm		
24.1 #	Power of Attorney (included on the signature pages hereto)		
31.1 #	Certification Pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934		
31.2 #	Certification Pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934		
32.1 ‡	Certification Pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002		
101.INS +#	XBRL Instance Document		

Exhibit No.	Description of Exhibit	Incorporated by reference herein	
		Form	Date
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.
+	XBRL (Extensible Business Reporting Language).
#	Filed herewith.
‡	Furnished herewith.
*	Confidential treatment has been granted or requested for certain portions of this exhibit. Such portions have been filed separately with the SEC pursuant to a confidential treatment request.

Report of Independent Registered Public Accounting Firm

To Board of Directors and Shareholders of Alkermes plc

In our opinion, the accompanying consolidated balance sheets as of December 31, 2015 and 2014 and the related consolidated statements of operations and comprehensive (loss) income, of shareholders' equity and of cash flows for the years ended December 31, 2015 and 2014 and for the nine months ended December 31, 2013 present fairly, in all material respects, the financial position of Alkermes plc and its subsidiaries at December 31, 2015 and 2014, and the results of their operations and their cash flows for the years ended December 31, 2015 and 2014, and for the nine months ended December 31, 2013 in conformity with accounting principles generally accepted in the United States of America. Also in our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2015, based on criteria established in Internal Control—Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). The Company's management is responsible for these financial statements, for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting, included in Management's Annual Report on Internal Control over Financial Reporting appearing under Item 9A. Our responsibility is to express opinions on these financial statements and on the Company's internal control over financial reporting based on our integrated audits. We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the financial statements are free of material misstatement and whether effective internal control over financial reporting was maintained in all material respects. Our audits of the financial statements included examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. Our audit of internal control over financial reporting included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audits also included performing such other procedures as we considered necessary in the circumstances. We believe that our audits provide a reasonable basis for our opinions.

As discussed in Note 2 to the consolidated financial statements, the Company changed the manner in which it classifies deferred taxes and debt issuance costs in 2015.

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
February 25, 2016

ALKERMES PLC AND SUBSIDIARIES
CONSOLIDATED BALANCE SHEETS
December 31, 2015 and 2014

	December 31, 2015	December 31, 2014
	(In thousands, except share and per share amounts)	
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 181,109	$ 224,064
Investments — short-term	353,669	407,102
Receivables, net	155,487	151,551
Inventory	38,411	51,357
Prepaid expenses and other current assets	26,286	29,289
Deferred tax assets — current	—	13,430
Total current assets	754,962	876,793
PROPERTY, PLANT AND EQUIPMENT, NET	254,819	265,740
INTANGIBLE ASSETS—NET	379,186	479,412
INVESTMENTS—LONG-TERM	264,071	170,480
GOODWILL	92,873	94,212
CONTINGENT CONSIDERATION	55,300	—
DEFERRED TAX ASSETS — LONG TERM	40,856	8,294
OTHER ASSETS	13,677	24,127
TOTAL ASSETS	$ 1,855,744	$ 1,919,058
LIABILITIES AND SHAREHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Accounts payable and accrued expenses	$ 168,735	$ 121,258
Long-term debt—short-term	65,737	6,750
Deferred revenue—short-term	1,735	2,574
Total current liabilities	236,207	130,582
LONG-TERM DEBT	284,207	349,006
OTHER LONG-TERM LIABILITIES	12,610	11,914
DEFERRED REVENUE—LONG-TERM	7,975	11,801
DEFERRED TAX LIABILITIES — LONG-TERM	470	18,918
Total liabilities	541,469	522,221
COMMITMENTS AND CONTINGENCIES (Note 17)		
SHAREHOLDERS' EQUITY:		
Preferred shares, par value, $0.01 per share; 50,000,000 shares authorized; zero issued and outstanding at December 31, 2015 and December 31, 2014, respectively	—	—
Ordinary shares, par value, $0.01 per share; 450,000,000 shares authorized; 152,128,941 and 148,545,150 shares issued; 150,700,989 and 147,538,519 shares outstanding at December 31, 2015, and December 31, 2014, respectively	1,518	1,482
Treasury shares, at cost (1,427,952 and 1,006,631 shares at December 31, 2015 and December 31, 2014, respectively)	(58,661)	(32,052)
Additional paid-in capital	2,114,711	1,942,878
Accumulated other comprehensive loss	(3,795)	(3,136)
Accumulated deficit	(739,498)	(512,335)
Total shareholders' equity	1,314,275	1,396,837
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	$ 1,855,744	$ 1,919,058

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

ALKERMES PLC AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE (LOSS) INCOME
Years Ended December 31, 2015 and 2014 and Nine Months Ended December 31, 2013

	Year Ended December 31, 2015	Year Ended December 31, 2014	Nine Months Ended December 31, 2013
	(In thousands, except per share amounts)		
REVENUES:			
Manufacturing and royalty revenues	$ 475,288	$ 516,876	$ 371,039
Product sales, net	149,028	94,160	57,215
Research and development revenue	4,019	7,753	4,657
Total revenues	628,335	618,789	432,911
EXPENSES:			
Cost of goods manufactured and sold (exclusive of amortization of acquired intangible assets shown below)	138,989	175,832	134,306
Research and development	344,404	272,043	128,125
Selling, general and administrative	311,558	199,905	116,558
Amortization of acquired intangible assets	57,685	58,153	38,428
Total expenses	852,636	705,933	417,417
OPERATING (LOSS) INCOME	(224,301)	(87,144)	15,494
OTHER INCOME (EXPENSE), NET:			
Interest income	3,330	1,972	711
Interest expense	(13,247)	(13,430)	(10,379)
Gain on the Gainesville Transaction	9,636	—	—
Decrease in the fair value of contingent consideration	(2,300)	—	—
Gain on sale of property, plant and equipment	2,862	41,933	—
Gain on sale of investment in Civitas Therapeutics, Inc.	—	29,564	—
Gain on sale of investment in Acceleron Pharma Inc.	—	15,296	—
Other income (expense), net	15	(2,220)	(429)
Total other income (expense), net	296	73,115	(10,097)
(LOSS) INCOME BEFORE INCOME TAXES	(224,005)	(14,029)	5,397
PROVISION (BENEFIT) FOR INCOME TAXES	3,158	16,032	(12,252)
NET (LOSS) INCOME	$ (227,163)	$ (30,061)	$ 17,649
(LOSS) INCOME PER COMMON SHARE:			
Basic	$ (1.52)	$ (0.21)	$ 0.13
Diluted	$ (1.52)	$ (0.21)	$ 0.12
WEIGHTED AVERAGE NUMBER OF COMMON SHARES OUTSTANDING:			
Basic	149,206	145,274	135,960
Diluted	149,206	145,274	144,961
COMPREHENSIVE (LOSS) INCOME:			
Net (loss) income	$ (227,163)	$ (30,061)	$ 17,649
Holding gains, net of tax of $(292), $7,739 and $8,217, respectively	(661)	1,586	13,092
Less: Reclassification adjustment for gains included in net (loss) income	—	(15,296)	—
COMPREHENSIVE (LOSS) INCOME	$ (227,824)	$ (43,771)	$ 30,741

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

ALKERMES PLC AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF SHAREHOLDERS' EQUITY
Years Ended December 31, 2015 and 2014 and Nine Months Ended December 31, 2013

	Ordinary Shares		Additional Paid-In	Accumulated Other Comprehensive	Accumulated	Treasury Stock		
	Shares	Amount	Capital	(Loss) Income	Deficit	Shares	Amount	Total
				(In thousands, except share data)				
BALANCE — March 31, 2013	134,065,107	$ 1,338	$ 1,458,857	$ (2,518)	$ (499,923)	(313,497)	$ (5,380)	$ 952,374
Issuance of ordinary shares under employee stock plans	4,417,464	44	49,033	—	—	—	—	49,077
Receipt of Alkermes' shares for the purchase of stock options or to satisfy minimum tax withholding obligations related to share based awards	—	—	788	—	—	(376,448)	(12,453)	(11,665)
Share-based compensation expense	—	—	33,265	—	—	—	—	33,265
Excess tax benefit from share-based compensation	—	—	11,394	—	—	—	—	11,394
Unrealized gains on marketable securities, net of tax of $8,217	—	—	—	13,092	—	—	—	13,092
Net income	—	—	—	—	17,649	—	—	17,649
BALANCE — December 31, 2013	138,482,571	$ 1,382	$ 1,553,337	$ 10,574	$ (482,274)	(689,945)	$ (17,833)	$ 1,065,186
Issuance of ordinary shares, net	5,917,160	59	248,347	—	—	—	—	248,406
Issuance of ordinary shares under employee stock plans	4,145,419	41	47,536	—	—	—	—	47,577
Receipt of Alkermes' shares for the purchase of stock options or to satisfy minimum tax withholding obligations related to share based awards	—	—	1,379	—	—	(316,686)	(14,219)	(12,840)
Share-based compensation expense	—	—	59,912	—	—	—	—	59,912
Excess tax benefit from share-based compensation	—	—	32,367	—	—	—	—	32,367
Unrealized gains on marketable securities, net of tax of $7,739	—	—	—	(13,710)	—	—	—	(13,710)
Net loss	—	—	—	—	(30,061)	—	—	(30,061)
BALANCE — December 31, 2014	148,545,150	$ 1,482	$ 1,942,878	$ (3,136)	$ (512,335)	(1,006,631)	$ (32,052)	$ 1,396,837
Issuance of ordinary shares under employee stock plans	3,538,308	35	44,934	—	—	—	—	44,969
Receipt of Alkermes' shares for the purchase of stock options or to satisfy minimum tax withholding obligations related to share based awards	45,483	1	704	—	—	(421,321)	(26,609)	(25,904)
Share-based compensation expense	—	—	97,619	—	—	—	—	97,619
Excess tax benefit from share-based compensation	—	—	28,576	—	—	—	—	28,576
Unrealized gains on marketable securities, net of tax of $292	—	—	—	(659)	—	—	—	(659)
Net loss	—	—	—	—	(227,163)	—	—	(227,163)
BALANCE — December 31, 2015	152,128,941	$ 1,518	$ 2,114,711	$ (3,795)	$ (739,498)	(1,427,952)	$ (58,661)	$ 1,314,275

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

ALKERMES PLC AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF CASH FLOWS
Years Ended December 31, 2015 and 2014 and Nine Months Ended December 31, 2013

	Year Ended December 31, 2015	Year Ended December 31, 2014	Nine Months Ended December 31, 2013
		(In thousands)	
CASH FLOWS FROM OPERATING ACTIVITIES:			
Net (loss) income	$ (227,163)	$ (30,061)	$ 17,649
Adjustments to reconcile net loss to cash flows from operating activities:			
Depreciation and amortization	85,596	98,087	70,765
Share-based compensation expense	97,341	59,579	33,409
Deferred income taxes	(37,580)	(19,192)	(15,393)
Excess tax benefit from share-based compensation	(28,576)	(32,367)	(11,394)
Gain on sale of investment in Civitas Therapeutics, Inc.	—	(29,564)	—
Gain on the Gainesville Transaction	(9,636)	—	—
Decrease in the fair value of contingent consideration	2,300	—	—
(Gain) loss on sale of property, plant and equipment	(3,272)	(40,099)	129
Gain on sale of investment of Acceleron Pharma Inc.	—	(15,296)	—
Other non-cash charges	(1,351)	9,192	(5,860)
Changes in assets and liabilities, net of divestiture:			
Receivables	(16,455)	(17,397)	(9,534)
Inventory, prepaid expenses and other assets	19,618	(31,237)	(6,345)
Accounts payable and accrued expenses	76,155	56,896	16,126
Deferred revenue	(629)	(996)	4,051
Other long-term liabilities	3,292	3,594	(1,382)
Cash flows (used in) provided by operating activities	(40,360)	11,139	92,221
CASH FLOWS FROM INVESTING ACTIVITIES:			
Additions of property, plant and equipment	(52,877)	(33,651)	(19,054)
Proceeds from the sale of equipment	535	44,365	52
Net proceeds from the Gainesville Transaction	49,966	—	—
Investment in Civitas Therapeutics, Inc.	—	27,190	(1,191)
Purchases of investments	(508,683)	(642,455)	(135,643)
Sales and maturities of investments	467,573	341,154	90,470
Cash flows used in investing activities	(43,486)	(263,397)	(65,366)
CASH FLOWS FROM FINANCING ACTIVITIES:			
Proceeds from the issuance of ordinary shares, net	—	248,406	—
Proceeds from the issuance of ordinary shares under share-based compensation arrangements	44,969	47,577	49,077
Excess tax benefit from share-based compensation	28,576	32,367	11,394
Employee taxes paid related to net share settlement of equity awards	(25,904)	(12,840)	(11,665)
Principal payments of long-term debt	(6,750)	(6,750)	(5,060)
Cash flows provided by financing activities	40,891	308,760	43,746
NET (DECREASE) INCREASE IN CASH AND CASH EQUIVALENTS	(42,955)	56,502	70,601
CASH AND CASH EQUIVALENTS—Beginning of period	224,064	167,562	96,961
CASH AND CASH EQUIVALENTS—End of period	$ 181,109	$ 224,064	$ 167,562
SUPPLEMENTAL CASH FLOW DISCLOSURE:			
Cash paid for interest	$ 12,323	$ 12,489	$ 9,596
Cash paid for taxes	$ 705	$ 2,799	$ 704
Non-cash investing and financing activities:			
Purchased capital expenditures included in accounts payable and accrued expenses	$ 6,054	$ 3,483	$ 1,969
Fair value of warrants received as part of the Gainesville Transaction	$ 2,123	$ —	$ —
Fair value of contingent consideration received as part of the Gainesville Transaction	$ 57,600	$ —	$ —

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

ALKERMES PLC AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

1. DESCRIPTION OF BUSINESS AND BASIS OF PRESENTATION

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

Change in Fiscal Year

On May 21, 2013, the Company's Audit and Risk Committee, with such authority delegated to it by the Company's board of directors, approved a change to its fiscal year-end from March 31 to December 31. This Annual Report reflects the Company's financial results for the twelve-month period from January 1, 2015 through December 31, 2015. The period ended December 31, 2014 reflects the Company's financial results for the twelve-month period from January 1, 2014 through December 31, 2014. The period ended December 31, 2013 reflects the Company's financial results for the nine-month period from April 1, 2013 through December 31, 2013.

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Principles of Consolidation

The consolidated financial statements include the accounts of Alkermes plc and its wholly-owned subsidiaries: Alkermes Ireland Holdings Limited; Daravita Pharma Ireland Limited; Daravita Limited; Alkermes Science Four Limited; Alkermes Science Five Limited; Alkermes Science Six Limited; Alkermes Pharma Ireland Limited; Alkermes U.S. Holdings, Inc.; Alkermes, Inc.; Eagle Holdings USA, Inc.; Alkermes Controlled Therapeutics, Inc.; Alkermes Europe, Ltd.; Alkermes Finance Ireland Limited; Alkermes Finance Ireland (No. 2) Limited; Alkermes Finance Ireland (No. 3) Limited; and Alkermes Finance S.à r.l. Intercompany accounts and transactions have been eliminated.

On March 7, 2015, the Company entered into a definitive agreement to sell its Gainesville, GA manufacturing facility, the related manufacturing and royalty revenue associated with certain products manufactured at the facility, and the rights to IV/IM and parenteral forms of Meloxicam (the "Gainesville Transaction") to Recro Pharma, Inc. ("Recro") and Recro Pharma LLC (together with Recro, the "Purchasers"). The consolidated financial statements include the accounts Alkermes Gainesville LLC, which represent the entities sold, for the period from January 1, 2015 through April 10, 2015; the year ended December 31, 2014; and the nine-month period from April 1, 2013 through December 31, 2013.

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, contingent consideration and litigation. The Company bases its estimates on historical experience and on various other assumptions that are believed to be reasonable, the results of which form the basis for making judgments about the carrying values of assets and liabilities. Actual results may differ from these estimates under different assumptions or conditions.

Cash and Cash Equivalents

The Company values its cash and cash equivalents at cost plus accrued interest, which the Company believes approximates their market value. The Company considers only those investments which are highly liquid, readily convertible into cash and so near their maturity, generally three months from the date of purchase, that they present

insignificant risk of change in value because of interest rate changes to be cash equivalents.

Accounts Receivable

Included in accounts receivable at December 31, 2015 and 2014, are unbilled receivables of $19.3 million and $26.3 million, respectively. The Company's allowance for doubtful accounts was $0.1 million and zero at December 31, 2015 and 2014, respectively.

Investments

The Company has investments in various types of securities, consisting primarily of U.S. government and agency obligations, corporate debt securities and debt securities issued by foreign agencies and backed by foreign governments. The Company generally holds its interest bearing investments with major financial institutions and in accordance with documented investment policies. The Company limits the amount of credit exposure to any one financial institution or corporate issuer. At December 31, 2015, substantially all these investments were classified as available for sale and were recorded at fair value.

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

For 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 its 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.

The Company's held-to-maturity investments are restricted investments held as collateral under letters of credit related to certain of the Company's agreements and are included in "Investments—long-term," in the accompanying consolidated balance sheets.

Fair Value of Financial Instruments

The Company's financial assets and liabilities are recorded at fair value and are classified as Level 1, 2 or 3 within the fair value hierarchy, as described in the accounting standards for fair value measurement. The Company's financial assets and liabilities consist of cash equivalents, investments, contingent consideration and warrants to purchase the common stock of a publicly traded company are classified within the fair value hierarchy as follows:

- *Level 1*–these valuations are based on a market approach using quoted prices in active markets for identical assets. Valuations of these products do not require a significant degree of judgment. Assets utilizing Level 1 inputs at December 31, 2015 included U.S. treasury securities and a fixed term deposit account and at December 31, 2014 included 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 at December 31, 2015 included U.S. government agency debt securities, debt securities issued by foreign agencies and backed by foreign governments and investments in corporate debt securities that are trading in the credit markets; and

- *Level 3*–these valuations are based on an income approach using certain inputs that are unobservable and are significant to the overall fair value measurement. Valuations of these products require a significant degree of judgment. At December 31, 2015, assets utilizing Level 3 inputs included contingent consideration and warrants to purchase the common stock of Recro.

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

Property, Plant and Equipment

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

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

Contingent Consideration

The Company records contingent consideration it receives at fair value on the acquisition date. The Company estimates the fair value of contingent consideration through valuation models that incorporate probability-adjusted assumptions related to the achievement of milestones and thus likelihood of receiving related payments. The Company revalues its contingent consideration each reporting period, with changes in the fair value of contingent consideration recognized within the consolidated statements of operations and comprehensive (loss) income. Changes in the fair value of contingent consideration can result from changes to one or multiple inputs, including adjustments to discount rates, changes in the amount or timing of cash flows, changes in the assumed achievement or timing of any development or sales-based milestones and changes in the assumed probability associated with regulatory approval.

The period over which the Company discounts its contingent consideration is based on the current development stage of the product candidate, the specific development plan for that product candidate, adjusted for the probability of completing the development steps, and when contingent payments would be triggered. In estimating the probability of success, the Company utilizes data regarding similar milestone events from several sources, including industry studies and the Company's own experience. These fair value measurements are based on significant inputs not observable in the market. Significant judgment was employed in determining the appropriateness of these assumptions at the acquisition date and for each subsequent period. Accordingly, changes in assumptions described above could have a material impact on the increase or decrease in the fair value of contingent consideration recorded in any given period.

Goodwill and Intangible Assets

Goodwill represents the excess cost of the Company's investment in the net assets of acquired companies over the fair value of the underlying identifiable net assets at the date of acquisition. The Company's goodwill consists solely of goodwill created as a result of the Company's acquisition of Elan Drug Technologies ("EDT") from Elan Corporation, plc in September 2011 and has been assigned to one reporting unit. A reporting unit is an operating segment or sub-

segment to which goodwill is assigned when initially recorded.

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

The Company performed its annual goodwill impairment test as of October 31, 2015. The Company elected to assess qualitative factors to determine whether it was necessary to perform the two-step impairment test. Based on the weight of all available evidence, including the significance in which the fair value of our reporting unit was in excess of its carrying value at the closing of the Gainesville Transaction and the increase in its fair value from the date of the Gainesville Transaction to October 31, 2015, we determined that the fair value of the reporting unit more-likely-than-not exceeded its carrying value.

The Company's finite-lived intangible assets, consisting of core developed technology and collaboration agreements acquired as part of the acquisition of EDT, were recorded at fair value at the time of their acquisition and are stated within the Company's consolidated balance sheets net of accumulated amortization and impairments. The finite-lived intangible assets are amortized over their estimated useful lives using the economic use method, which reflects the pattern that the economic benefits of the intangible assets are consumed as revenue is generated from the underlying patent or contract. The useful lives of the Company's intangible assets are primarily based on the legal or contractual life of the underlying patent or contract, which does not include additional years for the potential extension or renewal of the contract or patent.

Impairment of Long-Lived Assets

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

Revenue Recognition

Collaborative Arrangements

The Company has entered into collaboration agreements with pharmaceutical companies including Ortho-McNeil-Janssen Pharmaceuticals, Inc. and Janssen Pharmaceutica International, a division of Cilag International AG ("Janssen") for INVEGA® SUSTENNA®/XEPLION® and INVEGA TRINZA® as well as RISPERDAL® CONSTA®, Acorda Therapeutics, Inc. ("Acorda") for AMPYRA®/FAMPYRA® and AstraZeneca for BYDUREON®. Substantially all of the products developed under the Company's collaborative arrangements are currently being marketed as approved products. The Company receives payments for manufacturing services and/or royalties on product sales.

Manufacturing revenues—The Company recognizes manufacturing revenues from the sale of products it manufactures for resale by its collaborative partners. Manufacturing revenues are recognized 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 such products based on information supplied to it by the Company's collaborative partners, its historical transaction experience and other third-party data. Differences between actual manufacturing revenues and estimated manufacturing revenues are reconciled and adjusted for in the period in which they become known, which is generally the following quarter. The difference between actual and estimated manufacturing revenues has not been material.

Royalty revenues—The Company recognizes royalty revenues related to the sale of products by its collaborative partners that incorporates the Company's technologies. Royalties, with the exception of those from AMPYRA, are earned under the terms of a license agreement in the period the products are sold by the Company's collaborative partner and collectability is reasonably assured. Royalties on AMPYRA are earned in the period the product is shipped to Acorda. Certain of the Company's royalty revenues are recognized by the Company based on information supplied to the Company by its collaborative partners and require estimates to be made. Differences between actual royalty revenues and estimated royalty revenues are reconciled and adjusted for in the period in which they become known, which is generally the following quarter. The difference between actual and estimated royalty revenues has not been material.

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

Certain of the Company's collaboration agreements entitle it to additional payments upon the achievement of performance-based milestones. Milestones that involve substantial effort on the Company's part and the achievement of which are not considered probable at the inception of the collaboration are considered "substantive milestones," and are recognized in their entirety in the period in which the milestone is achieved. Consideration received from the achievement of milestones that are not considered to be "substantive milestones" are included with other collaboration consideration, such as upfront payments and research funding, and are recognized under the proportional performance method whereby revenue is limited to the lesser of the cumulative amount of payments received or the cumulative amount of revenue earned.

Product Sales, Net

The Company's product sales consist of sales of VIVITROL®, and upon its approval by the U.S. Federal Drug Administration ("FDA") in October 2015, ARISTADA®, in the U.S. to wholesalers, specialty distributors and specialty pharmacies. Product sales are recognized 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 of shipment:

- *Medicaid rebates*—relates to the Company's estimated obligations to states under established reimbursement arrangements. Rebate accruals are recorded in the same period the related revenue is recognized, resulting in a reduction of product revenue and the establishment of a liability which is included in other current liabilities. The Company's liability for Medicaid rebates consists of estimates for claims that a state will make for the current quarter, claims for prior quarters that have been estimated for which an invoice has not been received, invoices received for claims from the prior quarters that have not been paid, and an estimate of potential claims that will be made for inventory that exists in the distribution channel at period end;

- *Chargebacks*—wholesaler and specialty pharmacy chargebacks are discounts that occur when contracted customers purchase directly from an intermediary wholesale purchaser. Contracted customers, which consist primarily of federal government agencies purchasing under the federal supply schedule, generally purchase the product at its contracted price, plus a mark-up from the wholesaler. The wholesaler, in-turn, charges back to the Company the difference between the price initially paid by the wholesaler and the contracted price paid to the wholesaler by the customer. The allowance for chargebacks is based on actual and expected utilization of these programs. Chargebacks could exceed historical experience and the Company's estimates of future participation

in these programs. To date, actual chargebacks have not differed materially from the Company's estimates;

- *Product Discounts*—cash consideration, including sales incentives, given by us under distribution service agreements with a number of wholesaler, distributor and specialty pharmacy customers that provide them with the opportunity to earn discounts in exchange for the performance of certain services. To date, actual product discounts have not differed materially from the Company's estimates;

- *Co-pay Assistance*—the Company has a program whereby a patient can receive monetary assistance each month toward their product co-payment, co- insurance or deductible, provided the patient meets certain eligibility criteria. Reserves are recorded upon the product sale. To date, actual co-pay assistance has not differed materially from the Company's estimates; and

- *Product Returns*—the Company records a reserve for future product returns on 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 product sales, net. Once product is returned, it is destroyed. At December 31, 2015, the product return reserve was estimated to be approximately 1.5% of product sales and amounted to $6.7 million.

Other

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

Foreign Currency

The Company's functional and reporting currency is the U.S. dollar. Transactions in foreign currencies are recorded at the exchange rate prevailing on the date of the transaction. The resulting monetary assets and liabilities are translated into U.S. dollars at exchange rates prevailing on the subsequent balance sheet date. Gains and losses as a result of translation adjustments are recorded within "Other income (expense), net" in the accompanying consolidated statements of operations and comprehensive (loss) income. During the years ended December 31, 2015 and 2014 and the nine months ended December 31, 2013, the Company recorded a gain on foreign currency translation of $1.4 million $0.6 million and $0.2 million, respectively.

Concentrations

Financial instruments that potentially subject the Company to concentrations of credit risk are accounts receivable and marketable securities. Billings to large pharmaceutical companies account for the majority of the Company's accounts receivable, and collateral is generally not required from these customers. To mitigate credit risk, the Company monitors the financial performance and credit worthiness of its customers. The following represents revenue and receivables from the Company's customers exceeding 10% of the total in each category as of December 31, 2015, 2014 and 2013 and for the years ended December 31, 2015 and 2014 and the nine months ended December 31, 2013:

	Year Ended December 31, 2015		Year Ended December 31, 2014		Nine Months Ended December 31, 2013	
Customer	Receivables	Revenue	Receivables	Revenue	Receivables	Revenue
Janssen	44 %	40 %	44 %	41 %	46 %	44 %
Acorda	— %	17 %	17 %	13 %	12 %	12 %

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

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

Geographic Information

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

(In thousands)	Year Ended December 31, 2015	Year Ended December 31, 2014	Nine Months Ended December 31, 2013
Revenue by region:			
U.S.	$ 448,639	$ 398,189	$ 269,005
Ireland	3,902	7,691	5,722
Rest of world	175,794	212,909	158,184
Assets by region:			
Current assets:			
U.S.	$ 360,154	$ 385,715	$ 382,571
Ireland	394,281	490,577	187,023
Rest of world	527	501	544
Long-term assets:			
U.S.:			
Intangible assets	$ —	$ —	$ —
Goodwill	—	3,677	3,677
Other	294,158	226,479	222,818
Ireland:			
Intangible assets	$ 379,186	$ 479,412	$ 537,565
Goodwill	92,873	90,535	89,063
Other	334,565	242,162	151,586

Research and Development Expenses

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

Selling, General and Administrative Expenses

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

Advertising costs are expensed as incurred. During the years ended December 31, 2015 and 2014 and the nine months ended December 31, 2013, advertising costs totaled $10.6 million, $8.6 million and $5.3 million, respectively.

Share-Based Compensation

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

Stock Options

Stock option grants to employees expire ten years from the grant date and generally vest one-fourth per year over four years from the anniversary of the date of grant, provided the employee remains continuously employed with the Company, except as otherwise provided in the plan. Stock option grants to directors are for ten-year terms and generally

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

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

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

	Year Ended December 31, 2015	Year Ended December 31, 2014	Nine Months Ended December 31, 2013
Expected option term	5 - 7 years	5 - 7 years	5 - 7 years
Expected stock volatility	38 % - 46 %	39 % - 46 %	45 % - 48 %
Risk-free interest rate	1.29 % - 2.02 %	1.46 % - 2.24 %	0.75 % - 2.15 %
Expected annual dividend yield	—	—	—

Time-Vested Restricted Stock Units

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

Performance-Based Restricted Stock Units

Performance-based RSUs awarded to employees vest upon the achievement of certain performance criteria. The estimated fair value of these RSUs is based on the market value of the Company's stock on the date of grant. Compensation expense for performance-based RSUs is recognized from the moment the Company determines the performance criteria will be met to the date the Company deems the event is likely to occur. Cumulative adjustments are recorded quarterly to reflect subsequent changes in the estimate outcome of performance-related conditions until the date results are determined.

Income Taxes

The Company recognizes income taxes under the asset and liability method. Deferred income taxes are recognized for differences between the financial reporting and tax bases of assets and liabilities at enacted statutory tax rates in effect for the years in which the differences are expected to reverse. The effect on deferred taxes of a change in tax rates is recognized in income in the period that includes the enactment date. In evaluating the Company's ability to recover its deferred tax assets, the Company considers all available positive and negative evidence including its past operating results, the existence of cumulative income in the most recent fiscal years, changes in the business in which the Company operates and its forecast of future taxable income. In determining future taxable income, the Company is responsible for assumptions utilized including the amount of Irish, U.S. and other foreign pre-tax operating income, the reversal of temporary differences and the implementation of feasible and prudent tax planning strategies. These assumptions require significant judgment about the forecasts of future taxable income and are consistent with the plans

and estimates that the Company is using to manage the underlying businesses.

The Company accounts for uncertain tax positions using a more-likely-than-not threshold for recognizing and resolving uncertain tax positions. The evaluation of uncertain tax positions is based on factors including, but not limited to, changes in tax law, the measurement of tax positions taken or expected to be taken in tax returns, the effective settlement of matters subject to audit, new audit activity and changes in facts or circumstances related to a tax position. The Company evaluates its tax position on a quarterly basis. The Company also accrues for potential interest and penalties related to unrecognized tax benefits in income tax expense.

Comprehensive (Loss) Income

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

(Loss) Earnings Per Share

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

Segment Information

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

Employee Benefit Plans

401(K) Plan

The Company maintains a 401(k) retirement savings plan (the "401(k) Plan"), which covers substantially all of its U.S.-based employees. Eligible employees may contribute up to 100% of their eligible compensation, subject to certain Internal Revenue Service ("IRS") limitations. The Company 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 December 31, 2015 and 2014 and the nine months ended December 31, 2013, the Company contributed $6.6 million, $4.7 million and $3.1 million, respectively, to match employee deferrals under the 401(k) Plan.

Defined Contribution Plan

The Company maintains a defined contribution plan for its Ireland-based employees (the "Defined Contribution Plan"). The Defined Contribution Plan provides for eligible employees to contribute up to the maximum of 40%, depending upon their age, of their total taxable earnings subject to an earnings cap of €115,000. The Company provides a match of up to 18% of taxable earnings depending upon an individual's contribution level. During the years ended December 31, 2015 and 2014 and the nine months ended December 31, 2013, the Company contributed $3.0 million, $3.7 million and $2.9 million, respectively, in contributions to the Defined Contribution Plan.

New Accounting Pronouncements

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

In April 2014, the FASB adopted guidance that amends the requirements for reporting discontinued operations.

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

Under the amendment, only those disposals of components of an entity that represent a strategic shift that has (or will have) a major effect on an entity's operations and financial results will be reported as discontinued operations in the financial statements. Currently, many disposals, some of which may be routine in nature and not a change in an entity's strategy, are reported in discontinued operations. The Company adopted this guidance on January 1, 2015.

In May 2014, the FASB issued guidance that outlines a single comprehensive model for entities to use in accounting for revenue arising from contracts with customers and supersedes most current revenue recognition guidance, including industry-specific guidance. The guidance is based on the principle that an entity should recognize revenue to depict the transfer of goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. The guidance also requires additional disclosure about the nature, amount, timing and uncertainty of revenue and cash flows arising from customer contracts, including significant judgments and changes in judgments and assets recognized from costs incurred to fulfill a contract. Entities have the option of using either a full retrospective or a modified retrospective approach for the adoption of the new standard. The guidance becomes effective for the Company in its year ending December 31, 2018, and the Company could early adopt the standard for its year ending December 31, 2017. The Company is currently assessing the impact that this standard will have on its consolidated financial statements.

In June 2014, the FASB issued guidance that clarifies the accounting for share-based payments when the terms of an award provide that a performance target could be achieved after the requisite service period. Existing GAAP does not contain explicit guidance on how to account for these share-based payments. The new guidance requires that a performance target that affects vesting and that could be achieved after the requisite service period be treated as a performance condition. Entities have the option of prospectively applying the guidance to awards granted or modified after the effective date or retrospectively applying the guidance to all awards with performance targets that are outstanding as of the beginning of the earliest annual period presented in the financial statements. The guidance becomes effective for the Company in its year ending December 31, 2016, and early adoption is permitted. The Company retrospectively adopted this guidance for its year ended December 31, 2015 and it did not have an impact on its consolidated financial statements.

In January 2015, the FASB issued guidance that simplifies income statement presentation by eliminating the concept of extraordinary items. The guidance becomes effective for the Company in its year ending December 31, 2016 and is not expected to have an impact on the Company’s consolidated financial statements.

In April 2015, the FASB issued guidance simplifying the presentation of debt issuance costs. To simplify presentation of debt issuance costs, the amendments require that debt issuance costs related to a recognized debt liability be presented in the balance sheet as a direct deduction from the carrying amount of that debt liability, consistent with debt discounts. The guidance becomes effective for the Company in its year ending December 31, 2016, and early adoption is permitted. The Company retrospectively adopted the guidance for its year ended December 31, 2015 and as a result, reclassified approximately $1.7 million in deferred financing costs that would have appeared as “Other long-term assets” to “Long-term debt” in its accompanying consolidated balance sheet. Also, deferred financing costs of $2.2 million that were classified within “Other long-term assets” at December 31, 2014 were reclassified to “Long-term debt” to conform to the current period presentation.

In July 2015, the FASB issued guidance simplifying the measurement of inventory. To simplify measurement of inventory, the amendments require that entities measuring inventory utilizing methods other than last-in, first-out (“LIFO”), should record inventory at the lower of cost and net realizable value. Net realizable value is defined as the estimated selling prices in the ordinary course of business, less reasonably predictable costs of completion, disposal and transportation. The guidance becomes effective for the Company in its year ending December 31, 2016, and early adoption is permitted. The Company retrospectively adopted the guidance for its year ended December 31, 2015 and the guidance did not have an impact on its consolidated financial statements.

In November 2015, the FASB issued guidance simplifying the presentation of deferred income taxes. To simplify the presentation of deferred income taxes, the amendments require that deferred tax liabilities and assets be classified as noncurrent in a classified statement of financial position. The guidance becomes effective for the Company in its year ending December 31, 2017, and early adoption is permitted. The Company prospectively adopted this guidance for its year ended December 31, 2015.

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

3. DIVESTITURE

On March 7, 2015, the Company entered into a definitive agreement with Recro to sell its Gainesville, GA manufacturing facility, the related manufacturing and royalty revenue associated with certain products manufactured at the facility, and the rights to IV/IM and parenteral forms of Meloxicam to the Purchasers. The sale was completed on April 10, 2015 and, under the terms of the agreement, Recro paid the Company $54.0 million in cash and issued warrants to purchase an aggregate of 350,000 shares of Recro common stock at a per share exercise price of $19.46, which was two times the closing price of Recro's common stock on the day prior to closing. The Company is also eligible to receive low double-digit royalties on net sales of IV/IM and parenteral forms of Meloxicam and up to $120.0 million in milestone payments upon the achievement of certain regulatory and sales milestones related to IV/IM and parenteral forms of Meloxicam.

The gain on the Gainesville Transaction was determined as follows:

	April 10, 2015 (In thousands)
Sales Proceeds:	
Cash	$ 54,010
Fair value of warrants	2,123
Fair value of contingent consideration	57,600
Total consideration received	$ 113,733
Less net assets sold	(101,373)
Less transaction costs	(2,724)
Gain on the Gainesville Transaction	$ 9,636

The Company recorded the gain on the Gainesville Transaction within the accompanying consolidated statement of operations and comprehensive (loss) income. The Company determined that the sale of assets in connection with the Gainesville Transaction did not constitute a strategic shift and that it did not and will not have a major effect on its operations and financial results. Accordingly, the operations from the Gainesville Transaction are not reported in discontinued operations.

Geraldine Henwood, President and Chief Executive Officer of Recro, was a member of the Company's board of directors. On March 7, 2015, Ms. Henwood notified the board of the Company that she was resigning as a member of the board of directors effective immediately. Ms. Henwood's decision was not the result of any disagreement between the Company and herself on any matter, including with respect to the Company's operations, policies or practices.

During the year ended December 31, 2015, the Gainesville, GA facility and associated intellectual property ("IP") generated income before income taxes of $4.5 million and during the year ended December 31, 2014, generated income before income taxes of $22.8 million.

The Company determined the value of the Gainesville Transaction's contingent consideration using the following valuation approaches:

- The fair value of the two regulatory milestones were estimated based on applying the likelihood of achieving the regulatory milestones and applying a discount rate from the expected time each milestone occurs to the balance sheet date. The Company expects the regulatory milestone events to occur within the next two and three years, respectively, and used a discount rate of 4.0% and 5.3%, respectively, for each of these events;

- To estimate the fair value of future royalties on net sales of IV/IM and parenteral forms of Meloxicam, the Company assessed the likelihood of IV/IM and parenteral forms of Meloxicam being approved for sale and estimated the expected future sales given approval and IP protection. The Company then discounted these expected payments using a discount rate of 17.0%, which the Company believes captures a market participant's view of the risk associated with the expected payments; and

- The sales milestones were determined through the use of a real options approach, where net sales are simulated in a risk-neutral world. To employ this methodology, the Company used a risk-adjusted expected growth rate based on its assessments of expected growth in net sales of the approved IV/IM and parenteral forms of Meloxicam, adjusted by an appropriate factor capturing their respective correlation with the market. A resulting

expected (probability-weighted) milestone payment was then discounted at a cost of debt plus a risk adjustment, which ranged from 13.2% to 15.4%.

At December 31, 2015, the Company determined that the value of the Gainesville Transaction's contingent consideration was $55.3 million. This represents a decrease of $2.3 million from its original value, and has been recorded in the accompanying consolidated statements of operations and comprehensive (loss) income.

The warrants the Company received to purchase 350,000 shares of Recro common stock were determined to have a fair value of $2.1 million on the closing date of the transaction. At December 31, 2015, the Company determined that the value of these warrants had decreased to $1.8 million and are being recorded within "Other long-term assets" in the accompanying consolidated balance sheets. The company used a Black-Scholes model with the following assumptions to determine the fair value of these warrants at December 31, 2015:

Closing stock price at December 31, 2015	$ 9.00
Warrant strike price	$ 19.46
Expected term (years)	6.27
Risk-free rate	2.09 %
Volatility	80.0 %

The decrease in the fair value of the warrants of $0.3 million during the year ended December 31, 2015 was recorded within "Other income (expense), net" in the accompanying consolidated statements of operations and comprehensive (loss) income.

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

4. INVESTMENTS

Investments consist of the following:

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses: Less than One Year	Gross Unrealized Losses: Greater than One Year	Estimated Fair Value
		(In thousands)			
December 31, 2015					
Short-term investments:					
Available-for-sale securities:					
Corporate debt securities	$175,098	$ 20	$ (179)	$ —	$174,939
U.S. government and agency debt securities	141,789	51	(104)	—	141,736
International government agency debt securities	37,070	—	(76)	—	36,994
Total short-term investments	353,957	71	(359)	—	353,669
Long-term investments:					
Available-for-sale securities:					
U.S. government and agency debt securities	211,216	—	(764)	—	210,452
Corporate debt securities	38,381	—	(111)	—	38,270
International government agency debt securities	12,039	—	(71)	—	11,968
	261,636	—	(946)	—	260,690
Held-to-maturity securities:					
Fixed term deposit account	1,666	—	—	—	1,666
Certificates of deposit	1,715	—	—	—	1,715
Total long-term investments	265,017	—	(946)	—	264,071
Total investments	$618,974	$ 71	$ (1,305)	$ —	$617,740
December 31, 2014					
Short-term investments:					
Available-for-sale securities:					
U.S. government and agency debt securities	$226,387	$ 88	$ (15)	$ —	$226,460
Corporate debt securities	140,900	26	(66)	—	140,860
International government agency debt securities	39,774	13	(5)	—	39,782
Total short-term investments	407,061	127	(86)	—	407,102
Long-term investments:					
Available-for-sale securities:					
U.S. government and agency debt securities	100,429	—	(196)	(40)	100,193
Corporate debt securities	61,187	—	(84)	—	61,103
International government agency debt securities	7,568	—	(2)	(1)	7,565
	169,184	—	(282)	(41)	168,861
Held-to-maturity securities:					
Certificates of deposit	1,619	—	—	—	1,619
Total long-term investments	170,803	—	(282)	(41)	170,480
Total investments	$577,864	$ 127	$ (368)	$ (41)	$577,582

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

(In thousands)	Year Ended December 31, 2015	Year Ended December 31, 2014	Nine Months Ended December 31, 2013
Proceeds from the sales and maturities of marketable securities	$ 467,573	$ 341,154	$ 90,470
Realized gains	$ 111	$ 15,364	$ 16
Realized losses	$ 3	$ 31	$ —

The Company's available-for-sale and held-to-maturity securities at December 31, 2015 had contractual maturities in the following periods:

(In thousands)	Available-for-sale: Amortized Cost	Available-for-sale: Estimated Fair Value	Held-to-maturity: Amortized Cost	Held-to-maturity: Estimated Fair Value
Within 1 year	$ 327,936	$ 327,621	$ 1,715	$ 1,715
After 1 year through 5 years	287,657	286,738	1,666	1,666
Total	$ 615,593	$ 614,359	$ 3,381	$ 3,381

The investments with unrealized losses consisted primarily of corporate debt securities and U.S. Government and

agency debt securities. In making the determination that the decline in fair value of these securities was temporary, the Company considered various factors, including but not limited to: the length of time each security was in an unrealized loss position; the extent to which fair value was less than cost; financial condition and near-term prospects of the issuers; the Company's intent not to sell these securities, and the assessment that it is more-likely-than-not that the Company would not be required to sell these securities before the recovery of their amortized cost basis.

In May 2014, the Company entered into an agreement whereby it is committed to provide up to €7.4 million to a partnership, Fountain Healthcare Partners II, L.P. of Ireland ("Fountain"), which was created to carry on the business of investing exclusively in companies and businesses engaged in the healthcare, pharmaceutical and life sciences sectors. The Company's commitment represents approximately 7% of the partnership's total funding, and the Company is accounting for its investment in Fountain under the equity method. At December 31, 2015, the Company had made payments of, and its investment is equal to, $1.6 million (€1.3 million), which is included within "Other assets" in the accompanying consolidated balance sheets. During the years ended December 31, 2015 and 2014, the Company recorded a reduction in its investment in Fountain of $0.2 million and $0.1 million, respectively, which represented the Company's proportionate share of Fountain's net loss for this period.

The Company's investment in Civitas Therapeutics, Inc. ("Civitas") was zero and $2.0 million at December 31, 2015 and 2014, respectively, which was recorded within "Other assets" in the accompanying consolidated balance sheets. In October 2014, Civitas was acquired by Acorda for $525.0 million. As a result of this transaction, the Company received $27.2 million in 2014 and $2.4 million in 2015 after release of amounts held in escrow, for its approximate 6% equity interest in Civitas. Prior to its acquisition by Acorda, the Company's investment in Civitas consisted of various issues of preferred stock, certain of which were accounted for under the cost method or equity method, depending upon if the preferred stock was considered to be "in-substance" common stock and the Company's belief that it may have been able to exercise significant influence over the operating and financial policies of Civitas. During the years ended December 31, 2015 and 2014 and the nine months ended December 31, 2013, the Company recorded a reduction in its investment in Civitas of zero, $6.8 million and $1.2 million, respectively, which represented the Company's proportionate share of Civitas' net losses for these periods.

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

5. FAIR VALUE

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

(In thousands)	December 31, 2015	Level 1	Level 2	Level 3
Assets:				
Cash equivalents	$ 1,666	$ 1,666	$ —	$ —
U.S. government and agency debt securities	352,188	214,456	137,732	—
Corporate debt securities	213,209	—	213,209	—
International government agency debt securities	48,962	—	48,962	—
Contingent consideration	55,300	—	—	55,300
Common stock warrants	1,821	—	—	1,821
Total	$ 673,146	$ 216,122	$ 399,903	$ 57,121

	December 31, 2014	Level 1	Level 2	Level 3
Assets:				
U.S. government and agency debt securities	$ 326,653	$ 189,030	$ 137,623	$ —
Corporate debt securities	201,963	—	201,963	—
International government agency debt securities	47,347	—	47,347	—
Total	$ 575,963	$ 189,030	$ 386,933	$ —

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

The Company transfers its financial assets and liabilities, measured at fair value on a recurring basis, between the fair value hierarchies at the end of each reporting period.

There were no transfers of any securities from Level 1 to Level 2 or from Level 2 to Level 1 during the year ended December 31, 2015. The following table is a rollforward of the fair value of the Company's investments whose fair value was determined using Level 3 inputs at December 31, 2015:

(In thousands)	Fair Value
Balance, January 1, 2015	$ —
Acquisition of contingent consideration	57,600
Acquisition of common stock warrants	2,123
Decrease in fair value of contingent consideration	(2,300)
Decrease in fair value of warrants	(302)
Balance, December 31, 2015	$ 57,121

The Company's investments in U.S. government and agency debt securities, international government agency debt securities and corporate debt securities classified as Level 2 within the fair value hierarchy were initially valued at the transaction price and subsequently valued, at the end of each reporting period, utilizing market-observable data. The market-observable data included reportable trades, benchmark yields, credit spreads, broker/dealer quotes, bids, offers, current spot rates and other industry and economic events. The Company validated the prices developed using the market-observable data by obtaining market values from other pricing sources, analyzing pricing data in certain instances and confirming that the relevant markets are active.

The carrying amounts reflected in the consolidated balance sheets for cash and cash equivalents, accounts receivable, other current assets, accounts payable and accrued expenses approximate fair value due to their short-term nature. The fair value of the remaining financial instruments not currently recognized at fair value on the Company's consolidated balance sheets consisted of the $300.0 million, seven-year term loan bearing interest at LIBOR plus 2.75% with a LIBOR floor of 0.75% ("Term Loan B-1") and the $75.0 million, four-year term loan bearing interest at LIBOR plus 2.75%, with no LIBOR floor ("Term Loan B-2" and together with Term Loan B-1, the "Term Loan Facility"). The estimated fair value of these term loans, which was based on quoted market price indications (Level 2 in the fair value hierarchy) and may not be representative of actual values that could have been or will be realized in the future, was as follows at December 31, 2015:

(In thousands)	Carrying Value	Estimated Fair Value
Term Loan B-1	$ 287,207	$ 288,314
Term Loan B-2	$ 62,737	$ 62,184

6. INVENTORY

Inventory consists of the following:

(In thousands)	December 31, 2015	December 31, 2014
Raw materials	$ 16,445	$ 21,101
Work in process	12,423	14,824
Finished goods[1]	9,543	15,432
Total inventory	$ 38,411	$ 51,357

(1) At December 31, 2015 and 2014, the Company had $3.0 million and $4.4 million, respectively, of finished goods inventory located at its third-party warehouse and shipping service provider.

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)	December 31, 2015	December 31, 2014
Land	$ 5,913	$ 8,163
Building and improvements	136,797	149,158
Furniture, fixture and equipment	218,718	225,834
Leasehold improvements	16,597	12,971
Construction in progress	51,542	39,774
Subtotal	429,567	435,900
Less: accumulated depreciation	(174,748)	(170,160)
Total property, plant and equipment, net	$ 254,819	$ 265,740

In April 2015, as part of the Gainesville Transaction, the Company sold certain of its land, buildings and equipment that had a carrying value of $38.3 million. In April 2014, the Company sold certain of its land, buildings and equipment at its Athlone, Ireland facility that had a carrying value of $2.2 million, in exchange for $17.5 million. $3.0 million of the sale proceeds was placed in escrow pending the completion of certain additional services the Company was obligated to perform, which were completed in December 2015. The deferred sales proceeds were earned as "Gain on sale of property, plant and equipment" as the services were provided. In October 2014, the Company sold certain commercial-scale pulmonary manufacturing equipment located at its Chelsea, Massachusetts manufacturing facility, which had a carrying value of $0.4 million in exchange for $30.0 million. The gain of $29.6 million resulting from this transaction is included in "Gain on sale of property, plant and equipment" in the accompanying statements of operations and comprehensive (loss) income.

Depreciation expense was $27.9 million, $39.9 million and $32.3 million for the years ended December 31, 2015 and 2014 and the nine months ended December 31, 2013, respectively. Also, during the years ended December 31, 2015 and 2014 and the nine months ended December 31, 2013, the Company wrote off furniture, fixtures and equipment that had a carrying value of $0.1 million, $1.4 million and less than $0.1 million, respectively, at the time of disposition.

Amounts included as construction in progress in the consolidated balance sheets primarily include capital expenditures at the Company's manufacturing facility in Wilmington, Ohio. The Company continues to evaluate its manufacturing capacity based on expectations of demand for its products and will continue to record such amounts within construction in progress until such time as the underlying assets are placed into service. The Company continues to periodically evaluate whether facts and circumstances indicate that the carrying value of its long-lived assets to be held and used may not be recoverable.

8. GOODWILL AND INTANGIBLE ASSETS

Goodwill and intangible assets consist of the following:

		Year Ended December 31, 2015			Year Ended December 31, 2014		
(In thousands)	Weighted Amortizable Life (Years)	Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount	Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount
Goodwill		$ 92,873	$ —	$ 92,873	$ 94,212	$ —	$ 94,212
Finite-lived intangible assets:							
Collaboration agreements	12	$465,590	$ (168,218)	$297,372	$499,700	$ (127,393)	$372,307
NanoCrystal technology	13	74,600	(18,294)	56,306	74,600	(13,243)	61,357
OCR technologies	12	42,560	(17,052)	25,508	66,300	(20,552)	45,748
Total		$582,750	$ (203,564)	$379,186	640,600	(161,188)	479,412

The Company's finite-lived intangible assets consist of collaborative agreements and the NanoCrystal and OCR technologies acquired as part of the EDT acquisition. In April 2015, as part of the Gainesville Transaction, the Company reduced the value of its goodwill by $1.3 million and sold and/or licensed certain of its collaboration agreements with third-party pharmaceutical companies and Oral Controlled Release ("OCR") technology, which had a gross carrying amount of $34.1 million and $23.7 million, respectively.

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

The Company recorded $57.7 million, $58.2 million and $38.4 million of amortization expense related to its finite-lived intangible assets during the years ended December 31, 2015 and 2014 and the nine months ended December 31, 2013, respectively. Based on the Company's most recent analysis, amortization of intangible assets included within its consolidated balance sheets at December 31, 2015 is expected to be approximately $60.0 million, $60.0 million, $60.0 million, $55.0 million and $50.0 million in the years ending December 31, 2016 through 2020, respectively. Although the Company believes such available information and assumptions are reasonable, given the inherent risks and uncertainties underlying its expectations regarding such future revenues, there is the potential for the Company's actual results to vary significantly from such expectations. If revenues are projected to change, the related amortization of the intangible assets will change in proportion to the change in revenues.

On January 21, 2016, following the Company's press release regarding its ALKS 5461 development program, the Company's stock price declined by 44% from the previous day's closing price, which the Company considered to be an impairment triggering event. To determine if its goodwill was impaired, the Company assessed qualitative factors to determine whether it was necessary to perform the two-step impairment test. Based on the weight of all available evidence, the Company determined that the fair value of its reporting unit more-likely-than-not exceeded its carrying value.

9. ACCOUNTS PAYABLE AND ACCRUED EXPENSES

Accounts payable and accrued expenses consist of the following:

(In thousands)	December 31, 2015	December 31, 2014
Accounts payable	$ 37,401	$ 32,335
Accrued compensation	40,371	36,854
Accrued sales discounts, allowances and reserves	28,449	12,607
Accrued other	62,514	39,462
Total accounts payable and accrued expenses	$ 168,735	$ 121,258

10. LONG-TERM DEBT

Long-term debt consists of the following:

(In thousands)	December 31, 2015	December 31, 2014
Term Loan B-1, due September 25, 2019	$ 287,207	$ 289,376
Term Loan B-2, due September 25, 2016	62,737	66,380
Total	349,944	355,756
Less: current portion	(65,737)	(6,750)
Long-term debt	$ 284,207	$ 349,006

Term Loans

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

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

Year Ended December 31:	
2016	$ 65,813
2017	3,000
2018	3,000
2019	281,250
2020	—
Total	$ 353,063

Required quarterly principal payments of $0.8 million on Term Loan B-1 and $0.9 million on Term Loan B-2 began on December 31, 2012. Beginning on January 1, 2014, the Company became subject to mandatory prepayments of principal if certain excess cash flow thresholds, as defined in the Term Loan Facility, were met. During the year ended December 31, 2015, the Company was not subject to mandatory prepayments of principal. The Company may make prepayments of principal without premium or penalty.

The Term Loan Facility has an incremental facility capacity in an amount of $140.0 million, plus additional amounts as long as the Company meets certain conditions, including a specified leverage ratio. The Term Loan Facility includes a number of restrictive covenants that, among other things and subject to certain exceptions and baskets, impose operating and financial restrictions on the Company and certain of its subsidiaries. The Term Loan Facility also contains customary affirmative covenants and events of default. The Company was in compliance with its debt covenants at December 31, 2015.

At December 31, 2015, the Company's balance of unamortized deferred financing costs and unamortized original issue discount costs were $1.7 million and $1.4 million, respectively. These costs are being amortized to interest expense over the estimated repayment period of the Term Loan Facility using the effective interest method. During the years ended December 31, 2015 and 2014 and the nine months ended December 31, 2013, the Company had amortization expense of $0.9 million, $1.0 million and $0.8 million, respectively, related to deferred financing costs and original issue discount.

11. (LOSS) EARNINGS PER SHARE

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

(In thousands)	Year Ended December 31, 2015	Year Ended December 31, 2014	Nine Months Ended December 31, 2013
Numerator:			
Net loss	$ (227,163)	$ (30,061)	$ 17,649
Denominator:			
Weighted average number of ordinary shares outstanding	149,206	145,274	135,960
Effect of dilutive securities:			
Stock options	—	—	7,653
Restricted stock units	—	—	1,348
Dilutive ordinary share equivalents	—	—	9,001
Shares used in calculating diluted loss per share	149,206	145,274	144,961

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

(In thousands)	Year Ended December 31, 2015	Year Ended December 31, 2014	Nine Months Ended December 31, 2013
Stock options	9,179	9,260	1,404
Restricted stock units	1,351	1,834	—
Total	10,530	11,094	1,404

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

12. SHAREHOLDERS' EQUITY

Share Repurchase Program

On September 16, 2011, the board of directors authorized the continuation of the Alkermes, Inc. share repurchase program to repurchase up to $215.0 million of the Company's ordinary shares at the discretion of management from time to time in the open market or through privately negotiated transactions. At December 31, 2015, 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 December 31, 2015 and 2014, the Company did not acquire any ordinary shares under the repurchase program.

13. SHARE-BASED COMPENSATION

Share-based Compensation Expense

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

(In thousands)	Year Ended December 31, 2015	Year Ended December 31, 2014	Nine Months Ended December 31, 2013
Cost of goods manufactured and sold	$ 8,880	$ 6,940	$ 3,308
Research and development	24,201	14,422	7,799
Selling, general and administrative	64,260	38,217	22,302
Total share-based compensation expense	$ 97,341	$ 59,579	$ 33,409

During the years ended December 31, 2015 and 2014 and the nine months ended December 31, 2013, $1.1 million, $0.8 million and $0.4 million, respectively, of share-based compensation expense was capitalized and recorded as "Inventory" in the accompanying consolidated balance sheets.

Share-based Compensation Plans

The Company has two compensation plans pursuant to which awards are currently being made: (i) the 2011 Stock Option and Incentive Plan (the "2011 Plan"); and (ii) the 2008 Stock Option and Incentive Plan (the "2008 Plan"). The Company has two 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 1999 Stock Option Plan (the "1999 Plan"); and (ii) the 2006 Stock Option Plan for Non-Employee Directors (the "2006 Plan"). The 2011 Plan and the 2008 Plan provide for the issuance of non-qualified and incentive stock options, restricted stock, restricted stock units, cash-based awards and performance shares to employees, officers and directors of, and consultants to, the Company in such amounts and with such terms and conditions as may be determined by the compensation committee of the Company's board of directors, subject to provisions of the 2011 Plan and the 2008 Plan.

At December 31, 2015, there were 6.9 million shares of ordinary shares authorized for issuance under the Company's stock plans. The 2011 Plan provides that awards other than stock options will be counted against the total number of shares available under the plan in a 1.8-to-1 ratio and the 2008 Plan provides that awards other than stock options will be counted against the total number of shares available under the plan in a 2-to-1 ratio.

ALKERMES PLC AND SUBSIDIARIES
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Stock Options

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

	Number of Shares	Weighted Average Exercise Price
Outstanding, January 1, 2015	13,172,626	$ 22.32
Granted	2,697,610	$ 67.88
Exercised	(2,550,665)	$ 17.91
Forfeited	(340,765)	$ 52.94
Outstanding, December 31, 2015	12,978,806	$ 31.86
Exercisable, December 31, 2015	8,065,860	$ 19.34

The weighted average grant date fair value of stock options granted during the years ended December 31, 2015 and 2014 and the nine months ended December 31, 2013 was $28.88, $21.44 and $16.27, respectively. The aggregate intrinsic value of stock options exercised during the years ended December 31, 2015 and 2014 and the nine months ended December 31, 2013 was $127.7 million, $114.5 million and $65.6 million, respectively.

At December 31, 2015, there were 4.7 million stock options expected to vest with a weighted average exercise price of $51.94 per share, a weighted average contractual remaining life of 8.4 years and an aggregate intrinsic value of $128.8 million. At December 31, 2015, the aggregate intrinsic value of stock options exercisable was $484.3 million with a weighted average remaining contractual term of 5.0 years. The number of stock options expected to vest is determined by applying the pre-vesting forfeiture rate to the total outstanding options. The intrinsic value of a stock option is the amount by which the market value of the underlying stock exceeds the exercise price of the stock option.

At December 31, 2015, there was $61.3 million of unrecognized compensation cost related to unvested stock options, which is expected to be recognized over a weighted average period of 2.1 years. Cash received from option exercises under the Company's award plans during the years ended December 31, 2015 and 2014 and the nine months ended December 31, 2013 was $45.0 million, $47.6 million and $49.1 million, respectively, related to these awards.

Time-Vested Restricted Stock Units

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

	Number of Shares	Weighted Average Grant Date Fair Value
Unvested, January 1, 2015	1,760,914	$ 32.96
Granted	684,915	$ 71.16
Vested	(733,343)	$ 29.05
Forfeited	(166,854)	$ 45.52
Unvested, December 31, 2015	1,545,632	$ 50.38

The weighted average grant date fair value of time-vested RSUs granted during the years ended December 31, 2015 and 2014 and the nine months ended December 31, 2013 $71.16, $47.16 and $33.72, respectively. The total fair value of time-vested RSUs that vested during the years ended December 31, 2015 and 2014 and the nine months ended December 31, 2013, was $21.3 million, $15.4 million and $12.5 million, respectively.

At December 31, 2015, there was $35.7 million of total unrecognized compensation cost related to unvested time-vested RSUs, which will be recognized over a weighted average remaining contractual term of 1.9 years.

Performance-Vesting Restricted Stock Units

In March 2014, the board of directors awarded RSUs to all employees of the Company as of the date of the award, fifty percent of which vest upon the occurrence of the earlier of: (i) FDA approval for ARISTADA; or (ii) the achievement of the pre-specified primary endpoint in two phase 3 clinical studies of ALKS 5461; provided that, if such vesting event occurs during the first year after grant, the vesting of the initial 50% of the performance-based restricted stock unit award will not occur until the one-year anniversary of the grant date. The remaining fifty percent of the award will vest on the one-year anniversary of the vesting date of the initial portion. In September 2015, the Company determined that it was probable that these awards would vest and began to recognize expense from these awards. The initial portion of these awards vested in October 2015 upon the approval of ARISTADA by the FDA. In the year ended

December 31, 2015, the Company recognized $2.5 million, $3.1 million and $8.3 million in cost of goods manufactured and sold; R&D expense; and SG&A expense, respectively.

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

	Number of Shares	Weighted Average Grant Date Fair Value
Unvested, January 1, 2015	656,725	$ 47.17
Granted	—	$ —
Vested	(299,783)	$ 47.17
Forfeited	(76,277)	$ 47.15
Unvested, December 31, 2015	280,665	$ 47.17

The grant date fair value of the performance-vesting RSUs was equal to the market value of the Company's stock on the date of grant. At December 31, 2015, there was $10.1 million of unrecognized compensation cost related to these performance-vesting RSUs, which will be recognized through October 5, 2016.

14. COLLABORATIVE ARRANGEMENTS

The Company's business strategy includes forming collaborations to develop and commercialize its products, and to access technological, financial, marketing, manufacturing and other resources. The following table is the aggregate for all of the Company's collaborative arrangements:

	Year Ended December 31, 2015	Year Ended December 31, 2014	Nine Months Ended December 31, 2013
		(In thousands)	
MANUFACTURING AND ROYALTY REVENUE:			
Significant collaborative arrangements	$ 401,236	$ 365,904	$ 261,192
All other collaborative arrangements	74,052	150,972	109,847
Total manufacturing and royalty revenue	$ 475,288	$ 516,876	$ 371,039
RESEARCH AND DEVELOPMENT REVENUE:			
Significant collaborative arrangements	$ 582	$ 501	$ 921
All other collaborative arrangements	3,437	7,252	3,736
Total research and development revenue	$ 4,019	$ 7,753	$ 4,657
COST OF GOODS MANUFACTURED:			
Significant collaborative arrangements	$ 33,097	$ 34,148	$ 33,454
All other collaborative arrangements	93,908	127,028	92,534
Total cost of goods manufactured[1]	$ 127,005	$ 161,176	$ 125,988

(1) Includes only cost of goods manufactured under collaborative arrangements.

The Company's significant collaborative arrangements are described below:

Janssen

INVEGA SUSTENNA/XEPLION and INVEGA TRINZA

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 INVEGA TRINZA and related products.

Under its license agreement, the Company received milestone payments upon the achievement of certain development goals from Janssen; there are no further milestones to be earned under this agreement. The Company receives tiered royalty payments between 5% and 9% of INVEGA SUSTENNA/XEPLION and INVEGA TRINZA net sales in each country where the license is in effect, with the exact royalty percentage determined based on worldwide net sales. The tiered royalty payments consist of a patent royalty and a know-how royalty, both of which are determined on a county-by-country basis. The patent royalty, which equals 1.5% of net sales, is payable until the expiration of the last of the patents claiming the product in such country. The know-how royalty is a tiered royalty of 3.5%, 5.5% and 7.5% on

aggregate worldwide net sales of below $250 million, between $250 million and $500 million, and greater than $500 million, respectively. The know-how royalty is payable for the later of 15 years from first commercial sale of a product in each individual country or March 31, 2019, subject in each case to the expiry of the license agreement. These royalty payments may be reduced in any country based on patent litigation or on competing products achieving certain minimum sales thresholds. The license agreement expires upon the later of (i) March 31, 2019 or (ii) the expiration of the last of the patents subject to the agreement. After expiration, Janssen retains a non-exclusive, royalty-free license to develop, manufacture and commercialize the products.

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

Under its agreements with Janssen, the Company recognized royalty revenues from the sale of INVEGA SUSTENNA/XEPLION and INVEGA TRINZA of $149.7 million, $127.8 million and $82.9 million during the years ended December 31, 2015 and 2014 and the nine months ended December 31, 2013, respectively.

RISPERDAL CONSTA

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

Under license agreements, the Company granted Janssen and an affiliate of Janssen exclusive worldwide licenses to use and sell RISPERDAL CONSTA. Under its license agreements with Janssen, the Company receives royalty payments equal to 2.5% of Janssen's net sales of RISPERDAL CONSTA in each country where the license is in effect based on the quarter when the product is sold by Janssen. This royalty may be reduced in any country based on lack of patent coverage and significant competition from generic versions of the product. Janssen can terminate the license agreements upon 30 days' prior written notice to the Company. Either party may terminate the license agreements by written notice following a breach which continues for 90 days after the delivery of written notice thereof or the other party's insolvency. The licenses granted to Janssen expire on a country-by-country basis upon the later of: (i) the expiration of the last patent claiming the product in such country; or (ii) 15 years after the date of the first commercial sale of the product in such country, provided that in no event will the license granted to Janssen expire later than the twentieth anniversary of the first commercial sale of the product in such country, with the exception of certain countries where the fifteen-year limitation shall pertain regardless. After expiration, Janssen retains a non-exclusive, royalty-free license to manufacture, use and sell RISPERDAL CONSTA. The Company exclusively manufactures RISPERDAL CONSTA for commercial sale. Under its manufacturing and supply agreement with Janssen, the Company records manufacturing revenues when product is shipped to Janssen, based on 7.5% of Janssen's net unit sales price for RISPERDAL CONSTA for the calendar year.

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

Under its agreements with Janssen, the Company recognized manufacturing revenues related to RISPERDAL CONSTA of $76.5 million, $91.0 million and $82.5 million during the years ended December 31, 2015 and 2014 and the nine months ended December 31, 2013, respectively. Under its agreements with Janssen, the Company recognized royalty revenues related to RISPERDAL CONSTA of $24.2 million, $29.6 million and $24.7 million during the years ended December 31, 2015 and 2014 and the nine months ended December 31, 2013, respectively.

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Acorda

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

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

Acorda has the right to terminate the amended and restated license agreement upon 90 days' written notice. The Company has the right to terminate the amended and restated license agreement for countries in which Acorda fails to launch a product within a specified time after obtaining the necessary regulatory approval or fails to file regulatory approvals within a commercially reasonable time after completion of and receipt of positive data from all preclinical and clinical studies required for filing a marketing authorization application. Either party has the right to terminate the amended and restated license agreement by written notice following a breach of the other party, which is not cured within a certain time-period, or upon the other party's entry into bankruptcy or dissolution proceedings. If the Company terminates Acorda's license in any country, the Company is entitled to a license from Acorda of its patent rights and know-how relating to the product as well as the related data, information and regulatory files, and to market the product in the applicable country, subject to an initial payment equal to Acorda's cost of developing such data, information and regulatory files and to ongoing royalty payments to Acorda. Subject to the termination of the amended and restated license agreement, licenses granted under the amended and restated license agreement terminate on a country-by-country basis on the later of: (i) September 2018; or (ii) the expiration of the last to expire of our patents or the existence of a threshold level of competition in the marketplace.

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

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

- initiation of a phase 3 clinical trial: $1.0 million;
- acceptance of an New Drug Application ("NDA") by the FDA: $1.0 million;
- approval of the NDA by the FDA: $1.5 million; and
- the first commercial sale: $1.5 million.

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

The Company is entitled to development fees it incurs in developing formulations under the development and supplemental agreement and, if Acorda selects and commercializes any such formulation, to milestone payments (for new indications if not previously paid), license revenues and royalties in accordance with its amended and restated license agreement for the product, and either manufacturing fees as a percentage of net selling price for product manufactured by the Company or compensating fees for product manufactured by third parties.

If, under the development and supplemental agreement, Acorda selects a formulation not developed by the Company, then the Company will be entitled to various compensation payments and has the first option to manufacture such third-party formulation. The development and supplemental agreement expires upon the expiry or termination of the amended and restated license agreement and may be earlier terminated by either party following an uncured breach of the agreement by the other party.

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

During the years ended December 31, 2015 and 2014 and the nine months ended December 31, 2013, the Company recognized $104.7 million, $81.3 million and $51.6 million, respectively, of revenues from its arrangements with Acorda.

AstraZeneca

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

Pursuant to the development and license agreement, AstraZeneca has an exclusive, worldwide license to the Company's polymer-based microsphere technology for the development and commercialization of injectable extended-release formulations of exendins and other related compounds. The Company receives funding for research and development and will also receive royalty payments based on future product sales. Upon the achievement of certain development and commercialization goals, the Company received milestone payments consisting of cash and warrants for Amylin common stock and there are no further milestones to be earned under the agreement. In October 2005 and in July 2006, the Company amended the development and license agreement. Under the amended agreement: (i) the Company is responsible for formulation and is principally responsible for non-clinical development of any products that may be developed pursuant to the agreement and for manufacturing these products for use in early-phase clinical trials; and (ii) the Company transferred certain of its technology related to the manufacture of BYDUREON to Amylin and agreed to the manufacture of BYDUREON by Amylin.

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

Until December 31, 2021, the Company will receive royalties equal to 8% of net sales from the first 40 million units of BYDUREON sold in any particular calendar year and 5.5% of net sales from units sold beyond the first 40 million units for that calendar year. Thereafter, during the term of the development and license agreement, the Company will receive royalties equal to 5.5% of net sales of products sold. The Company was entitled to, and received $7.0 million milestone payments related to the first commercial sale of BYDUREON in the EU and $7.0 million the first commercial sale of BYDUREON in the U.S.

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

During the years ended December 31, 2015 and 2014 and the nine months ended December 31, 2013, the Company recognized $46.1 million, $36.6 million and $20.0 million, respectively, of revenues from its arrangements with respect to BYDUREON.

15. INCOME TAXES

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

(In thousands)	Year Ended December 31, 2015	Year Ended December 31, 2014	Nine Months Ended December 31, 2013
Current income tax provision:			
U.S. federal	$ 29,959	$ 35,147	$ 9,224
U.S. state	1,615	880	2,119
Ireland	77	820	20
Rest of world	94	95	69
Deferred income tax (benefit):			
U.S. federal	(18,336)	(2,654)	(18,317)
Ireland	(9,647)	(17,691)	(3,426)
U.S. state	(604)	(565)	(1,941)
Total tax provision (benefit)	$ 3,158	$ 16,032	$ (12,252)

The current income tax provision for the years ended December 31, 2015 and 2014 and the nine months ended December 31, 2013 was primarily due to U.S. federal and state taxes on income earned by the Company in the U.S. A $28.6 million, $32.4 million and an $11.4 million benefit were recorded to additional paid-in capital in the years ended December 31, 2015 and 2014 and the nine months ended December 31, 2013, respectively, primarily due to the utilization of current year tax benefits and NOL carryforwards derived from the exercise of employee stock options and vesting of restricted stock units.

The deferred income tax benefit for the years ended December 31, 2015 and 2014 was primarily due to current year temporary differences in the U.S. and the creation of a deferred tax asset in Ireland for current year operating losses. The deferred income tax benefit in the nine months ended December 31, 2013 was primarily due to the reversal of a valuation allowance on certain of the Company's U.S. federal and state deferred tax assets.

No provision for income tax has been provided on undistributed earnings of the Company's foreign subsidiaries because such earnings may be repatriated to Ireland without incurring any tax liability. Cumulative unremitted earnings of overseas subsidiaries totaled approximately $107.0 million at December 31, 2015.

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

(In thousands)	Year Ended December 31, 2015	Year Ended December 31, 2014	Nine Months Ended December 31, 2013
Ireland	$ (289,105)	$ (159,538)	$ (63,975)
U.S.	38,398	118,754	49,338
Rest of world	26,702	26,755	20,034
(Loss) income before provision (benefit) for income taxes	$ (224,005)	$ (14,029)	$ 5,397

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

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

(In thousands)	December 31, 2015	December 31, 2014
Deferred tax assets:		
Irish NOL carryforwards	$ 128,635	$ 83,278
Share-based compensation	42,519	30,655
Bonus accrual	7,704	6,835
Other	12,187	10,771
Less: valuation allowance	(106,746)	(71,796)
Total deferred tax assets	84,299	59,743
Deferred tax liabilities:		
Intangible assets	(26,935)	(31,169)
Property, plant and equipment	(15,217)	(21,919)
Other	(1,761)	(3,849)
Total deferred tax liabilities	(43,913)	(56,937)
Net deferred tax assets	$ 40,386	$ 2,806

The activity in the valuation allowance associated with deferred taxes consisted of the following:

(In thousands)	Balance at Beginning of Period	Additions [1]	Deductions [2]	Balance at End of Period
Deferred tax asset valuation for the nine months ended December 31, 2013	$ (86,714)	$ (11,833)	$ 28,888	$ (69,659)
Deferred tax asset valuation for the year ended December 31, 2014	$ (69,659)	$ (12,867)	$ 10,730	$ (71,796)
Deferred tax asset valuation for the year ended December 31, 2015	$ (71,796)	$ (34,950)	$ —	$ (106,746)

(1) The additions in each of the periods presented relate primarily to Irish NOL's.
(2) The reductions in the year ended December 31, 2014 and the nine months ended December 31, 2013 relate primarily to the release of valuation allowances held against U.S. deferred tax assets. $9.1 million of the decrease to the valuation allowance in the year ended December 31, 2014 was credited against additional paid-in capital.

In addition to deferred tax assets and liabilities, the Company recorded deferred charges related to certain intercompany asset transfers. The deferred charges will either be amortized as income tax expense over the economic life of the assets or recorded to expense when the assets are sold to a third party. Deferred charges are included in the following accounts:

(In thousands)	December 31, 2015	December 31, 2014
Prepaid expenses and other current assets	$ 188	$ 1,296
Other assets - long-term	1,050	8,836
Total deferred charges	$ 1,238	$ 10,132

At December 31, 2015 and 2014, the Company maintained a valuation allowance of $2.6 million and $1.7 million, respectively, against certain U.S. state deferred tax assets and $104.2 million and $70.1 million, respectively, against certain Irish deferred tax assets as the Company has determined that it is more-likely-than-not that these net deferred tax assets will not be realized. If the Company demonstrates consistent profitability in the future, the evaluation of the recoverability of these deferred tax assets could change and the remaining valuation allowances could be released in part or in whole.

Subsequent to the adoption of ASC 718 on April 1, 2006, an additional $58.1 million of tax benefits from stock option exercises and the vesting of restricted stock units, in the form of NOL carryforwards and tax credit carryforwards, have not been recognized in the financial statements and will be accounted for as a credit to additional paid-in capital rather than a reduction of income tax expense once they are realized.

As of December 31, 2015, the Company had $881.0 million of Irish NOL carryforwards, $5.5 million of U.S. federal NOL carryforwards, $7.2 million of state NOL carryforwards, $44.8 million of federal R&D credits, $9.8 million

of alternative minimum tax ("AMT") credits and $5.9 million of state tax credits which will either expire on various dates through 2035 or can be carried forward indefinitely. These loss carryforwards and credits are available to reduce certain future Irish and foreign taxable income and tax, respectively, if any. These loss carryforwards and credits are subject to review and possible adjustment by the appropriate taxing authorities. These loss carryforwards and credits, which may be utilized in any future period, may be subject to limitations based upon changes in the ownership of the company's stock. The Company has performed a review of ownership changes in accordance with the U.S. Internal Revenue Code and the Company has determined that it is more-likely-than-not that, as a result of the Business Combination, the Company experienced a change of ownership. As a consequence, the Company's U.S. federal NOL carryforwards and tax credit carryforwards are subject to an annual limitation of $127.0 million.

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

(In thousands, except percentage amounts)	Year Ended December 31, 2015	Year Ended December 31, 2014	Nine Months Ended December 31, 2013
Statutory tax rate	12.5 %	12.5 %	12.5 %
Income tax provision at statutory rate	$ (28,001)	$ (1,754)	$ 675
Change in valuation allowance	37,312	11,150	(17,347)
Foreign rate differential[1]	13,951	28,600	11,280
Share-based compensation	738	1,801	735
Uncertain tax positions[2]	1,213	1,440	(3,168)
U.S. state income taxes, net of U.S. federal benefit	557	727	2,202
Intercompany amounts[3]	(3,649)	(7,459)	(1,619)
Irish rate differential[4]	(7,318)	(4,775)	(4,396)
R&D credit	(12,193)	(14,013)	(1,596)
State tax law change	-	-	686
Other permanent items[5]	548	315	296
Income tax provision (benefit)	$ 3,158	$ 16,032	$ (12,252)
Effective tax rate	(1.4)%	(114.2)%	(227.0)%

(1) Represents income or losses of non-Irish subsidiaries, including U.S. subsidiaries, subject to tax at a rate other than the Irish statutory rate.
(2) Relates to uncertain tax positions adopted by the Company. In June 2013, the Company filed a change in accounting method with the Internal Revenue Service relating to accrued compensation. The method change was automatic and removed the uncertainty around the timing of the deduction for accrued compensation. The effective date of the method change was April 1, 2012. As a result, the Company released the uncertain tax position and accounted for the application of the method change in the fiscal year ended March 31, 2013.
(3) Intercompany amounts include cross-territory eliminations, the pre-tax effect of which has been eliminated in arriving at the Company's consolidated (loss) income before taxes.
(4) Represents income or losses of Irish companies subject to tax at a rate other than the Irish statutory rate.
(5) Other permanent items include, but are not limited to, non-deductible meals and entertainment expenses, non-deductible lobbying expenses and non-deductible compensation of senior officers of the Company.

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

(In thousands)	Unrecognized Tax Benefits
Balance, March 31, 2013	$ 7,258
Additions based on tax positions related to prior periods	881
Additions based on tax positions related to the current period	244
Decreases due to lapse of statute of limitations and settlement of prior period uncertain tax positions	(7,258)
Balance, December 31, 2013	$ 1,125
Additions based on tax positions related to prior periods	363
Additions based on tax positions related to the current period	1,077
Balance, December 31, 2014	$ 2,565
Additions based on tax positions related to the current period	1,213
Balance, December 31, 2015	$ 3,778

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

The unrecognized tax benefits at December 31, 2015, if recognized, would affect the Company's effective tax rate. The Company does not anticipate that the amount of existing unrecognized tax benefits will significantly increase or decrease within the next 12 months. The Company has elected to include interest and penalties related to uncertain tax positions as a component of its provision for taxes. For the years ended December 31, 2015 and 2014 and the nine months ended December 31, 2013, the Company's accrued interest and penalties related to uncertain tax positions were not material.

The Company's major taxing jurisdictions include Ireland and the U.S. (federal and state). These jurisdictions have varying statutes of limitations. In the U.S., the 2013 through 2015 fiscal years remain subject to examination by the respective tax authorities. In Ireland, the years 2011 to 2015 remain subject to examination by the Irish tax authorities. Additionally, because of the Company's Irish and U.S. loss carryforwards and credit carryforwards, certain tax returns from fiscal years 1999 onward may also be examined. These years generally remain open for three to four years after the loss carryforwards and credit carryforwards have been utilized.

16. TRANSITION PERIOD COMPARATIVE DATA

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

	Year Ended December 31,		
	2015	2014	2013 (unaudited)
	(In thousands, except per share amounts)		
Statement of Operations Data:			
Revenues	$ 628,335	$ 618,789	$ 596,333
Operating expenses	852,636	705,933	561,855
Operating (loss) income	(224,301)	(87,144)	34,478
Other income (expense) (net)	296	73,115	(21,215)
(Loss) income before income taxes	(224,005)	(14,029)	13,263
Income tax provision (benefit)	3,158	16,032	(7,385)
Net (loss) income	$ (227,163)	$ (30,061)	$ 20,648
(Loss) earnings per ordinary share - basic	$ (1.52)	$ (0.21)	$ 0.15
(Loss) earnings per ordinary share - diluted	$ (1.52)	$ (0.21)	$ 0.14
Weighted average ordinary shares outstanding - basic	149,206	145,274	135,297
Weighted average ordinary shares outstanding - diluted	149,206	145,274	144,012
Statement of Cash Flows Data:			
Cash flows (used in) provided by operations	$ (40,360)	$ 11,139	$ 147,525
Cash flows used in investing activities	(43,486)	(263,397)	(177,194)
Cash flows provided by financing activities	40,891	308,760	61,339
(Decrease) increase in cash and cash equivalents	$ (42,955)	$ 56,502	$ 31,670

17. COMMITMENTS AND CONTINGENCIES

Lease Commitments

The Company leases certain of its offices, research laboratories and manufacturing facilities under operating leases that expire through the year 2022. Certain of the leases contain provisions for extensions of up to ten years. These lease commitments are primarily related to the Company's corporate headquarters in Ireland and its corporate office and R&D facility in Massachusetts. As of December 31, 2015, the total future annual minimum lease payments under the Company's non-cancelable operating leases are as follows:

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

(In thousands)	Payment Amount
Year Ended:	
2016	$ 5,708
2017	5,897
2018	5,732
2019	5,406
2020	3,194
Thereafter	933
	$ 26,870

Rent expense related to operating leases charged to operations was $7.2 million, $5.9 million and $3.7 million for the years ended December 31, 2015 and 2014 and the nine months ended December 31, 2013, respectively. Each of these amounts was net of sublease income of $0.7 million. In addition to its lease commitments, the Company had open purchase orders totaling $399.0 million at December 31, 2015.

In December 2015, the Company entered into an agreement pertaining to its leased manufacturing facility located in Chelsea, Massachusetts, assigning its right, title and interest in the lease to Civitas. The Company had recognized an asset retirement obligation in connection with this leased property and upon entering into the agreement with Civitas, reversed this liability. As a result, in the year ended December 31, 2015, the Company recorded a $2.4 million gain within operating (loss) income in the accompanying consolidated statements of operations and comprehensive (loss) income.

Litigation

From time to time, the Company may be subject to legal proceedings and claims in the ordinary course of business. On a quarterly basis, the Company reviews the status of each significant matter and assess its potential financial exposure. If the potential loss from any claim, asserted or unasserted, or legal proceeding is considered probable and the amount can be reasonably estimated, the Company would accrue a liability for the estimated loss. Because of uncertainties related to claims and litigation, accruals are based on the Company's best estimates based on available information. On a periodic basis, as additional information becomes available, or based on specific events such as the outcome of litigation or settlement of claims, the Company may reassess the potential liability related to these matters and may revise these estimates, which could result in material adverse adjustments to the Company's operating results. At December 31, 2015, there are no potential losses from claims, asserted or unasserted, or legal proceedings the Company feels are probable of occurring.

ARISTADA

On July 13, 2015, Otsuka Pharmaceutical Development & Commercialization, Inc. ("Otsuka PD&C") filed a Citizen Petition with the FDA which requested that the FDA refuse to approve the NDA for ARISTADA or delay approval of such NDA until the exclusivity rights covering long-acting aripiprazole expire in December 2017. The FDA approved ARISTADA on October 5, 2015 and, concurrent with such approval, denied Otsuka PD&C's Citizen Petition.

On October 15, 2015, Otsuka Pharm. Co., Otsuka PD&C, and Otsuka America Pharmaceutical, Inc. (collectively, "Otsuka") filed an action for declaratory and injunctive relief with the United States District Court for the District of Columbia (the "Court") against Sylvia Mathews Burwell, Secretary, U.S. Department of Health and Human Services; Dr. Stephen Ostroff, Acting Commissioner, FDA; and the FDA, requesting that (a) the Court expedite the legal proceedings; (b) the Court declare that the FDA's denial of Otsuka's claimed exclusivity rights and approval of the ARISTADA NDA were arbitrary, capricious, an abuse of discretion, and otherwise not in accordance with law; (c) the Court vacate FDA's approval of the ARISTADA NDA and vacate any FDA decisions or actions underlying or supporting or predicated upon that approval; (d) the Court declare that Otsuka's claimed exclusivity rights preclude FDA from granting approval of the Alkermes NDA until the expiration of such exclusivity rights in December 2017; and (e) the Court grant any and all other, further, and additional relief, including all necessary and appropriate protective preliminary, interim, or permanent relief, as the nature of the cause may require, including all necessary and appropriate declarations of rights and injunctive relief. The Company believes Otsuka's action is without merit and will vigorously defend ARISTADA against such action. The Company successfully intervened in, and received the Court's approval to become a party to, this action. The Court held a hearing on the case in January 2016. The action is currently pending before the Court. For information about risks relating to this action, see "Item 1A—Risk Factors" of this Annual Report

and specifically the section entitled "Citizen Petitions and other actions filed with, or litigation against, the FDA or other regulatory agencies or litigation against Alkermes may negatively impact the approval of our products and our business."

AMPYRA

Ampyra ANDA Litigation

Ten separate Paragraph IV Certification Notices have been submitted to us and/or the Company's partner Acorda from Accord Healthcare, Inc.; Actavis Laboratories FL, Inc. ("Actavis"); Alkem Laboratories Ltd.; Apotex, Inc.; Aurobindo Pharma Ltd. ("Aurobindo"); Mylan Pharmaceuticals, Inc. ("Mylan"); Par Pharmaceutical, Inc. ("Par"); Roxane Laboratories, Inc.; Sun Pharmaceutical Industries Limited and Sun Pharmaceuticals Industries Inc. (collectively, "Sun"); and Teva Pharmaceuticals USA, Inc., advising that each of these companies had submitted an Abbreviated New Drug Application ("ANDA") to the FDA seeking marketing approval for generic versions of Ampyra (dalfampridine) Extended Release Tablets, 10 mg. The ANDA filers have challenged the validity of the Orange Book-listed patents for Ampyra, and they have also asserted that their generic versions do not infringe certain claims of these patents. In response, the Company and/or Acorda filed lawsuits against the ANDA filers in the U.S. District Court for the District of Delaware (the "Delaware Court") asserting infringement of U.S. Patent Nos. 5,540,938 (which the Company owns), 8,007,826, 8,354,437, 8,440,703, and 8,663,685 (which are owned by Acorda). Requested judicial remedies include recovery of litigation costs and injunctive relief. Lawsuits with eight of the ANDA filers have been consolidated into a single case. The Delaware Court has scheduled a Markman hearing on March 7, 2016, and has set a five-day bench trial starting on September 19, 2016. Mylan is challenging the jurisdiction of the Delaware Court with respect to the Delaware action. Due to Mylan's motion to dismiss, the Company, together with Acorda, also filed another patent infringement suit against Mylan in the U.S. District Court for the Northern District of West Virginia asserting the same U.S. patents and requesting the same judicial relief as in the Delaware action. On January 4, 2016, the Federal Circuit Court of Appeals held oral arguments on Mylan's appeal of the Delaware Court's jurisdictional decision. All lawsuits were filed within 45 days from the date of receipt of each of the Paragraph IV Certification Notices. As a result, a 30-month statutory stay of approval period applies to each of the ANDAs under the Hatch-Waxman Act. The 30-month stay starts from January 22, 2015, which is the end of the new chemical entity exclusivity period for Ampyra. This stay restricts the FDA from approving the ANDAs until July 2017 at the earliest, unless a Federal district court issues a decision adverse to all of the asserted Orange Book-listed patents prior to that date.

In the fourth quarter of 2015, the Company and/or Acorda entered into a settlement agreement with each of Actavis, Aurobindo, Par and Sun (collectively, the "Settling ANDA Filers") to resolve the patent litigation that the Company and/or Acorda brought against the Settling ANDA Filers in the Delaware Court as described above. As a result of the settlement agreements, the Settling ANDA Filers will be permitted to market a generic version of Ampyra in the U.S. at a specified date in 2027, or potentially earlier under certain circumstances. The parties have submitted their respective settlement agreements to the Federal Trade Commission and the Department of Justice, as required by federal law. The settlements with the Settling ANDA Filers do not resolve pending patent litigation that the Company and Acorda brought against the other ANDA filers, as described in this Annual Report.

The Company intends to vigorously enforce its intellectual property rights. For information about risks relating to the Ampyra Paragraph IV litigations and other proceedings see "Item 1A—Risk Factors" in this Annual Report and specifically the section entitled "We face claims against our intellectual property rights and competition from generic drug manufacturers."

Ampyra IPR Proceedings

A hedge fund (acting with affiliated entities and individuals and proceeding under the name of the Coalition for Affordable Drugs) has filed inter partes review petitions with the U.S. Patent and Trademark Office, challenging U.S. Patent Nos. 8,007,826, 8,354,437, 8,440,703, and 8,663,685 (which are owned by Acorda). The challenged patents are four of the five Ampyra Orange-Book listed patents. The 30-month statutory stay period based on patent infringement suits filed by us and Acorda against ANDA filers is not impacted by these filings, and remains in effect.

Exhibit 10.16.2

SEPARATION AGREEMENT

This Separation Agreement (the "Separation Agreement") is made between Rebecca J. Peterson ("Executive") and Alkermes, Inc. (the "Company," together with Executive, the "Parties").

WHEREAS, Executive has served as the Company's Senior Vice President, Corporate Communications since July 2012;

WHEREAS, the Parties entered into an Employee Agreement with respect to Inventions and Proprietary Information dated November 30, 2000 ("Confidentiality Agreement"), and an employment agreement dated July 30, 2012 and an amendment to that agreement as of July 22, 2015 (together, "Employee Agreement"). The Confidentiality Agreement and Employee Agreement as amended are hereinafter collectively referred to as the "Employment Documents";

WHEREAS, Executive entered into a Deed of Indemnification with Alkermes plc dated July 30, 2012 ("Deed");

WHEREAS, Executive holds restricted shares of the Alkermes plc ordinary stock and options to purchase shares of the Company's ordinary stock (all of which are unvested) that are governed by the Alkermes plc 2011 Stock Option and Incentive Plan, and associated stock option certificates and restricted stock certificates (collectively "Equity Documents");

WHEREAS, the Company and the Executive have mutually agreed that the Executive will resign from her employment with the Company;

WHEREAS, the Parties agree that Executive is not entitled to severance or separation benefits under the Employment Documents and that this Agreement shall supersede and replace the Employment Documents, including with respect to compensation, benefits, and severance, except to the extent that certain non-economic provisions and obligations of the Employment Documents are expressly preserved and incorporated by reference into this Separation Agreement; and

WHEREAS, the Company has agreed to provide Executive with, and wishes to set forth clearly the terms and conditions of, certain separation benefits (the "Separation Benefits") provided that, among other things, the Executive enters into and complies with this Separation Agreement which includes a general release of claims in favor of the Company and related persons and entities;

NOW, THEREFORE, for good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, the Parties agree as follows:

1. **Employment Separation.** Executive shall resign and Executive's employment with the Company shall end on October 21, 2015 ("Separation Date"). In connection

with the ending of Executive's employment, the Company shall pay Executive her base salary accrued to Executive through the Separation Date and pay Executive for all accrued but unused vacation time due to Executive through the Separation Date. Executive acknowledges that as of the Separation Date, Executive's accrued but unused vacation time totaled 564 hours.

2. **Business Expense Reimbursement.** The Company shall reimburse Executive for any outstanding, reasonable business expenses that Executive has incurred on the Company's behalf through the Separation Date, provided the Company receives appropriate documentation pursuant to the Company's business expense reimbursement policy on or before October 30, 2015.

3. **Separation Benefits**. The Parties agree that Executive's resignation from employment with the Company is not for "Good Reason" as defined in the Employee Agreement. Accordingly, the Parties agree that Executive is not entitled to the "Compensation Upon Termination" described in section 5(b) of the Employee Agreement. Nevertheless, in exchange for, among other things, her signing, delivering and not revoking a General Release of Claims in the form of Exhibit A hereto (the "Release"), the Company agrees to provide Executive with the following Separation Benefits:

(a) Severance Amount. The Company shall pay Executive $375,000 which represents an amount equal to one times the sum of the Executive's current Base Salary ("Severance Amount").

(b) Bonus Amount. The Company shall pay Executive a bonus of $140,623 ("Bonus Amount"). Executive acknowledges and agrees that she is not entitled to any other bonus or incentive compensation.

Provided Executive enters into and complies with this Separation Agreement and the Release, the Severance Amount and Bonus Amount shall be paid in a lump sum to the Executive within thirty (30) days of the date of signature of the Release. If Executive dies before the payment of the Severance Amount and Bonus Amount, the Severance Amount and Bonus Amount shall be paid to Executive's spouse; if he is not alive at the time, to Executive's estate.

(c) Unemployment. The Company agrees not to contest any claim that Executive has filed or may file asserting that Executive became eligible for unemployment insurance benefits from the Department of Unemployment Assistance of the Commonwealth of Massachusetts (the "DUA") as a result of the separation of Executive's employment with the Company. Executive acknowledges that any unemployment insurance eligibility determination shall be made by the DUA.

(d) Outplacement. The Company shall pay up to $25,000 of the cost of professional outplacement services utilized by Executive and provided by a legitimate outplacement services firm selected by Executive; provided that Executive begins

utilizing such services no later than three months after the Separation Date. The Company will pay the outplacement service firm directly.

(e) COBRA Benefits. Provided that the Executive is eligible for and timely elects continued coverage under the Consolidated Omnibus Budget Reconciliation Act of 1985, as amended ("COBRA"), under the Company's group health and dental insurance plans following the Separation Date, then the Company shall pay the applicable insurance premiums, employer and employee share, necessary to continue the health and dental insurance coverage in effect for Executive, until the earliest of: (i) Executive's eligibility for group medical care coverage through other employment; or (iii) the end of Executive's eligibility under COBRA for continuation coverage for medical care (18 months). The Company will also pay any administrative fee.

(f) Treatment of Executive's Stock Options. The stock options held by Executive immediately prior to the Separation Date are set forth on Exhibit B hereto (all of such options, the "Stock Options"). All Stock Options are exercisable until the earlier of 3 months following the Separation Date or the stated expiration date of such Stock Option. Subject to Executive entering into and complying with this Separation Agreement and the Release and the approval of the Compensation Committee of the Board of Directors of Alkermes plc (the "Compensation Committee"), the following Stock Options are hereby amended such that such options shall be fully vested as of the Separation Date:

(A) The remaining 2,120 shares of an Incentive Stock Option granted on March 3, 2014 at an exercise price of $47.16 per share;

(B) The remaining 44,005 shares of a Non-Qualified Stock Option granted on March 3, 2014 at an exercise price of $47.16 per share;

(C) The remaining 2,965 shares of an Incentive Stock Option granted on May 28, 2013 at an exercise price of $33.72 per share;

(D) The remaining 37,035 shares of a Non-Qualified Stock Option granted on May 28, 2013 at an exercise price of $33.72 per share;

(E) The remaining 6,042 shares of an Incentive Stock Option granted on May 21, 2012 at an exercise price of $16.55 per share; and

(F) The remaining 12,708 shares of a Non-Qualified Stock Option granted on May 21, 2012 at an exercise price of $16.55 per share.

The Parties acknowledge and agree that due to Executive's separation from employment with the Company, the following Incentive Stock Options shall remain unvested and terminate on the Separation Date: (i) the 1,403 shares of an Incentive Stock Option granted on February 26, 2015 at an exercise price of $71.23 per share; and (ii) the 52,597 shares of a Non-Qualified Stock Option granted on February 26, 2015 at an exercise price of $71.23 per share.

(g) Treatment of Executive's Restricted Stock Awards. The restricted stock awards granted to Executive prior to the Separation Date are set forth in Exhibit B hereto. Subject to Executive entering into and complying with this Separation Agreement and the Release and the approval of the Compensation Committee, the following restricted stock awards are hereby amended such that such restricted stock awards shall be fully vested as of the Separation Date:

(A) The remaining 13,000 shares of the Company's Common Stock pursuant to a Restricted Stock Award granted on February 26, 2015;

(B) The remaining 10,500 shares of the Company's Common Stock pursuant to a Restricted Stock Award granted on March 3, 2014;

(C) The remaining 7,500 shares of the Company's Common Stock pursuant to a Restricted Stock Award granted on May 28, 2013; and

(D) The remaining 2,500 shares of the Company's Common Stock pursuant to a Restricted Stock Award granted on May 21, 2012.

(h) Treatment of Executive's Performance Stock Units. The performance stock unit award granted to Executive prior to the Separation Date is set forth in Exhibit B hereto. Subject to Executive entering into and complying with this Separation Agreement and the Release and the approval of the Compensation Committee, the remaining time-vested portion of such performance stock unit award, consisting of 5,000 units, is hereby amended such that such performance stock unit award shall be fully vested as of the Separation Date.

4. **Termination of Employee Benefits.** Except as specifically set forth in this Agreement, Executive shall cease to be eligible for coverage and benefits under the Company's employee benefit plans, programs and policies as of the Separation Date, or by the terms of such plans, programs, and policies.

5. **Section 409A.** Anything in this Agreement to the contrary notwithstanding, if any payment or benefit that Executive becomes entitled to under this Agreement is considered deferred compensation subject to interest, penalties and additional tax

imposed pursuant to Section 409A(a) of the Code as a result of the application of Section 409A(a)(2)(B)(i) of the Code, then no such payment shall be payable or benefit shall be provided prior to the date that is the earlier of (A) six months after Executive's separation from service, or (B) Executive's death, and the initial payment shall include a catch-up amount covering amounts that would otherwise have been paid during the first six-month period but for the applications of this Section 5. The Parties intend that this Agreement will be administered in accordance with Section 409A of the Code and is either exempt from or in compliance with Section 409A of the Code. The Parties agree that this Agreement may be amended, as reasonably requested by either Party, and as may be necessary to fully comply with Section 409A of the Code and all related rules and regulations in order to preserve the payments and benefits provided hereunder without additional cost to either Party.

6. **Confidential Information, Non-solicitation and Cooperation.** Executive hereby acknowledges the continuing nature of her obligations set forth in Sections 1-3 and 6 of the Confidentiality Agreement and Section 7 (a), (b), (d) and (e) of the Employee Agreement (the "Continuing Obligations"), the terms of which are incorporated by reference herein as material terms of this Separation Agreement, and she hereby reaffirms those obligations, and agrees that the consideration provided by the Company under the terms of this Agreement is additional consideration for those obligations. The Parties agree that Executive will not violate Section 7(b) of the Employee Agreement or Section 2 of the Confidentiality Agreement if she is required to share Confidential Information by a lawfully issued subpoena or a duly issued court order, *provided that* she provides the Company with advance written notice and a reasonable opportunity to contest such subpoena or court order.

7. **Confidentiality of this Agreement**. This Section 7 is a material term of the Agreement and the Company has relied upon Executive's representations in this provision when agreeing to enter into the Agreement. The payment of the Separation Benefits will cease if Executive violates the terms of this Section and Executive shall nonetheless remain bound by Executive's obligations in this Agreement. Unless as required by a lawfully issued subpoena or a duly issued court order, Executive agrees that she shall not disclose, divulge or publish, directly or indirectly, any information regarding the substance, terms or existence of this Agreement and/or any discussion or negotiations relating to this Agreement, to any person or organization, including employees of the Company, other than Executive's immediate family and accountants/financial advisor, tax advisors, or attorneys when such disclosure is necessary for the accountants, financial advisor, tax advisor or attorneys to render professional services or for Executive to exercise any legal rights. Prior to any such disclosure that Executive may make, Executive shall secure from her attorney or accountant their agreement to maintain the confidentiality of such matters. Company agrees that it shall not disclose, divulge or publish, directly or indirectly, any information regarding the substance, terms or existence of this Agreement and/or any discussion or negotiations relating to this Agreement, to any third party or organization, other than as required under applicable laws, regulations and requirements or in response to legal proceedings. Both parties may also share this Agreement with any state or federal taxing authorities or the DUA. For

purposes of clarity, by complying with this paragraph, Executive will not be violating any sections of the Employment Documents.

8. **Return of Property**. Executive agrees to return immediately to the Company all Company property, including, without limitation, computer equipment or electronic devices (without deletions), software, keys and access cards, credit cards, files and any documents (electronic or otherwise) containing information concerning the Company, its business or its business relationships (in the latter two cases, actual or prospective). After returning all Company property, Executive commits to deleting and finally purging any duplicates of files or documents that may contain Company information from any non-Company computer device that remains Executive's property after the Separation Date.

9. **Advice of Counsel**. This Separation Agreement is a legally binding document and Executive's signature will commit Executive to its terms. Executive acknowledges that she has been advised to discuss all aspects of this Separation Agreement with her attorney, that she has carefully read and fully understands all of the provisions of this Separation Agreement and that Executive is knowingly and voluntarily entering into this Separation Agreement.

10. **Termination of Separation Benefits**. Executive's right to the Separation Benefits is conditional on her compliance with her obligations under this Separation Agreement, including her obligations set out in Section 6 herein. In the event that Executive fails to materially comply with her obligations set out in Section 6 herein, in addition to any other legal or equitable remedies it may have for such breach, the Company shall have the right to terminate the Separation Benefits payable hereunder. Such termination of those payments and benefits in the event of such material breach by Executive shall not affect Executive's ongoing obligations, and shall be in addition to and not in lieu of the Company's rights to injunctive relief and other legal and equitable remedies that the Company may have.

11. **Enforceability**. Executive acknowledges that, if any portion or provision of this Separation Agreement or any of the Continuing Obligations shall to any extent be declared illegal or unenforceable by a court of competent jurisdiction, then the remainder other than those as to which it is so declared illegal or unenforceable, shall not be affected thereby, and each portion and provision shall be valid and enforceable to the fullest extent permitted by law.

12. **Entire Agreement**. This Separation Agreement, including the Release, along with the Equity Documents, as modified herein, contain the entire understanding of the Parties relating to the subject matter contained herein and supersede all prior agreements or understanding between the Parties including the Employment Documents, except to the extent that certain provisions and obligations of the Employment Documents are expressly preserved and incorporated by reference into this Agreement, provided that the Deed is expressly not superseded by this Agreement. Executive acknowledges and agrees that she is not entitled to any payments or benefits under the Employment Documents or any other contract, employment agreement or plan or arrangement with the Company.

13. **Waiver and Successors and Assigns**. No waiver of any provision of this Separation Agreement shall be effective unless made in writing and signed by the waiving party. The failure of either Party to require the performance of any term or obligation of this Separation Agreement, or the waiver by either Party of any breach of this Separation Agreement, shall not prevent any subsequent enforcement of such term or obligation or be deemed a waiver of any subsequent breach. This Separation Agreement shall inure to the benefit of and be binding on the Company and its successors and assigns.

14. **Taxes**. The Company shall undertake to make deductions, withholdings and tax reports with respect to payments and benefits under this Separation Agreement and in connection with other compensation matters to the extent that it reasonably and in good faith determines that it is required to make such deductions, withholdings and tax reports. Payments under this Separation Agreement shall be in amounts net of any such deductions or withholdings. Nothing in this Separation Agreement shall be construed to require the Company to make any payments to compensate Executive for any adverse tax effect associated with any payments or benefits made to Executive in connection with Executive's employment with the Company.

15. **Governing Law; Interpretation**. This Separation Agreement shall be interpreted and enforced under the laws of the Commonwealth of Massachusetts without regard to conflict of law principles. In the event of any dispute, this Separation Agreement is intended by the Parties to be construed as a whole, to be interpreted in accordance with its fair meaning, and not to be construed strictly for or against either Party or the "drafter" of all or any portion of this Separation Agreement.

16. **Counterparts**. This Separation Agreement may be executed in any number of counterparts, each of which when so executed and delivered shall be taken to be an original, but all of which together shall constitute one and the same document. Facsimile and pdf signatures shall be deemed to be of equal force and effect as originals.

IN WITNESS WHEREOF, the Parties, intending to be legally bound, have executed this Separation Agreement on the date(s) indicated below.

ALKERMES, INC.

/s/ Madeline Coffin	October 21, 2015
Madeline Coffin	Date
Vice President, Human Resources	
/s/ Rebecca J. Peterson	October 21, 2015
Rebecca J. Peterson	Date

EXHIBIT A

General Release of Claims.

I, Rebecca J. Peterson, in consideration for, among other terms, the Separation Benefits, to which I acknowledge I would otherwise not be entitled, voluntarily release and forever discharge the Company, its affiliated and related entities, its and their respective predecessors, successors and assigns, its and their respective employee benefit plans and fiduciaries of such plans, and the current and former officers, directors, shareholders, employees, attorneys, accountants and agents of each of the foregoing in their official and personal capacities (collectively referred to as the "Releasees") generally from all claims, demands, debts, damages and liabilities of every name and nature, known or unknown ("Claims") that, as of the date when I sign this Agreement, I have, ever had, now claim to have or ever claimed to have had against any or all of the Releasees. This release includes, without limitation, all Claims:

- relating to my employment by and separation of employment from the Company;
- of wrongful discharge or violation of public policy;
- of breach of contract;
- of defamation or other torts;
- of retaliation or discrimination under federal, state or local law (including, without limitation, Claims of discrimination or retaliation under the Age Discrimination in Employment Act, the Americans with Disabilities Act, and Title VII of the Civil Rights Act of 1964);
- under any other federal or state statute (including, without limitation, Claims under the Worker Adjustment and Retraining Notification Act or the Fair Labor Standards Act);
- for wages, bonuses, incentive compensation, commissions, stock, stock options, vacation pay or any other compensation or benefits, either under the Massachusetts Wage Act, M.G.L. c. 149, §§148-150C, or otherwise; and
- for damages or other remedies of any sort, including, without limitation, compensatory damages, punitive damages, injunctive relief and attorney's fees;

provided, however, that this release shall not affect my vested rights under the Company's Section 401(k) plan, my rights under the Separation Agreement and the Equity Documents referenced in the Separation Agreement and my rights to indemnification and defense, if any, including but not limited to my rights as set forth in the Deed.

I agree that I shall not accept damages of any nature, other equitable or legal remedies for my own benefit, attorney's fees, or costs from any of the Releasees with respect to any Claim released hereby. As a material inducement to the Company to provide the Separation Benefits, I represent that I have not assigned to any third party any Claim released hereby.

I have had the opportunity to consider this Release for twenty-one (21) days before signing it. If I have signed this Release within less than twenty-one (21) days of the date of its delivery to me, I acknowledge by signing this Release that such decision was entirely voluntary and that I had the opportunity to consider this Release for the entire twenty-one (21) day period. For the period of seven (7) days from the date when I sign this Release, I have the right to revoke this Release by written notice to Kathryn L. Biberstein, Chief Legal Officer, Alkermes, Inc., 852 Winter St., Waltham, MA 02451. For such a revocation to be effective, it must be delivered so that it is received by the

Company at or before the expiration of the seven (7) day revocation period. This Release shall not become effective or enforceable during the revocation period. This Release shall become effective on the first business day following the expiration of the revocation period.

I understand that this Release is a legally binding document and my signature will commit me to its terms. I acknowledge that I have been advised by the Company to discuss all aspects of this Release with my attorney, that I have carefully read and fully understand all of the provisions of this Release and that I am knowingly and voluntarily signing this Release.

In signing this Release, I am not relying upon any promises or representations made by anyone at or on behalf of the Company, other than the promises set forth in the Separation Agreement.

_____

Rebecca J. Peterson

Dated: _____

EXHIBIT B

Rebecca Peterson Equity Statement

Stock Options

Grant Date	Plan	Total Shares Vested	Total Shares Unvested	Price
2/26/2015	2011/ISO	0	1,403	$71.23
2/26/2015	2011/NQ	0	52,597	$71.23
3/3/2014	2011/ISO	0	2,120	$47.16
3/3/2014	2011/NQ	0	44,005	$47.16
5/28/2013	2011/ISO	0	2,965	$33.72
5/28/2013	2011/NQ	0	37,035	$33.72
5/21/2012	2011/ISO	0	6,042	$16.55
5/21/2012	2011/NQ	0	12,708	$16.55

Restricted Stock Units

Grant Date	Plan	Total Shares Unvested
2/26/2015	2011	13,000
3/3/2014	2011	10,500
5/28/2013	2011	7,500
5/21/2012	2011	2,500

Performance Stock Units

Grant Date	Plan	Total Shares Unvested
3/3/2014	2011	5,000

Exhibit 10.2

LICENSE AGREEMENT

This Agreement is made as of the 13 day February of 1996, between MEDISORB TECHNOLOGIES INTERNATIONAL L.P., a Delaware limited partnership (hereinafter "Medisorb") and JANSSEN PHARMACEUTICA INC., a New Jersey corporation ("Janssen US").

WHEREAS, Medisorb and Janssen Pharmaceutica International, an affiliate of Janssen US, have entered into a certain Development Agreement, dated December 23, 1993 (the "Development Agreement"), for the development of a Product (as described below); and

WHEREAS, Janssen Pharmaceutica International has an option under the Development Agreement to enter into this License Agreement for the Medisorb technology required to make, use and sell the Product, which option Janssen Pharmaceutica International has assigned to Janssen US with the consent of Medisorb and which option Janssen US has elected to exercise; and

WHEREAS, the parties believe that it is in their mutual best interest for Medisorb to license to Janssen US on an exclusive basis in the Territory, Medisorb Patents and Technical Information within the Field, upon the terms and conditions set forth herein;

NOW, IT IS HEREBY AGREED AS FOLLOWS:

(1) Definitions: The following terms shall have the meanings ascribed to them herein, unless the context otherwise requires:

(a) "Affiliate" shall mean any company controlling, controlled by, or under common control with a party by ownership, directly or indirectly, of fifty percent (50%) or more of the total ownership or by the power to control the policies and actions of such company.

(b) "Development Program" shall mean the development activities conducted by the parties pursuant to the Development Agreement.

(c) "Field" shall mean the treatment of psychosis in humans. In this regard, psychosis shall include, but not be limited to, schizophrenia and related disorders, manic-depressive disorders, behavioral disturbances in dementia including for the avoidance doubt behavioral disturbances related to Alzheimer’s disease.

(d) "Improvements" shall mean any improvements or developments to or of the Patents and Technical Information in the Field which Medisorb may acquire, discover, invent, originate, make, conceive or have a right to, in whole or in part, during the term of this Agreement, whether or not such improvement or development is patentable.

(e) "Medisorb Polymers" shall mean bioresorbable aliphatic polyesters based on glycolide, lactide, caprolactone and combinations of such polymers, which are manufactured by Medisorb and utilized in Product(s) licensed under this Agreement.

(f) "NDA" shall mean a New Drug Application and all supplements filed pursuant to the requirements of the United States Food and Drug Administration, including all documents, data and other information concerning Product which are necessary for, or included in, FDA approval to market a Product as more fully defined in 21 C.F.R. 314.5 et seq. or any other similar application for marketing authorization filed with the appropriate regulatory authorities in other countries of the Territory (as defined hereinafter).

(g) "Net Sales" shall mean the gross amounts received from sales of Products during a calendar quarter to third parties by Janssen US, its Sublicensees or any Affiliate of either, less any: (i) applicable sales taxes; (ii) cash trade or quantity discounts; (iii) amounts repaid or credited by reason of rejections or return of goods; or (iv) freight, postage and duties paid for. No deduction from the gross sales price shall be made for any item of cost incurred by the seller in its own operations incident to the manufacture, sale or shipment of the product sold. For purposes hereof, Net Sales shall not include sales of a Product from Janssen US or an Affiliate of Janssen US to any Affiliate or Sublicensee of either; it being intended that Net Sales shall only include sales to unrelated third-parties.

(h) "Patents" shall mean (i) any and all existing issued patents and patent applications or parts thereof which describe and claim a depot formulation of Risperidone, or any chemical analogues of Risperidone with similar physiological activity, based on polymers of lactic and glycolic acids and the production and use thereof; (ii) any other patents and patent applications filed by or on behalf of Medisorb, or under which Medisorb has the rights to grant licenses, which are needed to practice the inventions; and (iii) any reissues, extensions, substitutions, confirmations, registrations, revalidations, additions, continuations, continuations-in-part, or divisions of or to any of the foregoing which are granted hereafter or any additional protection certificate granted with respect thereto.

(i) "Product(s)" shall mean any and all depot formulations of Risperidone (R 64766), or any chemical analogues of Risperidone with similar physiological activity, based on polymers of lactic and glycolic acids which are designed to deliver Risperidone (R 64766), or any of its chemical analogues, over an extended period.

(j) "Sublicensees" shall mean any company or companies, other than Janssen US's Affiliates, sublicensed by Janssen US.

(k) "Technical Information" shall mean all unpatented information, know-how, practical experience, procedures, methodology, specifications, formulae and data whether or not the same shall be patentable which have been heretofore developed or acquired by Medisorb prior to the date of this Agreement and which are necessary in order to use, manufacture or sell Products in the Field.

(l) "Territory" shall mean the United States, its Territories, Protectorates, Commonwealths, and all other political subdivisions of the United States.

(2) License Grant

(a) Medisorb hereby grants to Janssen US in the Territory an exclusive license under the Patents and Technical Information existing prior to the effective date of this Agreement, with the right to grant sublicenses thereunder, for all purposes within the Field to practice and use the Patents and Technical Information, including the rights to manufacture and have manufactured, to use and have used, and to sell and have sold Products. Medisorb exclusively retains all rights under the Patents and Technical Information outside the Field and for use other than in Products. The right to grant sublicenses granted hereunder is exclusive to Janssen US and shall not extend to Janssen US Affiliates or Sublicensees.

(b) Medisorb shall offer to Janssen US for incorporation into this License Agreement on reasonable terms and conditions, Medisorb Improvements in the Field which, if incorporated into Janssen US's then current commercial Product(s), would: (i) result in significant changes in either the specifications for such Product(s) or the processes for producing such Product(s), and (ii) would reasonably be expected to result in enhanced market value and/or profitability of such Product(s). Examples of such Improvements would include: (i) the development by Medisorb of a non-aqueous injection vehicle which offers significant advantages with respect to ease of administration and (ii) the development by Medisorb of technology enabling significantly extended (e.g. 2-4 weeks) duration of delivery of the active agent from a single administration. It is the parties' understanding that the effect of any such license amendment would, in general, be either an extension of the term of this Agreement for a mutually agreed period or a marginal increase in the then current royalty rate. All other Medisorb Improvements shall be made available to Janssen US for its use without further agreement. Proprietary rights to Improvements jointly developed by Medisorb and Janssen US or any of its Affiliates shall be governed by the terms of Section 5(c) of this Agreement.

(c) In the event that at any time during the term of this Agreement Medisorb is unable for any reason whatsoever to supply the Medisorb Polymers required by Janssen U.S. for use in Products, then the license granted under paragraph 2(a) above shall be expanded to include the Medisorb Technology required to make and use the Medisorb Polymers.

(3) Royalties:

(a) Janssen US shall pay or cause to be paid to Medisorb a running royalty with respect to all Products sold to customers in the Territory by Janssen US, its Affiliates and Sublicensees, payable quarter-annually in arrears within sixty (60) days following the end of Janssen US's regular fiscal quarters in any year during the term hereof, as follows: (i) 2.5% of the Net Sales of each unit of Product sold during the preceding calendar quarter during the term hereof, if such unit of Product was manufactured by Medisorb pursuant to a written contract for the supply of Product; or (ii) 5.0% of the Net Sales of each unit of Product sold during the preceding calendar quarter during the term hereof, if such unit of Product was not manufactured

by Medisorb pursuant to a written contract for the supply of Product. Any withholding or other tax that Janssen US or any of its Affiliates or Sublicensees are required by statute to withhold and pay on behalf of Medisorb with respect to the royalties payable to Medisorb under this Agreement shall be deducted from said royalties and paid contemporaneously with the remittance to Medisorb; provided, however, that in regard to any tax so deducted Janssen US shall furnish Medisorb with proper evidence of the taxes paid on its behalf.

(b) In the event that Product is not claimed in a valid Patent effective in the Territory and a similar product obtains a market share greater than 20% of the total market revenues for Products and similar products in such country, the parties agree to meet and negotiate in good faith an appropriate reduction in the royalty rate then in effect. In no event shall a reduction in royalty rates pursuant to this section result in royalty rates less than fifty-percent (50%) of the rates specified under Section 3(a)(i) and 3(a)(ii) of this Agreement. For the purposes of this section, "similar product" shall mean a generic version of the Product(s) where: (i) the active agent is risperidone, or a chemical analogue thereof and (ii) the excipient is comprised of lactic and/or glycolic acids. In the event that patent protection in the Territory for Product(s) becomes available subsequent to a royalty reduction pursuant to this section, the parties agree to (i) reinstitute the royalty otherwise applicable, and (ii) in the event that any recovery is obtained for prior infringement of the subsequently issued patent, the parties will first apply such recoveries to reimbursing Medisorb for royalties it would otherwise have received.

(c) Janssen US shall keep complete and adequate records with respect to the proceeds of Products on which it has to pay royalties payable hereunder for at least two (2) years after expiry of the year they concern. Medisorb shall have the right to have such records of Janssen US inspected and examined, at Medisorb's expense, for the purpose of determining the correctness of royalty payments made hereunder.

Such inspection shall be made by an independent, certified public accountant to whom Janssen US shall have no reasonable objection. Such accountant shall not disclose to Medisorb any information other than that necessary to verify the accuracy of the reports and payments made pursuant to this Agreement. It is understood that such examination with respect to any quarterly accounting period shall take place not later than two (2) years following the expiration of said period. Not more than one examination per year shall take place.

Based upon the verification of such reports and whenever there is reasonable doubt about the accuracy of the sales of Product realized by an Affiliate or sublicensee, Medisorb may reasonably request Janssen US to audit the books of such Affiliate or such sublicensee in accordance with any applicable contractual provision, in order to confirm the accuracy of such reports.

(4) Production of Product/Technology Transfer:

(a) Janssen US shall use its reasonable efforts consistent with its overall business practices and strategies to commercialize and market Product, or to have the same commercialized and marketed in the Territory.

(b) In the event that Janssen US determines to manufacture Product itself or through an Affiliate or have Product manufactured by a third party, Medisorb shall transfer to Janssen US and/or Affiliate all relevant Technical Information, and provide such technical assistance, upon mutually agreed terms and conditions, as is required by Janssen US in order to enable the manufacture of Product by Janssen US, its Affiliate or its designated third party manufacturer. However, with respect to such third party manufacturers, except as limited by a written Product manufacturing agreement between Janssen US and Medisorb, Medisorb will have a right of first refusal as to the manufacture and supply to Janssen US of all Product(s), and component bioabsorbable polymers utilized in such Product(s). Medisorb will have a period of thirty (30) days following written notice from Janssen US of terms it is offering to, or prepared to accept from, a third party manufacturer to notify Janssen US of its intention to exercise its right of first refusal to supply Product and/or component bioabsorbable polymers thereof to Janssen US, its Affiliates and Licensees on terms no less favorable to Janssen US than those offered by such third party manufacturer. Such third party manufacturer cannot be an in-kind competitor to Medisorb and must be reasonably acceptable to Medisorb with respect to confidential protection of Medisorb's Technical Information. In the event that at any time during the term of this Agreement Medisorb is unable for any reason whatsoever to supply the Medisorb Polymers required by Janssen U.S. for use in Products, then the right of first refusal under this paragraph respecting the supply of the component bioabsorbable polymers shall be eliminated. For the purposes of this section, an "in-kind" competitor shall mean any organization which regularly engages in the contract development and/or contract manufacture of injectable controlled release drug delivery systems comprising a polymeric excipient based on lactic and/or glycolic acids and/or other closely related monomers. This Section 4(b) specifically supersedes Section 7(B) of the Development Agreement, which Section 7(B) shall be of no further force or effect.

(5) Proprietary Rights

(a) Medisorb will retain title to and ownership of all technology (including, without limitation, all patents, inventions, and data relating thereto) relating to absorbable polymers, controlled release of active agents, and/or manufacturing methods or processes relating to such polymers and the controlled delivery systems for active agents based on such polymers previously owned by Medisorb or developed by Medisorb as a result of the Development Program or otherwise. Medisorb will pay its own costs and expenses in connection with the protection of any such technology, including all patent application and maintenance costs and Janssen US agrees to provide Medisorb with any necessary utility information.

Medisorb shall inform Janssen US of any patent application it wishes to file to protect proprietary rights defined in Article 5, resulting from either the Development Program or the preliminary Development Program and shall forward a copy of any such patent application to Janssen US at least one month prior to filing.

Medisorb shall consider any suggestions made by Janssen US for amplifying such application and shall accordingly amend the application where in Medisorb's opinion it is appropriate.

Medisorb shall not abandon part or whole of any of the patents or patent applications without having first consulted Janssen US, which shall have the right to further pursue any patents or patent applications which Medisorb wishes to abandon, or parts thereof, in its own name and at its own expense.

(b) Janssen US and/or its Affiliate will retain title to and ownership of all technology (including, without limitation, all patents, inventions, and data relating thereto) relating to Risperidone or any chemical analogues of Risperidone with similar physiological activity previously owned by Janssen US and/or its Affiliate or developed by Janssen US and/or affiliate as a result of this Agreement or otherwise. Janssen US and/or its Affiliate will pay its own costs and expenses in connection with the protection of any such technology, including all patent application and maintenance costs and Medisorb agrees to provide Janssen US with any necessary utility information.

(c) Any inventions, other than those falling under either section 5(a) or 5(b) hereof, having an inventorship jointly between at least one employee of Janssen US or an Affiliate of Janssen US and one employee of Medisorb or an Affiliate of Medisorb shall be jointly-owned by Janssen US or Janssen US Affiliate as the case may be and Medisorb. Each party will cooperate fully in the filing and prosecution of such patent applications.

Janssen US and Medisorb shall agree on which of both shall be responsible for the filing, prosecution and maintenance of any such joint patent applications and patents (hereinafter referred to as the "Responsible Party") in Territory. In principle, the party having contributed the most to the invention to be protected shall be the responsible party, unless agreed upon differently. Upon mutual consent, the responsible party may select an agent for drafting, filing and prosecuting a joint application. However, both parties shall agree who shall be the agent and to what extent this agent shall be used.

The Responsible Party shall consult the other party when drafting any new jointly owned patent application. The final draft shall be forwarded to the other party at least one month prior to filing to give the opportunity to make final comments.

The Responsible Party shall not abandon part or whole of any of the patents or patent applications without having first consulted the other party, which shall have the right to further pursue any patents or patent applications which the responsible party wishes to abandon, or parts thereof, in its own name and at its own expense.

All out-of-pocket costs made in relation to joint patent applications and patents in the Territory shall be shared equally by Janssen US and Medisorb. A statement of costs shall be made up on a quarterly basis and invoiced to the other party.

Medisorb shall grant to Janssen US an exclusive fully-paid up royalty free license with the right to sublicense to make, have made, use and sell under any such patents or patent applications for the duration of the patents, any continuations, continuations in part, divisions, patents of addition, reissues, renewals or extensions thereof or any supplementary protection certificates granted with respect thereto, in respect of any claims concerning the application of Risperidone or any chemical analogues of Risperidone with similar physiological activity. However, nothing contained in this paragraph shall obviate Janssen US's obligation to pay royalties under Section 3 hereof with respect to any Products developed hereunder.

Janssen US shall grant to Medisorb an exclusive fully paid-up royalty free license with the right to sublicense to make, have made, use and sell under any such patents or patent applications for the duration of the patents, any continuations, continuations in part, divisions, patents of addition, reissues, renewals or extensions thereof or any supplementary protection certificates granted with respect thereto, in respect of any claims concerning the application of bioabsorbable polymers in the field of human and/or veterinary medicine.

(d) In addition, each party will retain exclusive title to its respective confidential information in accordance with the provisions of Article 9 below.

(6) Patent Infringement

(a) In the event that either party becomes aware that any third party is infringing in the Territory any patents included within the Patents, the party becoming aware of such infringement shall promptly give notice of such infringement to the other party. Any possible action against such alleged infringement of the Patents will be carried out by either or both of the parties in accordance with the provisions specified hereinafter in paragraphs (b), (c), (d) and (e).

(b) Whenever it would concern a patent or patent application falling within the definition of Patents and of which Medisorb retains full title and ownership pursuant to Article 5 a), Medisorb shall use all reasonable efforts to take action against such infringement in its own name, at its own expense and on its own behalf.

If Medisorb fails to take action against such infringement, or if Medisorb does not use reasonable efforts in carrying out such action after commencement thereof, within thirty (30) days after the notice referred to in paragraph (a) above or after having become aware of such infringement, Janssen US shall be entitled at its own discretion and at its own expense, to take immediate action against such infringement in its own name, at its own expense and on its own behalf. Medisorb will give all reasonable assistance to Janssen in taking such action in accordance with Article 6(e), including giving Janssen the authority to file and prosecute such suit and, if necessary, being named a party in such action. If Janssen US commences or assumes such action, Janssen US may credit up to fifty percent (50%) of any royalty otherwise due to Medisorb for sales in such country or countries against the amount of the expenses and costs of such action, including without limitation, attorney fees actually incurred by Janssen US. The amount of

expenses so deducted shall be paid to Medisorb out of the recoveries, if any, received by Janssen US as a result of such action. Except for such repayment of royalties deducted, Janssen US shall be entitled to retain all recoveries therefrom.

In no event shall Medisorb settle with such infringing third party in the Field without the prior written consent of Janssen US.

(c) Whenever it would concern a patent or patent application falling within the definition of Patents and of which Janssen US or any of its Affiliates retains full title and ownership pursuant to Article 5 B), Janssen US shall have the right but not the obligation to take action against such infringement in its own name, at its own cost and on its own behalf. If Janssen US fails to take action against such infringement, or if Janssen US does not use reasonable efforts in carrying out such action after commencement thereof, within thirty (30) days after the notice referred to in paragraph (a) above or after having become aware of such infringement, Medisorb shall be entitled at its own discretion and at its own expense, to take action against such infringement. Medisorb shall be entitled to retain all recoveries, if any, therefrom.

(d) Whenever it would concern a patent or patent application falling within the definition of Patents and of which Janssen US or any of its Affiliates and Medisorb jointly retain full title and ownership pursuant to Article 5 (c), and whenever in such case the infringing product would be a drug product falling within the definition of the Field, Janssen US shall have the right but not the obligation to take action against such infringement in its own name, at its own cost and on its own behalf. If Janssen US fails to take action against such infringement, or if Janssen US does not use reasonable efforts in carrying out such action after commencement thereof, within thirty (30) days after the notice referred to in paragraph (a) above or after having become aware of such infringement, Medisorb shall be entitled at its own discretion and at its own expense, to take action against such infringement, it being understood that Janssen US will have a continuing right to take over any such action at its own expense and shall pay to Medisorb from any recoveries Janssen US receives (i) Medisorb's expenses and (ii) from any sums remaining after deduction of Medisorb's and Janssen US's expenses, an amount proportionate to Medisorb's expenses in relation to Janssen US's expenses.

Whenever it would concern a patent or patent application falling within the definition of Patents and of which Janssen US or any of its Affiliates and Medisorb jointly retain full title and ownership pursuant to Article 5 (c), and whenever in such case the infringing product would be a drug product falling outside the definition of the Field, Medisorb shall have the right but not the obligation to take action against such infringement in its own name, at its own cost and on its own behalf. If Medisorb fails to take action against such infringement, or if Medisorb does not use reasonable efforts in carrying out such action after commencement thereof, within thirty (30) days after the notice referred to in paragraph (a) above or after having become aware of such infringement, Janssen US shall be entitled at its own discretion and at its own expense, to take action against such infringement, it being understood that Medisorb will have a continuing right to take over any such action at its own expense. If Janssen US commences or assumes such action, Janssen US may credit up to fifty percent (50%) of any royalty otherwise payable to

Medisorb payable hereunder against the amount of the expenses and costs of such action, including without limitation, attorney fees actually incurred by Janssen US. The amount of expenses so deducted shall be paid to Medisorb out of the recoveries, if any, received by Janssen US as a result of such action. Except for such repayment of royalties deducted, Janssen US shall be entitled to retain all recoveries therefrom.

(e) Each party agrees to cooperate reasonably with the other party in such litigation, including making available to the other party records, information, and evidence relevant to the infringement of the Patent.

(7) Third Party Intellectual Property Rights

(a) Medisorb warrants that to the best of its current knowledge and belief the Products to be developed hereunder will not infringe the patent rights of any third party.

(b) In the event that the manufacture, use or sale of the Product would constitute an infringement of the rights of a third party in the Territory because of the use of the Patents or Medisorb's know how, each party shall, as soon as it becomes aware of the same, notify the other thereof in writing, giving in the same notice full details known to it of the rights of such third party and the extent of any alleged infringement. The parties shall after receipt of such notice meet to discuss the situation, and, to the extent necessary attempt to agree on a course of action in order to permit Janssen US to practice the license granted hereunder. Such course of action may include: (a) modifying the Product or its manufacture so as to be noninfringing; (b) obtaining an appropriate license from such third party; or (c) fight the claim or suit. In the event that within a short period of time, the parties fail to agree on an appropriate course of action Janssen US may decide upon the course of action in the interest of the further development, manufacturing or commercialization of the Product.

(c) In the event that the parties cannot agree on modifying the Product or in the case that such modification would not be economically viable or regulatory feasible, Janssen US, whenever it relates to know how, whether patented or not, owned by Janssen US in accordance with the provisions of Article 5 (b) and (c), or Medisorb, whenever it relates to know how, whether patented or not, owned by Medisorb in accordance with the provisions of Article 5 (a), will have the right to negotiate with such third party for such license. Both parties hereto will in any event in good faith consult with each other with respect to such negotiations and the party negotiating such license as indicated above, will make every effort to minimize the amount of license fees and royalties payable thereunder. In no event shall either party as a result of such settlement, grant a sublicense or cross license to the third party to settle the suit, without the prior written approval of the other party. In the event that such negotiations result in a consummated agreement, any license fee and/or royalties to be paid thereunder shall be paid by the party responsible for the negotiations as indicated above, fifty percent (50%) of any license fees or royalties paid by Janssen US under such license will be creditable against royalties due to Medisorb hereunder.

(d) In the event that either or both parties would further to such notification under Paragraph 7 (b) decide to defend such suit or claim in which a third party alleges that the manufacture, use or selling of the Product in the Territory infringes said third party's patent in, Janssen US shall have the right to apply up to fifty percent (50%) of the royalties due to Medisorb on the sales of the allegedly infringing Product against its litigation expenses.

(8) Term:

(a) Except as otherwise provided herein, this Agreement and the term of the license granted to Janssen US hereunder shall commence on the date first written above and shall expire (i) upon expiration of the last to expire Patent or (ii) fifteen (15) years after the date of the first commercial sale of Product in the Territory, whichever is later; provided, that in no event shall the license granted hereunder expire later than the twentieth anniversary of the first commercial sale of Product. After expiration of the license granted to Janssen US hereunder, Janssen US shall retain a fully paid-up non-exclusive license to manufacture, use and sell Products in the Field in the Territory.

(b) Medisorb may convert the exclusive license granted under this Agreement to non-exclusive if Janssen US does not maintain the following minimum annual royalty payments to Medisorb. With respect to the entire Territory, the minimum royalty obligation will first apply to the twelve month period following the anniversary of the end of the month in which the Product was launched. During the first twelve month period and each subsequent twelve month period that such minimum royalty obligation is applicable, the minimum royalty amount to be paid by Janssen US will be calculated by multiplying the applicable royalty rate by five percent of the actual aggregate net sales of other risperidone products in the Territory during such twelve month period.

Janssen US shall have the right to make up any shortfall in minimum royalty payments from Product sales in the Territory provided, such make-up payment is made at the same time and in the same manner as required for the underlying minimum royalty obligation.

(c) In the event that either party shall enter or be put into voluntary or compulsory liquidation or have a receiver appointed or default in the observance or performance of its obligations under this Agreement and shall fail to remedy such default within ninety (90) days after the delivery of written notice from the other party, the other party shall be entitled upon giving written notice to terminate this Agreement.

(d) Janssen US may terminate this Agreement without cause upon 30 days prior written notice. Thereafter, Janssen US shall have no further rights or privileges with respect to the use of Medisorb Technology in Products and Medisorb shall be under no further obligation of non-competition or exclusive dealing.

(e) Any early termination of the Agreement shall be without prejudice to the rights of either party against the other accrued under this Agreement prior to termination.

(f) Upon any termination of this Agreement, any remaining inventory of Product may be sold, provided all royalties otherwise due hereunder are paid with respect to such sales.

(g) All rights and licenses granted under or pursuant to this Agreement by Medisorb to Janssen U.S. are, and shall otherwise be deemed to be, for purposes of Section 365(n) of Title 11, U.S. Code (the "Bankruptcy Code"), licenses to "intellectual property" as defined under section 101(60) of the Bankruptcy Code. The parties agree that Janssen, as a licensee of such rights under this Agreement, shall retain and may fully exercise all of its rights and elections under the Bankruptcy Code.

(9) Confidentiality:

(a) Each party agrees to keep confidential and to not use for any purpose other than as set forth herein all technical information and materials supplied by the other hereunder and any information a party may acquire about the other or its activities as a result of entering into this Agreement, provided that such obligation shall not apply to technical information or material which: (i) was in the receiving party's possession without restriction prior to receipt from the other party or its Affiliates; (ii) was in the public domain at the time of receipt; (iii) becomes part of the public domain through no fault of the receiving party; (iv) shall be lawfully received from a third party with a right of further disclosure; (v) shall be required to be disclosed by law, by regulation or by the rules of any securities exchange.

(b) Except as may be otherwise provided herein, the confidentiality obligations as set out in this Section shall continue so long as this Agreement remains in force and thereafter for a period of seven (7) years.

(c) Janssen US shall cause its Affiliates and Sublicensees to abide by the obligations of confidentiality with respect to unpublished information within the Patents and Technical Information.

(d) Any confidential information relating to the subject matter of this Agreement imparted to the other party prior to the execution of this Agreement shall be considered to fall under the terms of this Agreement.

(10) Disclaimer of Warranty: Medisorb makes no representations or warranties, express or implied, with respect to the Medisorb Patents and Technical Information licensed to Janssen US hereunder, including without limitation any warranties of merchantability or fitness for a particular purpose.

(11) Liability

(a) Janssen US agrees to indemnify, defend and hold harmless Medisorb from and against any liability, loss, damages and expenses (including reasonable attorney fees) Medisorb may suffer as the result of claims, demands, costs or judgments which may be made or instituted against Medisorb by reason of personal injury or damage to property arising out or caused by Janssen US's promotion, use and sale of the Product, except where such liabilities claims, demands, costs or judgments are caused by Medisorb's failure to provide Janssen US with any information as specified in Section 12 (c) and Article 13. Medisorb will notify Janssen US as soon as it becomes aware of any such claim or action and agrees to give reasonable assistance in the investigation and defense of such claim or action it being understood that it shall allow Janssen US to control the disposition of the same.

(b) Medisorb agrees to indemnify, defend and hold harmless Janssen US from and against any liability, loss, damages and expenses (including reasonable attorney fees) Janssen US may suffer as the result of claims, demands, costs or judgments which may be made or instituted against Janssen US by reason of personal injury or damage to property arising out or caused by Medisorb's failure to provide Janssen US with any information as specified in Section 12 (c) and Article 13.

(c) In no event shall either party be liable for loss of profits, loss of goodwill or any consequential or incidental damages of any kind of the other party.

(12) Product Information and Adverse Drug Events

(a) As Janssen US has superior knowledge of the end-use applications to which Products licensed hereunder will be put, Janssen US is responsible for providing third parties with adequate information as to the medical profile of such Products. Janssen US will provide Medisorb with copies of the product information document which is part of the NDA for the Product.

(b) Medisorb does not claim the expertise to judge whether Product(s) will perform acceptably in Janssen US's application(s). Janssen US is the sole judge as to whether Product(s) will perform acceptably in Janssen US's application(s). Janssen US represents and warrants on an on-going basis during the term of this agreement that it has the capability to assess the suitability of Product(s) in Janssen US's application(s) and agrees to conduct adequate testing to confirm the safety and efficacy of Products prior to commercialization.

(c) Medisorb will provide to Janssen US promptly after its discovery by Medisorb, any information in its possession which indicates adverse effects in humans associated with the Products, including the bioabsorbable polymeric components thereof, licensed hereunder. For the purpose of this Agreement "adverse event" shall mean an experience which is noxious and unintended and which occurs at doses normally used in man for the prophylaxis, diagnosis or therapy of a disease or for the modification of a physiological function and any report of an overdose.

(13) Government Approvals

Janssen US shall be responsible for conducting all necessary testing as well as determining what, if any, government approvals are required for the use and sale of Product licensed hereunder and shall comply with all such requirements prior to and following the sale or distribution of such Products.

Medisorb shall cooperate fully with Janssen US in obtaining regulatory approvals for Product licensed hereunder and shall, at Janssen US's request, provide appropriate regulatory authorities with any and all information concerning Medisorb's technology, Medisorb polymers and Medisorb's manufacturing process for such Product.

In this respect Medisorb undertakes that it has submitted or will as soon as possible submit a type IV Drug Master File to the FDA identifying Medisorb's method of manufacture, release specifications and testing methods used in the manufacture of Medisorb Polymers and a type I Drug Master File of Medisorb's manufacturing facilities where Product may be manufactured. Medisorb will authorize Janssen U.S. at its request to cross-reference any Drug Master Files relating to the Medisorb Polymers.

(14) Force Majeure: Neither party shall be liable for its failure to perform any of its obligations hereunder if such failure is occasioned by a contingency beyond its reasonable control including, but not limited to, occurrences such as strikes or other labor disturbances, lock out, riot, war, default by a common carrier, fire, flood, storm, earthquake, other acts of God, inability to obtain raw materials, failure of plant facilities or government regulation, act or failure to act. Each party shall notify the other immediately upon occurrence or cessation of any such contingencies. If such contingency continues unabated for at least 180 consecutive days, either party shall have the right to terminate this Agreement without further obligation beyond those actually incurred prior to such termination.

(15) Press Communications: Neither party shall originate any publicity, news release or public announcement, written or oral relating to this Agreement, including its existence, without the prior written approval of the other party.

(16) Notices: Any legal notice required or permitted hereunder shall be considered properly given if in writing and sent by first class mail, certified mail or by telefacsimile to the party being notified at the respective address of such party as follows:

If to Medisorb:

Medisorb Technologies International L.P.
6954 Cornell Road
Cincinnati, OH 45242

Facsimile: 513-489-2348

If to Janssen US:

Janssen U.S.
1125 Trenton-Harbourton Road
P.O. Box 200
Titusville, New Jersey 08560-0200

Facsimile: 609-630-2616

with a copy to Janssen Pharmaceutica International
Kollerstrasse 38
6300 Zug 6
Switzerland
Facsimile: 00-41-42449565

Such notice shall be effective upon receipt or upon refusal to accept such notice. In any case, notice shall be presumed effective no later than five (5) days after such notice is sent.

Neither party shall originate any publicity, news release or public announcement, written or oral, relating to this Agreement, including its existence, without the written approval of the other party.

(17) Assignment: This Agreement shall not be assigned by either party without the prior written consent of the other party; provided, however, that assignment shall be permitted without such consent to any party, not less than 50% of the total interest of which owns, is owned by, or is under common control with the assigning party. In the event of any such permitted assignment the assignee shall be subject to and shall agree in writing to be bound by the terms and conditions of this Agreement.

(18) Dispute Resolution: The parties shall amicably discuss and negotiate any matters which arise under this Agreement and are not specifically set forth hereunder. If any disputes arise under this Agreement, the parties shall use their reasonable efforts to meet and resolve such disputes. In the event that the parties are unable to resolve any such disputes, then both parties hereby agree to submit said disputes to the jurisdiction of the competent courts of the State of New Jersey and agree that any litigation in any way related to this Agreement shall be submitted to such courts and that same shall be subject to the laws of the State of New Jersey without regard to its rules respecting choice of law.

(19) Severability: In the event any one or more of the provisions of this Agreement should for any reason be held by any court or authority having jurisdiction over this Agreement or any of the parties hereto to be invalid, illegal or unenforceable such provision or provisions shall be validly reformed to as nearly approximate the intent of the parties as possible

and, if unreformable; shall be divisible and deleted in such jurisdiction, elsewhere this Agreement shall not be affected.

(20) Captions: The captions of this Agreement are for convenience only, and shall not be deemed of any force or effect whatsoever in construing this Agreement.

(21) Waiver: The failure on the party of a party to exercise or enforce any right conferred upon it hereunder shall not be deemed to be a waiver of any such right, nor operate to bar the exercise or enforcement thereof at any time thereafter.

(22) Survival: The following Articles of this Agreement shall survive the termination or expiration of this Agreement: 5, 9, 10, 11, 15, 17, and 18.

(23) Miscellaneous: This Agreement may be executed by the parties hereto in counterparts, each of which when so executed and delivered shall be considered to be an original, but all such counterparts shall together constitute but one and the same instrument. This Agreement is the complete agreement of the parties and supersedes all previous understandings and agreements relating to the subject matter hereof. Neither this Agreement nor any of the terms hereof may be terminated, amended, supplemented, waived or modified orally, but only by an instrument in writing signed by the party against whom enforcement of the termination, amendment, supplement, waiver or modification is sought.

IN WITNESS WHEREOF, the duly authorized representatives of the parties hereto have executed this Agreement as of the day and year first above written.

JANSSEN PHARMACEUTICA INC.

By: /s/ Paula F. Costa
Name: Paula F. Costa
Title: President
Date: February 13, 1996

{Second Janssen Signatory}

By: /s/ Bruce D. Given
Name: Bruce D. Given
Title: Group Vice President
Date: February 16, 1996

MEDISORB TECHNOLOGIES INTERNATIONAL L.P.
by: Medisorb Technologies
International, Inc.,
its General Partner

By: /s/ David R. Lohr
Name: David R. Lohr
Title: President
Date: January 31, 1996

2011 Plan – US certificate

Stock Option Award Certificate

(INCENTIVE STOCK OPTION)
(Time Vested)

ID: XXXXXXXX
Connaught House
1 Burlington Rd.
Dublin 4, Ireland

«FIRST_NAME» «MIDDLE_NAME» «LAST_NAME»
«ADDRESS_LINE_1»
«ADDRESS_LINE_2»
«ADDRESS_LINE_3»
«CITY», «STATE» «ZIP_CODE»

Option Number:
Plan:

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.

Vesting details are available via your Bank of America Merrill Lynch Benefits Online account. The Incentive Stock Option shall expire on the earlier to occur of: the 10th anniversary of the date of grant or three months after termination of your service relationship with the Company (unless otherwise provided below).

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 Stock Option Award Certificate and the Alkermes plc 2011 Stock Option and Incentive Plan, as amended (the "Plan").

_____ _____

Alkermes plc Date

2011 Plan – Irish certificate

Stock Option Award Certificate

(NON-QUALIFIED STOCK OPTION)
(Performance-Based Award)

ID: XXXXXXXX
Connaught House
1 Burlington Rd.
Dublin 4, Ireland

«FIRST_NAME» «MIDDLE_NAME» «LAST_NAME»
«ADDRESS_LINE_1»
«ADDRESS_LINE_2»
«ADDRESS_LINE_3»
«CITY», «STATE» «ZIP_CODE»

Option Number:
Plan:

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 right to acquire the shares subject to the Non-Qualified Stock Option will become fully vested as described below. The Non-Qualified Stock Option shall expire on the earlier to occur of: the 10th anniversary of the date of grant or three months after termination of your service relationship with the Company (unless otherwise provided below). .

***ADD PERFORMANCE CRITERIA ***

*** ADD VESTING SCHEDULE***

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 grant of this Option (as defined in the Plan) does not infer any right to or expectation of the grant of any Options on the same basis, or at all, in any future year. Participation in the Plan shall in no way give rise to any right on your part to compensation for any claim for loss in relation to the Plan, including:

(a) any loss or reduction of any rights or expectations under the Plan in any circumstances or for any reason (including lawful or unlawful termination of employment or the employment relationship);
(b) any exercise of a discretion or a decision taken in relation to an Option or to the Plan, or any failure to exercise a discretion or take a decision; or
(c) the operation, suspension, termination or amendment of the Plan.

By participating in the Plan, you consent to the collection, processing, transmission and storage by the Company and/or its subsidiaries, in any form whatsoever, of any data of a professional or personal nature which is necessary for the purposes of introducing and administering the Plan. The Company may share such information with any subsidiary or affiliate, any trustee, registrars, brokers, other third party administrator or other person who obtains or is to obtain control of the Company or acquires the Company, or undertaking or part-undertaking which employs you, whether within or outside of the European Economic Area.

The foregoing Non-Qualified Stock Option has been granted under and is governed by the terms and conditions of this Stock Option Award Certificate and the Alkermes plc 2011 Stock Option and Incentive Plan, as amended (the "Plan").

_____	_____
Alkermes plc	Date

2011 Plan – US certificate

Stock Option Award Certificate

(NON-QUALIFIED STOCK OPTION)
(Time Vested)

ID: XXXXXXXX
Connaught House
1 Burlington Rd.
Dublin 4, Ireland

«FIRST_NAME» «MIDDLE_NAME» «LAST_NAME»
«ADDRESS_LINE_1»
«ADDRESS_LINE_2»
«ADDRESS_LINE_3»
«CITY», «STATE» «ZIP_CODE»

Option Number:
Plan:

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.

Vesting details are available via your Bank of America Merrill Lynch Benefits Online account. The Non-Qualified Stock Option shall expire on the earlier to occur of: the 10th anniversary of the date of grant or three months after termination of your service relationship with the Company (unless otherwise provided below).

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 Non-Qualified Stock 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 Stock Option Award Certificate and the Alkermes plc 2011 Stock Option and Incentive Plan, as amended (the "Plan").

_____ _____

Alkermes plc Date

2011 Plan – US certificate

Stock Option Award Certificate

(NON-QUALIFIED STOCK OPTION)
(Performance-Based Award)

ID: XXXXXXXX
Connaught House
1 Burlington Rd.
Dublin 4, Ireland

«FIRST_NAME» «MIDDLE_NAME» «LAST_NAME»
«ADDRESS_LINE_1»
«ADDRESS_LINE_2»
«ADDRESS_LINE_3»
«CITY», «STATE» «ZIP_CODE»

Option Number:
Plan:

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 right to acquire the shares subject to the Non-Qualified Stock Option will become fully vested as described below. The Non-Qualified Stock Option shall expire on the earlier to occur of: the 10th anniversary of the date of grant or three months after termination of your service relationship with the Company (unless otherwise provided below).

***ADD PERFORMANCE CRITERIA ***

*** ADD VESTING SCHEDULE***

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, as amended.

_____ _____

Alkermes plc Date

2011 Plan – US certificate

Restricted Stock Unit Award Certificate

(Performance-based award)

ID: XXXXXXXX
Connaught House
1 Burlington Rd.
Dublin 4, Ireland

«FIRST_NAME» «MIDDLE_NAME» «LAST_NAME»
«ADDRESS_LINE_1»
«ADDRESS_LINE_2»
«ADDRESS_LINE_3»
«CITY», «STATE» «ZIP_CODE»

Option Number:
Plan:

ID:

Effective on «GRANT_DATE», you have been granted a Restricted Stock Unit ("RSU") award. The RSU award is for a total of «SHARES_GRANTED» shares of Alkermes plc (the "Company") ordinary shares.

The RSU award is granted under and is governed by the terms and conditions of this Restricted Stock Unit Award Certificate and the Alkermes plc 2011 Stock Option and Incentive Plan, as amended (the "Plan"). Unless otherwise defined in this Award Certificate, all capitalized terms shall be as defined in the Plan.

The right to acquire the shares subject to the RSU award is based upon:

ADD PERFORMANCE CRITERIA AND ANY RELEVANT FORFEITURE LANGUAGE

*** ADD VESTING SCHEDULE***

You must be employed by the Company on a vesting date in order to receive the RSU award shares that vest on that date. For the purpose of the terms of this RSU award, 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.

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 RSU award shall vest in full on such termination of employment.

_____ _____

Alkermes plc Date

2011 Plan – Irish certificate

Restricted Stock Unit Award Certificate

(Performance-based award)

ID: XXXXXXXX
Connaught House
1 Burlington Rd.
Dublin 4, Ireland

«FIRST_NAME» «MIDDLE_NAME» «LAST_NAME»
«ADDRESS_LINE_1»
«ADDRESS_LINE_2»
«ADDRESS_LINE_3»
«CITY», «STATE» «ZIP_CODE»

Option Number:
Plan:

ID:

Effective on «GRANT_DATE», you have been granted a Restricted Stock Unit ("RSU") award. The RSU award is for a total of «SHARES_GRANTED» shares of Alkermes plc (the "Company") ordinary shares.

The RSU award is granted under and is governed by the terms and conditions of this Restricted Stock Unit Award Certificate and the Alkermes plc 2011 Stock Option and Incentive Plan, as amended (the "Plan"). Unless otherwise defined in this Award Certificate, all capitalized terms shall be as defined in the Plan.

The right to acquire the shares subject to the RSU award is based upon:

ADD PERFORMANCE CRITERIA AND ANY RELEVANT FORFEITURE LANGUAGE

*** ADD VESTING SCHEDULE***

You must be employed by the Company on a vesting date in order to receive the RSU award shares that vest on that date. For the purpose of the terms of this RSU award, 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.

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 RSU award shall vest in full on such termination of employment.

The grant of this RSU award does not infer any right to or expectation of the grant of any RSU awards on the same basis, or at all, in any future year. Participation in the Plan shall in no way give rise to any right on your part to compensation for any claim for loss in relation to the Plan, including:

(a) any loss or reduction of any rights or expectations under the Plan in any circumstances or for any reason (including lawful or unlawful termination of employment or the employment relationship);
(b) any exercise of a discretion or a decision taken in relation to the RSU award or to the Plan, or any failure to exercise a discretion or take a decision; or
(c) the operation, suspension, termination or amendment of the Plan.

By participating in the Plan, you consent to the collection, processing, transmission and storage by the Company and/or its subsidiaries, in any form whatsoever, of any data of a professional or personal nature which is necessary for the purposes of introducing and administering the Plan. The Company may share such information with any subsidiary or affiliate, any trustee, registrars, brokers, other third party administrator or other person who obtains or is to obtain control of the Company or acquires the Company, or undertaking or part-undertaking which employs you, whether within or outside of the European Economic Area.

_____ _____

Alkermes plc Date

2011 Plan – Irish certificate

Stock Options Award Certificate

(NON-QUALIFIED STOCK OPTION)
(Time Vested)

ID: XXXXXXXX
Connaught House
1 Burlington Rd.
Dublin 4, Ireland

«FIRST_NAME» «MIDDLE_NAME» «LAST_NAME»
«ADDRESS_LINE_1»
«ADDRESS_LINE_2»
«ADDRESS_LINE_3»
«CITY», «STATE» «ZIP_CODE»

Option Number:
Plan:

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.

Vesting details are available via your Bank of America Merrill Lynch Benefits Online account. The Non-Qualified Stock Option shall expire on the earlier to occur of: the 10th anniversary of the date of grant or three months after termination of your service relationship with the Company (unless otherwise provided below).

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 Non-Qualified Stock 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 grant of this Option (as defined in the Plan) does not infer any right to or expectation of the grant of any Options on the same basis, or at all, in any future year. Participation in the Plan shall in no way give rise to any right on your part to compensation for any claim for loss in relation to the Plan, including:

(a) any loss or reduction of any rights or expectations under the Plan in any circumstances or for any reason (including lawful or unlawful termination of employment or the employment relationship);
(b) any exercise of a discretion or a decision taken in relation to an Option or to the Plan, or any failure to exercise a discretion or take a decision; or
(c) the operation, suspension, termination or amendment of the Plan.

By participating in the Plan, you consent to the collection, processing, transmission and storage by the Company and/or its subsidiaries, in any form whatsoever, of any data of a professional or personal nature which is necessary for the purposes of introducing and administering the Plan. The Company may share such information with any subsidiary or affiliate, any trustee, registrars, brokers, other third party administrator or other person who obtains or is to obtain control of the Company or acquires the Company, or undertaking or part-undertaking which employs you, whether within or outside of the European Economic Area.

The foregoing Non-Qualified Stock Option has been granted under and is governed by the terms and conditions of this Stock Option Award Certificate and the Alkermes plc 2011 Stock Option and Incentive Plan, as amended (the "Plan").

_____	_____
Alkermes plc	Date

Exhibit 10.3

LICENSE AGREEMENT

This Agreement is made as of the 21 day February of 1996, between MEDISORB TECHNOLOGIES INTERNATIONAL L.P., a Delaware limited partnership (hereinafter "Medisorb") and JANSSEN PHARMACEUTICA INTERNATIONAL, a division of Cilag International AG, a Swiss business corporation ("Janssen").

WHEREAS, the parties have entered into a certain Development Agreement, dated December 23, 1993 (the "Development Agreement"), for the development of a Product (as described below); and

WHEREAS, Janssen has an option under the Development Agreement to enter into this License Agreement for the Medisorb technology required to make, use and sell the Product, which option Janssen has elected to exercise; and

WHEREAS, the parties believe that it is in their mutual best interest for Medisorb to license to Janssen on an exclusive basis in the Territory, Medisorb Patents and Technical Information within the Field, upon the terms and conditions set forth herein;

NOW, IT IS HEREBY AGREED AS FOLLOWS:

(1) Definitions: The following terms shall have the meanings ascribed to them herein, unless the context otherwise requires:

(a) "Affiliate" shall mean any company controlling, controlled by, or under common control with a party by ownership, directly or indirectly, of fifty percent (50%) or more of the total ownership or by the power to control the policies and actions of such company.

(b) "Development Program" shall mean the development activities conducted by the parties pursuant to the Development Agreement.

(c) "Field" shall mean the treatment of psychosis in humans. In this regard, psychosis shall include, but not be limited to, schizophrenia and related disorders, manic-depressive disorders, behavioral disturbances in dementia including for the avoidance doubt behavioral disturbances related to Alzheimer's disease.

(d) "Improvements" shall mean any improvements or developments to or of the Patents and Technical Information in the Field which Medisorb may acquire, discover, invent, originate, make, conceive or have a right to, in whole or in part, during the term of this Agreement, whether or not such improvement or development is patentable.

(e) "International Registration Dossier" ("IRF") shall mean the Product registration file compiled by Janssen Pharmaceutica N.V., Beerse, Belgium on behalf of Janssen, the contents and format being such that it can be submitted as such to national health authorities or be used as a basis for a national application for marketing authorization for the Products in the specific format required by such national health authorities.

(f) "Medisorb Polymers" shall mean bioresorbable aliphatic polyesters based on glycolide, lactide, caprolactone and combinations of such polymers, which are manufactured by Medisorb and utilized in Product(s) licensed under this Agreement.

(g) "Net Sales" shall mean the gross amounts received from sales of Products during a calendar quarter to third parties by Janssen, its Sublicensees or any Affiliate of either, less any: (i) applicable sales taxes; (ii) cash trade or quantity discounts; (iii) amounts repaid or credited by reason of rejections or return of goods; or (iv) freight, postage and duties paid for. No deduction from the gross sales price shall be made for any item of cost incurred by the seller in its own operations incident to the manufacture, sale or shipment of the product sold. For purposes hereof, Net Sales shall not include sales of a Product from Janssen or an Affiliate of Janssen to any Affiliate or Sublicensee of either; it being intended that Net Sales shall only include sales to unrelated third-parties.

(h) "Patents" shall mean (i) any and all existing issued patents and patent applications or parts thereof which describe and claim a depot formulation of Risperidone, or any chemical analogues of Risperidone with similar physiological activity, based on polymers of lactic and glycolic acids and the production and use thereof; (ii) any other patents and patent applications filed by or on behalf of Medisorb, or under which Medisorb has the rights to grant licenses, which are needed to practice the inventions; and (iii) any reissues, extensions, substitutions, confirmations, registrations, revalidations, additions, continuations, continuations-in-part, or divisions of or to any of the foregoing which are granted hereafter or any additional protection certificate granted with respect thereto.

(i) "Product(s)" shall mean any and all depot formulations of Risperidone (R 64766), or any chemical analogues of Risperidone with similar physiological activity, based on polymers of lactic and glycolic acids which are designed to deliver Risperidone (R 64766), or any of its chemical analogues, over an extended period.

(j) "Sublicensees" shall mean any company or companies, other than Janssen's Affiliates, sublicensed by Janssen.

(k) "Technical Information" shall mean all unpatented information, know-how, practical experience, procedures, methodology, specifications, formulae and data whether or not the same shall be patentable which have been heretofore developed or acquired by Medisorb prior to the date of this Agreement and which are necessary in order to use, manufacture or sell Products in the Field.

(l) "Territory" shall mean worldwide with the exception of the United States, its Territories, Protectorates, Commonwealths, and all other political subdivisions of the United States.

(2) License Grant

(a) Medisorb hereby grants to Janssen in the Territory an exclusive license under the Patents and Technical Information existing prior to the effective date of this Agreement, with the right to grant sublicenses thereunder, for all purposes within the Field to practice and use the Patents and Technical Information, including the rights to manufacture and have manufactured, to use and have used, and to sell and have sold Products. Medisorb exclusively retains all rights under the Patents and Technical Information outside the Field and for use other than in Products. The right to grant sublicenses granted hereunder is exclusive to Janssen and shall not extend to Janssen Affiliates or Sublicensees.

(b) Medisorb shall offer to Janssen for incorporation into this License Agreement on reasonable terms and conditions, Medisorb Improvements in the Field which, if incorporated into Janssen's then current commercial Product(s), would: (i) result in significant changes in either the specifications for such Product(s) or the processes for producing such Product(s), and (ii) would reasonably be expected to result in enhanced market value and/or profitability of such Product(s). Examples of such Improvements would include: (i) the development by Medisorb of a non-aqueous injection vehicle which offers significant advantages with respect to ease of administration and (ii) the development by Medisorb of technology enabling significantly extended (e.g. 2-4 weeks) duration of delivery of the active agent from a single administration. It is the parties' understanding that the effect of any such license amendment would, in general, be either an extension of the term of this Agreement for a mutually agreed period or a marginal increase in the then current royalty rate. All other Medisorb Improvements shall be made available to Janssen for its use without further agreement. Proprietary rights to Improvements jointly developed by Medisorb and Janssen shall be governed by the terms of Section 5(c) of this Agreement.

(c) In the event that at any time during the term of this Agreement Medisorb is unable for any reason whatsoever to supply the Medisorb Polymers required by Janssen for use in Products, then the license granted under paragraph 2(a) above shall be expanded to include the Medisorb Technology required to make and use the Medisorb Polymers.

(3) Royalties:

(a) Janssen shall pay or cause to be paid to Medisorb a running royalty with respect to all Products sold to customers by Janssen, its Affiliates and Sublicensees, payable quarter-annually in arrears within sixty (60) days following the end of each three (3) month period ending on March 31, June 30, September 30 or December 31 in any year during the term hereof, as follows: (i) 2.5% of the Net Sales of each unit of Product sold during the preceding calendar quarter during the term hereof, if such unit of Product was manufactured by Medisorb pursuant to a written contract for the supply of Product; or (ii) 5.0% of the Net Sales of each unit of Product sold during the preceding calendar quarter during the term hereof, if such unit of Product was not manufactured by Medisorb pursuant to a written contract for the supply of Product. Any

withholding or other tax that Janssen or any of its Affiliates are required by statute to withhold and pay on behalf of Medisorb with respect to the royalties payable to Medisorb under this Agreement shall be deducted from said royalties and paid contemporaneously with the remittance to Medisorb; provided, however, that in regard to any tax so deducted Janssen shall furnish Medisorb with proper evidence of the taxes paid on its behalf.

(b) In the event that, in a country where Product is not claimed in a valid Patent, a similar product obtains a market share greater than 20% of the total market revenues for Products and similar products in such country, the parties agree to meet and negotiate in good faith an appropriate reduction in the royalty rate then in effect. In no event shall a reduction in royalty rates pursuant to this section result in royalty rates less than fifty-percent (50%) of the rates specified under Section 3(a)(i) and 3(a)(ii) of this Agreement. For the purposes of this section, "similar product" shall mean a generic version of the Product(s) where: (i) the active agent is risperidone, or a chemical analogue thereof and (ii) the excipient is comprised of lactic and/or glycolic acids. In the event that patent protection for Product(s) becomes available subsequent to a royalty reduction pursuant to this section, the parties agree to (i) reinstitute the royalty otherwise applicable, and (ii) in the event that any recovery is obtained for prior infringement of the subsequently issued patent, the parties will first apply such recoveries to reimbursing Medisorb for royalties it would otherwise have received.

(c) Janssen shall keep complete and adequate records with respect to the proceeds of Products on which it has to pay royalties payable hereunder for at least two (2) years after expiry of the year they concern. Medisorb shall have the right to have such records of Janssen inspected and examined, at Medisorb's expense, for the purpose of determining the correctness of royalty payments made hereunder.

Such inspection shall be made by an independent, certified public accountant to whom Janssen shall have no reasonable objection. Such accountant shall not disclose to Medisorb any information other than that necessary to verify the accuracy of the reports and payments made pursuant to this Agreement. It is understood that such examination with respect to any quarterly accounting period shall take place not later than two (2) years following the expiration of said period. Not more than one examination per year shall take place.

Based upon the verification of such reports and whenever there is reasonable doubt about the accuracy of the sales of Product realized by an Affiliate or sublicensee, Medisorb may reasonably request Janssen to audit the books of such Affiliate or such sublicensee in accordance with any applicable contractual provision, in order to confirm the accuracy of such reports.

(4) Production of Product/Technology Transfer:

(a) Janssen shall use its reasonable efforts to commercialize and market Product, or to have the same commercialized and marketed.

(b) In the event that Janssen determines to manufacture Product itself or have Product manufactured by a third party, Medisorb shall transfer to Janssen all relevant Technical Information, and provide such technical assistance, upon mutually agreed terms and conditions, as is required by Janssen in order to enable the manufacture of Product by Janssen or its designated third party manufacturer. However, with respect to such third party manufacturers, except as limited by a written Product manufacturing agreement between Janssen and Medisorb, Medisorb will have a right of first refusal as to the manufacture and supply to Janssen of all Product(s), and component bioabsorbable polymers utilized in such Product(s). Medisorb will have a period of thirty (30) days following written notice from Janssen of terms it is offering to, or prepared to accept from, a third party manufacturer to notify Janssen of its intention to exercise its right of first refusal to supply Product and/or component bioabsorbable polymers thereof to Janssen, its Affiliates and Licensees on terms no less favorable to Janssen than those offered by such third party manufacturer. Such third party manufacturer cannot be an in-kind competitor to Medisorb and must be reasonably acceptable to Medisorb with respect to confidential protection of Medisorb's Technical Information. In the event that at any time during the term of this Agreement Medisorb is unable for any reason whatsoever to supply the Medisorb Polymers required by Janssen for use in Products, then the right of first refusal under this paragraph respecting the supply of the component bioabsorbable polymers shall be eliminated. For the purposes of this section, an "in-kind" competitor shall mean any organization which regularly engages in the contract development and/or contract manufacture of injectable controlled release drug delivery systems comprising a polymeric excipient based on lactic and/or glycolic acids and/or other closely related monomers. This Section 4(b) specifically supercedes Section 7(B) of the Development Agreement, which Section 7(B) shall be of no further force or effect.

(c) The right of first refusal granted to Medisorb pursuant to Section 4(b) above shall be contingent upon: (i) Medisorb and Janssen reaching an agreement concerning the financing, scheduling and construction in Europe of a Medisorb manufacturing facility within twelve (12) months of the date first above written or the initiation of Phase III human clinical trials, whichever is later, and (ii) prior to the qualification of Medisorb's European manufacturing facility, Medisorb using reasonable efforts to supply from its United States manufacturing facilities all of Janssen's commercial requirements for Product pursuant to the Product Supply Agreement anticipated by Section 7(A) of the Development Agreement.

(5) Proprietary Rights

(a) Medisorb will retain title to and ownership of all technology (including, without limitation, all patents, inventions, and data relating thereto) relating to absorbable polymers, controlled release of active agents, and/or manufacturing methods or processes relating to such polymers and the controlled delivery systems for active agents based on such polymers previously owned by Medisorb or developed by Medisorb as a result of the Development Program or otherwise. Medisorb will pay its own costs and expenses in connection with the protection of any such technology, including all patent application and maintenance costs and Janssen agrees to provide Medisorb with any necessary utility information.

Medisorb shall inform Janssen of any patent application it wishes to file to protect proprietary rights defined in Article 5, resulting from either the Development Program or the preliminary Development Program and shall forward a copy of any such patent application to Janssen at least one month prior to filing.

Medisorb shall consider any suggestions made by Janssen for amplifying such application and shall accordingly amend the application where in Medisorb's opinion it is appropriate.

Nine months after the first filing, Medisorb shall propose a list of countries in which it intends to file foreign equivalents. Janssen shall be given the opportunity to propose further countries to be added to the list. In case the adding of some or all of these further countries is unacceptable to Medisorb, Janssen shall have the right to file patent applications in those countries, in Medisorb's name and at Janssen expense. Medisorb shall assist in the transfer of rights for the latter patent applications and shall provide all information necessary to file and prosecute such patent applications.

Medisorb shall not abandon part or whole of any of the patents or patent applications without having first consulted Janssen, which shall have the right to further pursue any patents or patent applications which Medisorb wishes to abandon, or parts thereof, in its own name and at its own expense.

(b) Janssen and/or its Affiliate will retain title to and ownership of all technology (including, without limitation, all patents, inventions, and data relating thereto) relating to Risperidone or any chemical analogues of Risperidone with similar physiological activity previously owned by Janssen and/or its Affiliate or developed by Janssen as a result of this Agreement or otherwise. Janssen and/or its Affiliate will pay its own costs and expenses in connection with the protection of any such technology, including all patent application and maintenance costs and Medisorb agrees to provide Janssen with any necessary utility information.

(c) Any inventions, other than those falling under either section 5(a) or 5(b) hereof, having an inventorship jointly between at least one employee of Janssen or an Affiliate of Janssen and one employee of Medisorb or an Affiliate of Medisorb shall be jointly-owned by Janssen and Medisorb. Each party will cooperate fully in the filing and prosecution of such patent applications.

Janssen and Medisorb shall agree on which of both shall be responsible for the filing, prosecution and maintenance of any such joint patent applications and patents (hereinafter referred to as the "Responsible Party"). In principle, the party having contributed the most to the invention to be protected shall be the responsible party, unless agreed upon differently. Upon mutual consent, the responsible party may select an agent for drafting, filing and prosecuting a joint application. However, both parties shall agree who shall be the agent and to what extent this agent shall be used.

The Responsible Party shall consult the other party when drafting any new jointly owned patent application. The final draft shall be forwarded to the other party at least one month prior to filing to give the opportunity to make final comments.

The Responsible Party shall propose a list of countries in which it intends to file such patent applications. The other party shall be given the opportunity to propose further countries to be added to the list. In case the adding of some or all of these further countries is unacceptable to the Responsible Party, the other party shall have the right to file patent applications in those countries, in its own name and at its own expense. The Responsible Party shall assist in the transfer of rights for the latter patent applications and shall provide all information necessary to file and prosecute such patent applications.

The Responsible Party shall not abandon part or whole of any of the patents or patent applications without having first consulted the other party, which shall have the right to further pursue any patents or patent applications which the responsible party wishes to abandon, or parts thereof, in its own name and at its own expense.

All out-of-pocket costs made in relation to joint patent applications and patents shall be shared equally by Janssen and Medisorb. A statement of costs shall be made up on a quarterly basis and invoiced to the other party.

Medisorb shall grant to Janssen an exclusive fully-paid up royalty free license with the right to sublicense to make, have made, use and sell under any such patents or patent applications for the duration of the patents, any continuations, continuations in part, divisions, patents of addition, reissues, renewals or extensions thereof or any supplementary protection certificates granted with respect thereto, in respect of any claims concerning the application of Risperidone or any chemical analogues of Risperidone with similar physiological activity. However, nothing contained in this paragraph shall obviate Janssen's obligation to pay royalties under Section 3 hereof with respect to any Products developed hereunder.

Janssen shall grant to Medisorb an exclusive fully paid-up royalty free license with the right to sublicense to make, have made, use and sell under any such patents or patent applications for the duration of the patents, any continuations, continuations in part, divisions, patents of addition, reissues, renewals or extensions thereof or any supplementary protection certificates granted with respect thereto, in respect of any claims concerning the application of bioabsorbable polymers in the field of human and/or veterinary medicine.

(d) In addition, each party will retain exclusive title to its respective confidential information in accordance with the provisions of Article 9 below.

(6) Patent Infringement

(a) In the event that either party becomes aware that any third party is infringing any patents included within the Patents in any country or countries, the party becoming

aware of such infringement shall promptly give notice of such infringement to the other party. Any possible action against such alleged infringement of the Patents will be carried out by either or both of the parties in accordance with the provisions specified hereinafter in paragraphs (b), (c), (d) and (e).

(b) Whenever it would concern a patent or patent application falling within the definition of Patents and of which Medisorb retains full title and ownership pursuant to Article 5 a), Medisorb shall use all reasonable efforts to take action against such infringement in its own name, at its own expense and on its own behalf.

If Medisorb fails to take action against such infringement, or if Medisorb does not use reasonable efforts in carrying out such action after commencement thereof, within thirty (30) days after the notice referred to in paragraph (a) above or after having become aware of such infringement, Janssen shall be entitled at its own discretion and at its own expense, to take immediate action against such infringement in its own name, at its own expense and on its own behalf. If Janssen commences or assumes such action, Janssen may credit up to fifty percent (50%) of any royalty otherwise due to Medisorb for sales in such country or countries against the amount of the expenses and costs of such action, including without limitation, attorney fees actually incurred by Janssen. The amount of expenses so deducted shall be paid to Medisorb out of the recoveries, if any, received by Janssen as a result of such action. Except for such repayment of royalties deducted, Janssen shall be entitled to retain all recoveries therefrom.

In no event shall Medisorb settle with such infringing third party in the Field without the prior written consent of Janssen.

(c) Whenever it would concern a patent or patent application falling within the definition of Patents and of which Janssen retains full title and ownership pursuant to Article 5 B), Janssen shall have the right but not the obligation to take action against such infringement in its own name, at its own cost and on its own behalf. If Janssen fails to take action against such infringement, or if Janssen does not use reasonable efforts in carrying out such action after commencement thereof, within thirty (30) days after the notice referred to in paragraph (a) above or after having become aware of such infringement, Medisorb shall be entitled at its own discretion and at its own expense, to take action against such infringement. Medisorb shall be entitled to retain all recoveries, if any, therefrom.

(d) Whenever it would concern a patent or patent application falling within the definition of Patents and of which Janssen and Medisorb jointly retain full title and ownership pursuant to Article 5 (c), and whenever in such case the infringing product would be a drug product falling within the definition of the Field, Janssen shall have the right but not the obligation to take action against such infringement in its own name, at its own cost and on its own behalf. If Janssen fails to take action against such infringement, or if Janssen does not use reasonable efforts in carrying out such action after commencement thereof, within thirty (30) days after the notice referred to in paragraph (a) above or after having become aware of such infringement, Medisorb shall be entitled at its own discretion and at its own expense, to take action against such

infringement, it being understood that Janssen will have a continuing right to take over any such action at its own expense and shall pay to Medisorb from any recoveries Janssen receives (i) Medisorb's expenses and (ii) from any sums remaining after deduction of Medisorb's and Janssen's expenses, an amount proportionate to Medisorb's expenses in relation to Janssen's expenses.

Whenever it would concern a patent or patent application falling within the definition of Patents and of which Janssen and Medisorb jointly retain full title and ownership pursuant to Article 5 (c), and whenever in such case the infringing product would be a drug product falling outside the definition of the Field, Medisorb shall have the right but not the obligation to take action against such infringement in its own name, at its own cost and on its own behalf. If Medisorb fails to take action against such infringement, or if Medisorb does not use reasonable efforts in carrying out such action after commencement thereof, within thirty (30) days after the notice referred to in paragraph (a) above or after having become aware of such infringement, Janssen shall be entitled at its own discretion and at its own expense, to take action against such infringement, it being understood that Medisorb will have a continuing right to take over any such action at its own expense. If Janssen commences or assumes such action, Janssen may credit up to fifty percent (50%) of any royalty otherwise payable to Medisorb payable hereunder against the amount of the expenses and costs of such action, including without limitation, attorney fees actually incurred by Janssen. The amount of expenses so deducted shall be paid to Medisorb out of the recoveries, if any, received by Janssen as a result of such action. Except for such repayment of royalties deducted, Janssen shall be entitled to retain all recoveries therefrom.

(e) Each party agrees to cooperate reasonably with the other party in such litigation, including making available to the other party records, information, and evidence relevant to the infringement of the Patent.

(7) Third Party Intellectual Property Rights

(a) Medisorb warrants that to the best of its current knowledge and belief the Products to be developed hereunder will not infringe the patent rights of any third party.

(b) In the event that the manufacture, use or sale of the Product would constitute an infringement of the rights of a third party in a country because of the use of the Patents or Medisorb's know how, each party shall, as soon as it becomes aware of the same, notify the other thereof in writing, giving in the same notice full details known to it of the rights of such third party and the extent of any alleged infringement. The parties shall after receipt of such notice meet to discuss the situation, and, to the extent necessary attempt to agree on a course of action in order to permit Janssen to practice the license granted hereunder. Such course of action may include: (a) modifying the Product or its manufacture so as to be noninfringing; (b) obtaining an appropriate license from such third party; or (c) fight the claimor suit. In the event that within a short period of time, the parties fail to agree on an appropriate course of action Janssen may decide upon the course of action in the interest of the further development, manufacturing or commercialization of the Product.

(c) In the event that the parties cannot agree on modifying the Product or in the case that such modification would not be economically viable or regulatorily feasible, Janssen, whenever it relates to know how, whether patented or not, owned by Janssen in accordance with the provisions of Article 5 (b) and (c), or Medisorb, whenever it relates to know how, whether patented or not, owned by Medisorb in accordance with the provisions of Article 5 (a), will have the right to negotiate with such third party for such license. Both parties hereto will in any event in good faith consult with each other with respect to such negotiations and the party negotiating such license as indicated above, will make every effort to minimize the amount of license fees and royalties payable thereunder. In no event shall either party as a result of such settlement, grant a sublicense or cross license to the third party to settle the suit, without the prior written approval of the other party. In the event that such negotiations result in a consummated agreement, any license fee and/or royalties to be paid thereunder shall be paid by the party responsible for the negotiations as indicated above, fifty percent (50%) of any license fees or royalties paid by Janssen under such license will be creditable against royalties due to Medisorb with respect to such country or countries.

(d) In the event that either or both parties would further to such notification under Paragraph 7 (b) decide to defend such suit or claim in which a third party alleges that the manufacture, use or selling of the Product infringes said third party's patent in a country, Janssen shall have the right to apply up to fifty percent (50%) of the royalties due to Medisorb on the sales of the allegedly infringing Product against its litigation expenses.

(8) Term:

(a) Except as otherwise provided herein, this Agreement and the term of the license granted to Janssen hereunder shall commence on the date first written above and shall expire (i) upon expiration of the last to expire Patent in such country or (ii) fifteen (15) years after the date of the first commercial sale of Product in such country, whichever is later; provided, that in no event shall the license granted hereunder expire later than the twentieth anniversary of the first commercial sale of Product in any country with the exception of the following countries where the fifteen (15) year minimum shall pertain regardless: Canada, France, Germany, Italy, Japan, Spain and the United Kingdom. After expiration of the license granted to Janssen hereunder, Janssen shall retain a fully paid-up non-exclusive license to manufacture, use and sell Products in the Field in the Territory.

(b) Medisorb may convert the exclusive license granted under this Agreement to non-exclusive if Janssen does not maintain the following minimum annual royalty payments to Medisorb:

(i) With respect to the entire Territory, excluding Japan, the minimum royalty obligation will first apply to the twelve month period following the anniversary of the end of the ;month in which the Product was launched in the third major country. For the purpose of this Article only, major country shall mean France, Germany, United Kingdom or Italy.

During the first twelve month period that such minimum royalty obligation is applicable, the minimum royalty amount to be paid by Janssen will be calculated by multiplying the applicable royalty rate by five percent of the actual aggregate net sales of other risperidone products during such twelve month period in the three major countries referred to above.

As from the subsequent twelve month period the minimum annual royalty amount to be paid by Janssen will be calculated by multiplying the applicable royalty rate by 5% of the aggregate net sales of other risperidone products during such period in all countries where Product has been launched and marketed for a period of minimally twelve months prior to the actual reference twelve month period; and

(ii) In Japan the minimum royalty obligation will be first applied to the twelve month period following the anniversary of the end of the month in which the Product was launched. The minimum annual royalty amount to be paid by Janssen will be calculated by multiplying the applicable royalty rate by an amount representing 2% of the aggregate net sales of other risperidone products in Japan during such period.

Janssen shall have the right to make up any shortfall in minimum royalty payments from Product sales, both in Japan and in the rest of the Territory provided, such make-up payment is made at the same time and in the same manner as required for the underlying minimum royalty obligation.

Janssen may elect to have its exclusive rights converted into non-exclusive rights on a country by country basis. As a consequence thereof, such country's other risperidone products sales will no longer be taken into account for calculating the above minimum royalty obligation.

(c) In the event that either party shall enter or be put into voluntary or compulsory liquidation or have a receiver appointed or default in the observance or performance of its obligations under this Agreement and shall fail to remedy such default within ninety (90) days after the delivery of written notice from the other party, the other party shall be entitled upon giving written notice to terminate this Agreement.

(d) Janssen may terminate this Agreement without cause upon 30 days prior written notice. Thereafter, Janssen shall have no further rights or privileges with respect to the use of Medisorb Technology in Products and Medisorb shall be under no further obligation of non-competition or exclusive dealing.

(e) Any early termination of the Agreement shall be without prejudice to the rights of either party against the other accrued under this Agreement prior to termination.

(f) Upon any termination of this Agreement, any remaining inventory of Product may be sold, provided all royalties otherwise due hereunder are paid with respect to such sales.

(9) Confidentiality:

(a) Each party agrees to keep confidential and to not use for any purpose other than as set forth herein all technical information and materials supplied by the other hereunder and any information a party may acquire about the other or its activities as a result of entering into this Agreement, provided that such obligation shall not apply to technical information or material which: (i) was in the receiving party's possession without restriction prior to receipt from the other party or its Affiliates; (ii) was in the public domain at the time of receipt; (iii) becomes part of the public domain through no fault of the receiving party; (iv) shall be lawfully received from a third party with a right of further disclosure; (v) shall be required to be disclosed by law, by regulation or by the rules of any securities exchange.

(b) Except as may be otherwise provided herein, the confidentiality obligations as set out in this Section shall continue so long as this Agreement remains in force and thereafter for a period of seven (7) years.

(c) Janssen shall cause its Affiliates and Sublicensees to abide by the obligations of confidentiality with respect to unpublished information within the Patents and Technical Information.

(d) Any confidential information relating to the subject matter of this Agreement imparted to the other party prior to the execution of this Agreement shall be considered to fall under the terms of this Agreement.

(10) Disclaimer of Warranty: Medisorb makes no representations or warranties, express or implied, with respect to the Medisorb Patents and Technical Information licensed to Janssen hereunder, including without limitation any warranties of merchantability or fitness for a particular purpose.

(11) Liability

(a) Janssen agrees to indemnify, defend and hold harmless Medisorb from and against any liability, loss, damages and expenses (including reasonable attorney fees) Medisorb may suffer as the result of claims, demands, costs or judgments which may be made or instituted against Medisorb by reason of personal injury or damage to property arising out or caused by Janssen's promotion, use and sale of the Product, except where such liabilities claims, demands, costs or judgments are caused by Medisorb's failure to provide Janssen with any information as specified in Section 12 (c) and Article 13. Medisorb will notify Janssen as soon as it becomes aware of any such claim or action and agrees to give reasonable assistance in the investigation and defense of such claim or action it being understood that it shall allow Janssen to control the disposition of the same.

(b) Medisorb agrees to indemnify, defend and hold harmless Janssen from and against any liability, loss, damages and expenses (including reasonable attorney fees) Janssen

may suffer as the result of claims, demands, costs or judgments which may be made or instituted against Janssen by reason of personal injury or damage to property arising out or caused by Medisorb's failure to provide Janssen with any information as specified in Section 12 (c) and Article 13.

(c) In no event shall either party be liable for loss of profits, loss of goodwill or any consequential or incidental damages of any kind of the other party.

(12) Product Information and Adverse Drug Events

(a) As Janssen has superior knowledge of the end-use applications to which Products licensed hereunder will be put, Janssen is responsible for providing third parties with adequate information as to the medical profile of such Products. Janssen will provide Medisorb with copies of the IPID (International Product Information Document) and the IPPI (International Patient Package Insert), which are all part of the IRF for the Product. For the purpose of this Agreement IPID refers to the document that summarizes all medically relevant features of the Product, including the instructions for use meant to inform the medical profession, whereas the IPPI is a patient-oriented document, based upon the IPID that summarizes all relevant information on the Product in lay language. Janssen will keep Medisorb informed of any revisions or amendments in the IPID and IPPI of the Product.

(b) Medisorb does not claim the expertise to judge whether Product(s) will perform acceptably in Janssen's application(s). Janssen is the sole judge as to whether Product(s) will perform acceptably in Janssen's application(s). Janssen represents and warrants on an on-going basis during the term of this agreement that it has the capability to assess the suitability of Product(s) in Janssen's application(s) and agrees to conduct adequate testing to confirm the safety and efficacy of Products prior to commercialization.

(c) Medisorb will provide to Janssen promptly after its discovery by Medisorb, any information in its possession which indicates adverse effects in humans associated with the Products, including the bioabsorbable polymeric components thereof, licensed hereunder. For the purpose of this Agreement "adverse event" shall mean an experience which is noxious and unintended and which occurs at doses normally used in man for the prophylaxis, diagnosis or therapy of a disease or for the modification of a physiological function and any report of an overdose.

(13) Government Approvals

Janssen shall be responsible for conducting all necessary testing as well as determining what, if any, government approvals are required for the use and sale of Product licensed hereunder and shall comply with all such requirements prior to and following the sale or distribution of such Products.

Medisorb shall cooperate fully with Janssen in obtaining regulatory approvals for Product licensed hereunder and shall, at Janssen's request, provide appropriate regulatory authorities with any and all information concerning Medisorb's technology, Medisorb polymers and Medisorb's manufacturing process for such Product.

In this respect Medisorb undertakes that it has submitted or will as soon as possible submit a type IV Drug Master File to the FDA identifying Medisorb's method of manufacture, release specifications and testing methods used in the manufacture of its bioabsorbable polymers and a type I Drug Master File of Medisorb's manufacturing facilities where Product may be manufactured. Medisorb will authorize Janssen at its request to cross-reference any Medisorb Drug Master Files relating to the Medisorb Polymers.

(14) Force Majeure: Neither party shall be liable for its failure to perform any of its obligations hereunder if such failure is occasioned by a contingency beyond its reasonable control including, but not limited to, occurrences such as strikes or other labor disturbances, lock out, riot, war, default by a common carrier, fire, flood, storm, earthquake, other acts of God, inability to obtain raw materials, failure of plant facilities or government regulation, act or failure to act. Each party shall notify the other immediately upon occurrence or cessation of any such contingencies. If such contingency continues unabated for at least 180 consecutive days, either party shall have the right to terminate this Agreement without further obligation beyond those actually incurred prior to such termination.

(15) Press Communications: Neither party shall originate any publicity, news release or public announcement, written or oral relating to this Agreement, including its existence, without the prior written approval of the other party.

(16) Notices: Any legal notice required or permitted hereunder shall be considered properly given if in writing and sent by first class mail, certified mail or by telefacsimile to the party being notified at the respective address of such party as follows:

If to Medisorb:

Medisorb Technologies International L.P.
6954 Cornell Road
Cincinnati, OH 45242
USA
Facsimile: 513-489-2348

If to Janssen:

Janssen Pharmaceutica
Kollerstrasse 38
6300 Zug 6
Switzerland
Facsimile: 00-41-42449565

Such notice shall be effective upon receipt or upon refusal to accept such notice. In any case, notice shall be presumed effective no later than five (5) days after such notice is sent.

Neither party shall originate any publicity, news release or public announcement, written or oral, relating to this Agreement, including its existence, without the written approval of the other party.

(17) Assignment: This Agreement shall not be assigned by either party without the prior written consent of the other party; provided, however, that assignment shall be permitted without such consent to any party, not less than 50% of the total interest of which owns, is owned by, or is under common control with the assigning party. In the event of any such permitted assignment the assignee shall be subject to and shall agree in writing to be bound by the terms and conditions of this Agreement.

(18) Dispute Resolution: The parties shall amicably discuss and negotiate any matters which arise under this Agreement and are not specifically set forth hereunder. If any disputes arise under this Agreement, the parties shall use their best efforts to meet and resolve such disputes. In the event that the parties are unable to resolve any such disputes, then both parties hereby agree to submit said disputes to the jurisdiction of the competent Courts of Zurich, Switzerland, and agree that any litigation in any way related to this Agreement shall be submitted to such Courts and that same shall be subject to Swiss law.

(19) Severability: In the event any one or more of the provisions of this Agreement should for any reason be held by any court or authority having jurisdiction over this Agreement or any of the parties hereto to be invalid, illegal or unenforceable such provision or provisions shall be validly reformed to as nearly approximate the intent of the parties as possible and, if unreformable; shall be divisible and deleted in such jurisdiction, elsewhere this Agreement shall not be affected.

(20) Captions: The captions of this Agreement are for convenience only, and shall not be deemed of any force or effect whatsoever in construing this Agreement.

(21) Waiver: The failure on the party of a party to exercise or enforce any right conferred upon it hereunder shall not be deemed to be a waiver of any such right, nor operate to bar the exercise or enforcement thereof at any time thereafter.

(22) Survival: The following Articles of this Agreement shall survive the termination or expiration of this Agreement: 5, 9, 10, 11, 15, 17, and 18.

(23) Miscellaneous: This Agreement may be executed by the parties hereto in counterparts, each of which when so executed and delivered shall be considered to be an original, but all such counterparts shall together constitute but one and the same instrument. This

Agreement is the complete agreement of the parties and supersedes all previous understandings and agreements relating to the subject matter hereof. Neither this Agreement nor any of the terms hereof may be terminated, amended, supplemented, waived or modified orally, but only by an instrument in writing signed by the party against whom enforcement of the termination, amendment, supplement, waiver or modification is sought.

IN WITNESS WHEREOF, the duly authorized representatives of the parties hereto have executed this Agreement as of the day and year first above written.

JANSSEN PHARMACEUTICA INTERNATIONAL
A division of Cilag International AG

By: /s/ Erik Rombouts
Name: Erik Rombouts
Title: Operations Director
Date: February 21, 1996

{Second Janssen Signatory}

By: /s/ Heinz Schmid
Name: Heinz Schmid
Title: General Manager
Date: February 21, 1996

MEDISORB TECHNOLOGIES INTERNATIONAL L.P.

by: Medisorb Technologies
International, Inc.,
its General Partner

By: /s/ David R. Lohr
Name: David R. Lohr
Title: President
Date: January 31, 1996

Exhibit 10.4

MANUFACTURING AND SUPPLY AGREEMENT

Entered into this 6th day of August 1997 (hereinafter "Effective Date") by and between

JPI PHARMACEUTICA INTERNATIONAL, a division of Cilag AG International Zug, a company duly organized and existing under the laws of Switzerland, having its principal office in CH-6300 Zug, Kollerstrasse 38, Switzerland (hereinafter referred to as "JPI")

and

JANSSEN PHARMACEUTICA Inc., 1125 Trenton-Harbourton Road, Titusville, NJ 08560, USA (hereinafter referred to as "JANSSEN US") (JPI and JANSSEN US collectively referred to herein as "JANSSEN")

and

Alkermes Controlled Therapeutics Inc. II, a company organized and existing under the laws of the Commonwealth of Pennsylvania, having its principal office at 64 Sidney Street, Cambridge, MA 02139-4136, U.S.A. (hereinafter referred to as "ACT II").

WITNESSETH

WHEREAS, JPI and ACT II (as assignee of Medisorb Technologies International LP ("MTI")) have entered into an agreement dated December 23, 1993 for the development of a Risperidone depot formulation incorporating ACT II's proprietary technology concerning bioabsorbable polymer technologies as duly amended by the Second Amendment of March 8, 1997 (hereinafter "Development Agreement"); and

WHEREAS, JANSSEN and ACT II (an assignee of MTI) have entered into two License agreements dated February 21, 1996 granting JANSSEN certain exclusive rights with respect to the use of ACT II's proprietary technology in the development, manufacturing, promotion and sale of Risperidone depot formulations (hereinafter "License Agreements"); and

WHEREAS, further to the provisions of Article 4 (b) of the License Agreements, ACT II has a right of first refusal with respect to the manufacture of such Risperidone depot formulations and JANSSEN has further to such provision agreed to entrust the manufacturing of Products (as hereinafter defined) to ACT II under the terms and conditions set forth hereinafter.

ARTICLE 1 : DEFINITIONS

The following terms shall, for the purpose of this Agreement, have the following meaning unless the context clearly requires otherwise and the singular shall include the plural and vice versa:

1.1 "Affiliate" shall mean any company controlling, controlled by, or under common control with a party by ownership, directly or indirectly, of fifty percent (50%) or more of the total ownership or by the power to control the policies and actions of such company.

1.2 "Compound" shall mean the active ingredient risperidone.

1.3 "Final Product" shall mean the final presentation form of the Product approved and marketed by Janssen, their Affiliates and licensees, ready for sale to the final customer.

1.4 "Janssen GMP Manual" shall mean the Janssen Pharmaceutica GMP Policies Manual, a numbered copy of which has been provided to ACT II and which Manual, together with any possible amendment and/or addition is deemed to constitute an integral part of this Agreement.

1.5 "Licensed Net Selling Price" shall mean the weighted average price offered by JANSSEN, their Affiliates or licensees in a given calendar year to independent third parties for the Final Product for sale in the Territory, less deductions for (i) transportation charges, including insurance; (ii) sales and excise taxes paid by JANSSEN, their Affiliates or licensees and any other governmental charges imposed upon the production, importation, use or sale of the Final Product; (iii) trade, cash and ordinary business discounts allowed and (iv) allowances or credits

to customers on account of rejection or return of Final Product (v) and managed care rebates or allowances and mandatory price allowances imposed by governments.

If JANSSEN, its Affiliates or licensees sell Final Product in a country in such a manner that the net sales value of the same is not readily identifiable then the net sales determination for that country shall be whichever is the higher of (i) the fair market value of such Final Product or (ii) the proportion of the bundled price attributed to the Final Product by JANSSEN, its Affiliates or licensees whenever the Final Product is sold as part of a package of products or services.

For the purpose hereof "fair market value" shall mean, without limitation, the value of Final Products sold to similar third parties in similar quantities. If the fair market value can not be determined in any given country, the fair market value will be determined by the value of the Final Product sold to similar customers in countries with similar pricing and reimbursement structures and for similar quantities.

1.6 "Manufacture, Manufacturing" shall mean all steps and operations involved in the production of Product, starting from Compound, including supply of the polymers or other critical excipients, pharmaceutical formation, packaging, in process and quality control and storage of Compound and Product, until delivery for shipment of the Product to JANSSEN US, JPI or their designee.

1.7 "Manufacturing Fee" shall mean the fee to be paid by JPI and JANSSEN US to ACT II in consideration for the Manufacture of Products supplied to each of them in accordance with the terms hereof and which fee will be calculated as a percentage of the Licensed Net Selling Price per unit of Product in accordance with the mechanism set forth in Article 6.

1.8 "Manufacturing Process" shall mean the process and environment required to Manufacture Product as described in regulatory filings.

1.9 "Materials" shall mean all or any of the materials, except for Compound, required for the Manufacture of Product (including but not limited to inactive ingredients, diluents, excipients, vials, containers).

1.10 "Product" shall mean a depot formulation of Risperidone, based on ACT II technologies utilizing polymers of lactic and glycolic acids which are designed to

deliver Compound over an extended period, in appropriately labelled siliconized vials or any other immediate container agreed by both parties and as set forth in the Specifications.

1.11 "Specifications" shall mean the agreed specifications of the Product, to be attached hereto as Exhibit A, including quality control tests to be performed by JANSSEN and a list of the methodologies to be used in performing those tests.

1.12 "Territory" shall mean worldwide.

ARTICLE 2: PROGRAM OF COMMERCIAL MANUFACTURE AND SUPPLY OF PRODUCTS

2.1 Subject to the terms and conditions of this Agreement, JANSSEN hereby appoints ACT II as their exclusive supplier of Product for their entire requirements in the Territory and ACT II agrees to Manufacture Product in its own premises for the exclusive purpose to supply Product to JANSSEN or their designee.

2.2 ACT II will provide at its own cost and expense, all equipment and machinery for the Manufacture of the Product, except for those capital items owned by JANSSEN US and identified in Exhibit B attached hereto. ACT II will only use such equipment and machinery which complies with the Manufacturing Process and any other requirements, such as the DMF, agreed with JANSSEN. ACT II shall maintain such equipment and machinery in good condition and properly validated.

2.3 In order to assist ACT II in its production planning, both parties will discuss and agree at the latest upon finalisation of the Phase III Clinical Trials in accordance with the Development Agreement on a rolling ordering and forecast mechanism (12-24 months) duly considering amongst others the required leadtimes to Manufacture the Product and to acquire the primary container or any other Material. In principle the first period of such rolling forecast will be considered a firm commitment, the other periods being indicative and non binding. Such forecast will be periodically updated at the moment of sending the orders for the next period.

To the extent required such a forecast mechanism may include a buffer mechanism providing for an upper and lower variation limit of the eventual orders against the latest forecast and a reasonable buffer mechanism in connection with required delivery dates and ordered quantities of Product.

The eventually agreed forecast mechanism ("hereinafter Forecast Mechanism") will be attached hereto as Exhibit E and will be used both by JPI and by JANSSEN US, it being understood that JANSSEN US and JPI may use a slightly different Forecast Mechanism format reflecting potential differences in the flow of goods.

2.4 JPI and JANSSEN US will each, in accordance with the Forecast Mechanism, send firm orders to ACT II indicating the requirements for Products, together with the required delivery dates and destination, and shall at the same time advise ACT II of the estimated requirements for the following periods in accordance with the Forecast Mechanism. JPI and/or JANSSEN US will ship Compound to ACT II in quantities sufficient and with sufficient lead time to enable ACT II to Manufacture the ordered Products. Together with the batch(es) of Compound, JPI and/or JANSSEN US will send all required documents and certificates. The Compound shipped to ACT II will comply with agreed specifications to be attached hereto as Exhibit F. In order to insure an adequate supply of Compound, ACT II will provide inventory data for each batch of Product shipped to JANSSEN as well as quarterly summaries of inventory transactions.

2.5 Upon receipt of the Compound, ACT II will inspect the batch(es) in accordance with to be agreed test procedures. Within thirty (30) business days following receipt of a shipment of Compound, ACT II shall inform JPI or JANSSEN US, depending on who was responsible for the shipment, in writing of any qualitative and/or quantitative shortcomings of the supplied Compound. In the event of a justifiable claim, JPI or JANSSEN US as the case may be shall replace or cause to have replaced such quantities of Compound in the shortest possible time and dispose of any defective batch(es) at its own expense.

Upon receipt (with sufficient lead time) and control of the Compound, ACT II will proceed with the Manufacture of the Products in accordance with the time schedule required to meet the requested delivery dates.

2.6 All Product Manufactured by ACT II under this Agreement shall be manufactured and packed strictly in accordance with the Specifications and Manufacturing

Process and in accordance with the provisions of any applicable Drug Master File to which JANSSEN is granted access in accordance with the provisions of Article 5.3.

ACT II shall be responsible for obtaining Materials in such quantities as are necessary for the Manufacturing of the amounts of Product ordered by JANSSEN.

ACT II shall be responsible for the quality, purity, identity and potency of the Materials used and shall only buy and use such Materials in the Manufacturing of the Product, which strictly comply with the applicable quality requirements and Specifications.

ACT II shall not change the validated Manufacturing Process of the Product or use any different material in the processing thereof that may have an impact on any regulatory approval in connection with the Product without JANSSEN US' (in connection with the United States) and/or JPI's (in connection with the rest of the Territory) explicit prior written approval and shall give the assistance reasonably required by JANSSEN US or JPI in preparing the supplement to any regulatory approval in connection with any change previously approved by JANSSEN US or JPI.

2.7 ACT II shall Manufacture Product in batches as specified in the Specifications and Manufacturing Process and within an agreed upon yield. To this end the initial percentage of average loss of Compound in the Manufacture of Product will be agreed upon separately by both parties upon finalization of the validation of the full scale Manufacturing Process of Product and will be attached as Exhibit G to this Agreement. JANSSEN and ACT II shall on a yearly basis review the average production-loss percentages with a view to making whatever adjustment which may, from time to time, be required. For any loss of Compound that ACT II may incur in the Manufacturing of Product exceeding the then applicable yield variance calculated on a yearly basis, ACT II shall pay JANSSEN a compensation of $10,000 USD per kilogram of Compound. For the purpose of such loss computations materials used in the Manufacture of control and retain samples, which are to be retained by ACT II, shall be excluded.

2.8 To minimize the likelihood of a supply deficiency with respect to Products, by the end of Phase III clinical trials in the development of the Product in accordance with the Development Agreement, both parties shall discuss and agree on a Disaster Recovery and Back-Up plan to be prepared by ACT II. Such plan shall consider the possibility of (re)building (including validation and approval) a plant

within an acceptable period of time (such period to be determined in common agreement) in case ACT II's current premises would be destroyed as well as transferring the Manufacture to a manufacturing facility of JANSSEN or any of their Affiliates or the facilities of a third party. Such third party will be an industry recognized reputable manufacturer having experience in making injectable pharmaceutical products.

2.9 The parties hereto will at regular instances review the long term capacity of ACT II's plant taking into account the most current forecast of the Final Product with a view to determine the need to have additional manufacturing capacity, either at the existing facility of ACT II or in any other manufacturing facility and either with ACT II or any of its Affiliates or with JANSSEN or any of their Affiliates.

2.10 The parties hereto acknowledge that after ACT II has supplied the Product for Phase III clinical trial and prior to the start of the commercial Manufacturing of the Product, ACT II's manufacturing facility for the Product should be kept in a manufacturing ready condition so as to minimize the risk of supply deficiencies at the moment of start up of the commercial Manufacturing. In order to do so ACT II will commit such resources and undertake such maintenance activities and training programs as agreed by both parties in a Manufacturing Readiness Plan. Such Manufacturing Readiness Plan will be attached to this Agreement as Exhibit H. In consideration of such manufacturing readiness activities, JANSSEN will pay a monthly fee to ACT II of $80,000 USD. ACT II will send monthly invoices to JPI or JANSSEN US in connection with such fees in accordance with timely provided instructions and JPI and/or JANSSEN US will pay such invoices within thirty days of invoice.

The parties hereto will use good faith efforts to investigate the possibility to utilize ACT II's manufacturing facility for other manufacturing requirements of JANSSEN or any of their Affiliates during such interim period. To the extent any such project would be identified and agreed by the parties, the parties will in good faith negotiate an appropriate reduction of the monthly $80,000 USD fee payable by JANSSEN.

2.11 The parties hereto agree that during the term of this Agreement, JANSSEN will order and purchase a minimum number of Product during any given calendar year starting on the first commercial launch of the Final Product (the year of first commercial launch to be calculated on a pro rata basis). Such minimum numbers

are expressed in kilograms of bulk Product (excluding for this purpose the vials) and are set forth in Exhibit C attached hereto. In the event that JANSSEN does not achieve the applicable minimum quantity of the Product to be Manufactured during a given calendar year, the parties hereto will in good faith renegotiate an adjusted Manufacturing Fee, duly considering the effect of the shortfall. In the event the parties can not agree an adjusted Manufacturing Fee, ACT II will be entitled to terminate this Agreement upon giving a one year prior notice. ACT II shall provide such commercially reasonable assistance and other information in order for JANSSEN to manufacture or have manufactured the Product after such one year notice period.

ARTICLE 3: QUALITY ASSURANCE - GMP COMPLIANCE

3.1 ACT II will Manufacture the Product in accordance with them current Good Manufacturing Practices ("GMP") standards, including, but not limited to the requirements set forth in Janssen's GMP Manual, the requirements imposed by the Food and Drug Administration of the United States ("FDA"), the Japanese health authorities and EU GMP guidelines.

3.2 ACT II shall perform in process and final quality control on Product. For each batch of Product, ACT II shall take a sample or samples as specified in the JANSSEN GMP Manual. Such sample(s) and records shall be retained in accordance with the provisions of the Janssen GMP Manual.
In addition ACT II will on an annual basis submit revalidation data to JANSSEN or their designee in compliance with the provisions of the Sterilization Policy in the Janssen GMP Manual.

3.3 JANSSEN shall have the right, upon reasonable advance notice and during regular business hours, to send its quality control inspectors to inspect and audit the processes, facilities and equipment being used by ACT II in the Manufacturing of the Product and the polymers used in Product to assure compliance with Articles 2 and 3 of this Agreement as well as any applicable laws, rules and regulations, provided that such quality control inspectors shall be subject to the confidentiality provisions provided for in Article 7. Such inspection and audit shall be conducted at JPI's or JANSSEN US' (as the case may be) sole cost and expense and in a

manner so as to minimize disruption of ACT II's business operations. The above audit right shall also extend to ACT II's supplier of the siliconized vials.

ACT II shall or shall cause its suppliers of the siliconized vials or any other primary container to remedy, within the timelimits provided for in the GMP audit report or determined in accordance with the Janssen GMP Manual any deficiencies reported by such auditor in the audit report issued following any such audit and which deficiencies relate to GMP, Specifications, Manufacturing Process, applicable laws, rules and regulations including JANSSEN's current quality control procedures, provided that, with respect to the latter, ACT II received an updated version prior to any such audit. ACT II and JANSSEN will reasonably collaborate with each other in order to insure that the manufacturer of the siliconized vials or any other primary container complies with applicable GMP rules (including the JANSSEN GMP Manual) and Specifications and Manufacturing Process. Such collaboration includes the possibility to organise joint audits or to have such GMP audit performed by JANSSEN. During such period, ACT II shall continuously use commercially reasonable efforts to remedy such deficiencies as promptly as possible. In the event that ACT II does not remedy any of such deficiencies within the above-referred timelimits, then JANSSEN shall be entitled to cover by Manufacturing themselves or to have a third party manufacture the Products. ACT II shall provide such commercially reasonable assistance and other information as shall be necessary in order for JANSSEN to manufacture itself or have a third party manufacture the related Products. In the event that JANSSEN uses a third party manufacturer for the Product pursuant to this Article, JANSSEN shall require such third party to be bound by the same confidentiality provisions as are contained in this Agreement.

3.4 In the event ACT II receives a deficiency notice from the FDA or any other regulatory agency regarding its compliance with any applicable laws, rules and regulations regarding its Manufacture of the Product, ACT II shall promptly notify JPI and JANSSEN US.

ACT II shall use commercially reasonable effects to remedy such deficiencies as promptly as possible and in any event within the time period requested by the agency. In the event that ACT II does not remedy any of such deficiencies within the period provided for in the notice of the regulatory agency, then JANSSEN shall be entitled to manufacture or have manufactured the Products in accordance with the provisions of Article 3.3.

3.5 Upon reasonable request of JANSSEN US, JPI or any of their Affiliates, ACT II will enter into a separate Quality Assurance Agreement with JANSSEN US, JPI or any such Affiliate, which Quality Assurance Agreement will confirm the quality assurance provisions set forth in this Agreement and will clearly identify the respective responsibilities of the parties in the Manufacturing of the Product.

ARTICLE 4: SHIPMENT - RISK AND TITLE

4.1 By the required delivery date, ACT II will ship the Products to JANSSEN or their designee in accordance with the ordering instructions as set forth in Article 2 hereof. Together with such shipment ACT II will send shipping documents and Certificates of Analysis of the batches shipped.
Products shall be shipped using a carrier appointed by JANSSEN on the basis of FOB, port of shipment. The term "FOB" shall be interpreted in accordance with the latest INCOTERMS.

4.2 Upon receipt of a batch of Product JPI, JANSSEN US or their designee shall perform or have performed an inspection of the batch documents and perform such test on the Product in accordance with procedures to be agreed upon. Should a batch of Product or the Manufacturing Process thereof fail to meet the established standards of quality as set forth in Article 3 or should the Product or the Manufacturing thereof not comply with the Specifications or Manufacturing Process, JPI or JANSSEN US, as the case may be, shall inform ACT II in writing of the alleged shortcomings within fifteen (15) business days after receiving such defect, specifying the nature of the defect and the batch number.

ACT II shall, at JPI's or JANSSEN US' option, depending who ordered the batch (i) re-process or replace in accordance with the Specifications and the Manufacture Process, at its own cost (which cost excludes the cost of the Compound), the whole or part of the deficient batch of Product so rejected, or, if the related Manufacturing Fee due by JPI or JANSSEN US in accordance with Article 6 was already paid, provide either (ii) a refund of the Manufacturing Fee paid in relation to the rejected batch(es) or (iii) issue a credit note for future orders for the full amount of the Manufacturing Fee paid in relation to the rejected batch(es) and shall destroy upon JPI's or JANSSEN US' instructions the rejected batch of Product which can not be corrected or improved. Furthermore, ACT II compensate or credit JPI or JANSSEN US $10,000 USD per kilogram of

Compound for JPI's or JANSSEN US' cost for the Compound used in such deficient batch of Product. If JANSSEN US or JPI request the receipt of such $10,000 USD payment, such payment will be made within forty five (45) days date of invoice.

Both parties will make good faith efforts to resolve disagreements in connection with any such alleged shortcomings. In the event the in-house experts of the parties are unable to agree on any alleged shortcoming of the Product or the Manufacturing process thereof, then the parties will appoint an independent expert skilled in the art who will analyse samples of the alleged deficient batch and all process deviations. Both parties will supply such expert with copies of specifications, documents, test results etc., that the expert may reasonably require in connection with such analysis. The expert's decision as to whether such batch has met the specifications shall be final and binding to the parties. The expenses of such expert shall be borne by the party whose contention is rejected by the expert.

4.3 Title in the Compound and Product shall at any time remain with JPI or JANSSEN US, depending on which company ordered the Product, whereas title to the Material shall remain with ACT II until incorporation in the Product. Risk of loss and damage in relation to the Compound and the Product shall pass to ACT II upon delivery of the Compound at the ACT II premises and shall again pass to JPI and/or JANSSEN US upon delivery of the Product to the common carrier. ACT II shall provide adequate and safe storage for the Compound and Products while at its premises and shall have sufficient insurance coverage in connection with the above risk.

4.4 ACT II represents and warrants that at the time of Manufacture all Product supplied hereunder shall be manufactured and supplied by ACT II in accordance with the Specifications and Manufacturing Process and in compliance with (i) this Agreement and (ii) any applicable law, rule or regulations.

EXCEPT FOR THE ABOVE WARRANTY, THERE ARE NO WARRANTIES OF MERCHANTIBILITY OR FITNESS FOR A PARTICULAR PURPOSE.

ARTICLE 5: REGULATORY PROVISIONS

5.1 JANSSEN and its Affiliates will be responsible for filing any regulatory approval application in connection with the Product and the Final Product, in their own name and at their own cost, all in accordance with the provisions of the Development Agreement and the License Agreement.

5.2 ACT II will give reasonable regulatory support in connection with regulatory approvals filed by JANSSEN in relation to the Product and/or the Final Product and will do so free of charge. Amongst others, ACT II will prepare and maintain all the necessary supporting documentation requested by JANSSEN such as certificates or other administrative documents required for reference in any regulatory filing, in a format requested by JANSSEN. Notwithstanding the above, it is agreed that if any such request from JANSSEN or the health authorities in a given country entails extraordinary costs beyond the normal and ordinary regulatory support efforts in connection with the filing and maintenance of the regulatory approvals directed to the Product or Final Product, the parties will in good faith discuss and agree on a sharing mechanism with respect to such extraordinary costs related to such support activities in such country or countries.

5.3 ACT II shall be responsible for obtaining and maintaining all necessary permits and approvals to Manufacture the Products and in general to perform its responsibilities as set forth in this Agreement.

Amongst others ACT II shall submit a Drug Master File ("DMF") with the health authorities identifying ACT II's method of manufacture, release specifications and testing methods used in the manufacture of the polymers and shall cause the supplier of the siliconized vials or any other primary container to do the same in relation to such vials or such other primary container. Similarly ACT II shall prepare and file an appropriate facility DMF with respect to the facilities where ACT II Manufactures the Product and the polymers. ACT II shall cause the supplier of the siliconized vials (or any other primary container) or any other Material used in the Manufacture of Product to do the same.

Upon request by JPI or JANSSEN US, ACT II agrees to provide JPI, JANSSEN US or their Affiliates or licensees with a Letter of Authorisation permitting the Health Authorities to refer to ACT II's DMF in its review of JANSSEN's or their Affiliates' applications for Product manufactured by ACT II. ACT II shall cause

the supplier of the siliconized vials (or any other primary container) or any other Material used in the Manufacture of Product to do the same.

A representative of JANSSEN will be entitled to review at ACT II's facilities those parts of the polymer DMF and the appropriate facility DMF pertaining to the Manufacture of Product.

ACT II shall maintain its Manufacturing facilities, Manufacturing records and its DMF's in such a manner as required to live up to the above obligation during the entire term of this Agreement.

JANSSEN shall not file with FDA or any other regulatory agency any changes with respect to the Manufacturing Process or Specifications without ACT II's prior consent.

ACT II shall keep JANSSEN updated of any changes in the DMF related to the polymers and/or the appropriate facility DMF requested by the FDA or any other regulatory agency and Parties will discuss the same before any changes are implemented.

5.4 JANSSEN shall inform ACT II promptly (and whenever possible within 24 hours of receipt by JPI and/or JANSSEN US) of any information or request for information received from the FDA or any other regulatory agency relating to the NDA and/or registration of Product whenever such information or communication is related to ACT II technology. Parties shall promptly discuss such information and in the event that a reply is required to such formal question from the FDA or any other regulatory agency or any communication has to be made with respect to Product and related to ACT II technology, Parties will agree on the content of any communication before it is made.

5.5 ACT II shall inform JANSSEN promptly (and whenever possible within 24 hours of receipt by ACT II) of any information or request for information received from the FDA or any other regulatory agency relating to ACT II technology whenever such information or communication is relevant to Product. It being understood that ACT II shall not disclose to JANSSEN any third party confidential information or trade secrets. Parties shall promptly discuss such information and in the event that a reply is required to such formal question from the FDA or any other regulatory agency or any communication has to be made that involves Product, Parties will agree on the content of such communication before it is made.

ARTICLE 6: MANUFACTURING FEE

6.1 In consideration of the manufacturing activities to be performed by ACT II hereunder, JPI and JANSSEN US will pay the Manufacturing Fee for the Products supplied to each of them. The Manufacturing Fee will be calculated as a certain percentage of the Licensed Net Selling Price. The actual percentage that shall apply with respect to a given calendar year will be determined in a function of the total volume of Products Manufactured by ACT II and invoiced to JANSSEN during such calendar year and will be calculated in accordance with the brackets set forth in Exhibit D attached hereto.

The actual Manufacturing Fee due during any given calendar year will be calculated as follows;

6.1.1 The Manufacturing Fee for the initial batches of Product Manufactured and invoiced by ACT II prior to the expiration of the first calendar year following the first commercial launch of the Final Product shall be calculated as a percentage of the estimated weighted average price offered by JANSSEN, its Affiliates or licensees to independent unrelated third parties for the Final Product. Such weighted average price will be calculated by multiplying the forecasted net selling price of the Final Product (expressed in USD at the exchange rates then applied by JANSSEN in accordance with its normal accounting procedures) in each country of Territory where JANSSEN intends to launch the Final Product in the calendar year following the calendar year of the first commercial launch of the Final Product times the total number of units of the Final Product JANSSEN forecasts to sell in those countries during such period. The actual percentage to be paid as Manufacturing Fee in such period will be calculated on the basis of the total number of units of the Product ACT II is required to Manufacture and ship to JANSSEN during such period based on the forecast provided by JANSSEN in accordance with Article 2.3.

Within ten (10) business days following the end of every calendar quarter either party may request a recalculation of the then applicable Manufacturing Fee whenever there is a deviation of more than twenty five

Percent (25%) in the total number of Products actually Manufactured and shipped by ACT II to JANSSEN during such quarter and the number of units forecasted by JANSSEN. The parties will at such moment recalculate and adjust the Manufacturing Fee based on (i) the revised supply forecast and (ii) the then current Licensed Net Selling Price.

In the month of January following such first full calendar year adjustment shall be made if there is deviation between (i) the estimated weighted average price and the actual Licensed Net Selling Price of the Final Product (expressed in USD at the exchange rates then applied by JANSSEN in accordance with its normal accounting procedures) and /or (ii) the total volume of units of Product actually Manufactured and invoiced by ACT II during such period.

Any corrective payment to be made resulting from such reconciliation will be paid by the party owing such a payment within forty five (45) days after such reconciliation and in accordance with the provisions of Article 6.4.

6.1.2 The Manufacturing Fee for any calendar year following the initial period as specified under Article 6.1.1 above will be calculated on the basis of the forecasted (i) Licensed Net Selling Price (expressed in USD at the exchange rates then applied by JANSSEN in accordance with its normal accounting procedures) and (ii) the amount of Product expressed in units to be Manufactured and shipped by ACT II for such calendar year.

Within ten (10) business days following the end of every calendar quarter either party may request a recalculation of the then applicable Manufacturing Fee whenever there is a deviation of more than twenty five percent (25%) in the total number of Products actually Manufactured and shipped by ACT II during such quarter and the number of units forecasted by JANSSEN. The parties will at such moment recalculate and adjust the Manufacturing Fee for the remainder of the calendar year based on (i) the revised supply forecast and (ii) the then current Licensed Net Selling Price.

In the month of January following any calendar year adjustment shall be made if there is deviation between (i) the estimated weighted average price and the actual Licensed Net Selling Price of the Final Product (expressed in USD at the exchange rates then applied by JANSSEN in accordance with

its normal accounting procedures) and/or (ii) the total volume of units of Product actually Manufactured and invoiced by ACT II during such calendar year. Any corrective payment to be made resulting from such reconciliation will be paid by the party owing such a payment within forty five (45) days after such reconciliation and in accordance with the provisions of Article 6.4.

6.2 JANSSEN will keep accurate records of the Licensed Net Selling Price with a view to determine the accuracy of the Manufacturing Fee calculation for a period of at least two (2) years after expiry of the year they concern. ACT II shall have the right to nominate an independent certified public accountant acceptable to and approved by JANSSEN US or JPI as the case may be who shall have access, on reasonable notice, to JPI's or JANSSEN US' records during reasonable business hours for the purpose of verifying the calculation of the Licensed Net Selling Price. 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 ACT II information relating solely to the accuracy of the Licensed Net Selling Price calculation.

6.3 ACT II shall invoice JPI or JANSSEN US for the Manufacturing Fee due with respect to each batch of Product supplied to each of them or their respective designee when shipped pursuant to Article 4. JPI and JANSSEN US shall be pay such invoice within forty-five (45) days after the date of the invoice.

6.4 All payments required to be paid hereunder shall be made in United States Dollars by wire transfer of immediately available funds to the financial institution, account number, account party's name and wire transfer information designated in writing by ACT II to JPI and JANSSEN US as the place of payment.

6.5 No party shall have the right to reduce, by set off, counterclaim, adjustment or otherwise, any amount owed by it to the other party pursuant to this Agreement, unless explicitly provided for otherwise.

ARTICLE 7: CONFIDENTIALITY

The parties refer to Article to the confidentiality provisions of Article 9 of the License Agreements which provisions are incorporated by reference herein.

ARTICLE 8: RECALL

In the event of a Product recall ("Recall"), JPI or JANSSEN US, as the case may be, shall be responsible for the coordination of Recall activities. Where the Recall is caused by ACT II's negligence or willful misconduct or breach of this Agreement and without prejudice to the provisions of Article 10, ACT II agrees to pay the following costs and expenses of any Recall: (i) costs of retrieving the Product previously delivered to JPI's or JANSSEN US' agents or customers, (ii) costs and expenses that JPI and/or JANSSEN US is required to pay for reasonable notification, shipping and handling charges, provided JPI and/or JANSSEN US provides ACT II with supporting documentation of all such reimbursable costs and expenses, and (iii) cost of replacing Products that are unsalable as a result of the Recall. If the Recall is not primarily caused by ACT II's negligence, willful misconduct or breach, JPI and/or JANSSEN US shall pay all of the costs and expenses described above for such Recall.

ARTICLE 9: INDEMNIFICATIONS

9.1 JANSSEN shall indemnify, defend and hold ACT II and its Affiliates, and each of their officers, directors, employees, agents and consultants (each an "ACT II Indemnitee") harmless from, against and in respect of any damages, claims made by third parties, losses, liabilities, charges, actions, suits, proceedings, penalties and reasonable costs and expenses (including without limitation reasonable attorneys' fees) (collectively, the "Losses"), arising out of or resulting from the use by or administration to any person of Product or Final Product of JPI, its Affiliates or licensees, except to the extent such Losses arose or resulted primarily from the failure of ACT II or its Affiliates to Manufacture Products in accordance with GMP, the Specifications and Manufacturing Process for such Product(s) or from ACT II's failure to comply with its obligations or covenants contained herein, so long as (i) the ACT II Indemnitee allows JANSSEN to participate in or, at JANSSEN's sole option but without any obligation, to conduct at JPI's expense the defense of a claim or action for which indemnification is sought under this Article 9.1. (provided that the ACT II Indemnitee may participate in such defense at its own expense), and (ii)

neither party may compromise or settle such claim or action without the other party's prior written consent, which shall not be unreasonably withheld ; provided, however, that a ACT II Indemnitee shall not be indemnified under this Article 9.1 to the extent that actions taken or failed to have been taken by JANSSEN under the direction of, or at request of, the ACT II Indemnitee were the primary cause of the events giving rise to the ACT II Indemnitee's claim for indemnification.

9.2 ACT II shall indemnify, defend and hold JANSSEN, their Affiliates and Licensees and each of their officers, directors, employees, agents and consultants (each a "JANSSEN Indemnitee") harmless from and against all Losses to the extent such losses arise out of or result from the failure of ACT II or its Affiliates to Manufacture the Product(s) in accordance with the Specifications and Manufacturing Process, or, its failure to comply with its obligations or covenants contained herein, unless such failure was the result of actions taken or failed to have been taken by the ACT II under the direction of, or at the request of JANSSEN. The JANSSEN Indemnitee shall allow ACT II to participate in, or, at ACT II's sole option, to conduct at ACT II's expense the defense of a claim or action for which indemnification is sought under this Article 9.2. (provided that the JANSSEN Indemnitee may participate in such defense at its own expense), and neither party shall compromise or settle such claim or action without the other party's prior written consent, which shall not be unreasonably withheld.

9.3 In no event shall either party be liable for any consequential or indirect damages of the other party, including but not limited to lost profits.

9.4 Both parties shall obtain, and shall maintain at all times during the term of this Agreement, an insurance policy or policies providing coverage against product liability claims related to the above indemnification.

ARTICLE 10: TERM AND TERMINATION

10.1 The term of this Agreement shall be commensurate with the term of the License Agreements, unless sooner terminated as provided hereinafter.

10.2 This Agreement may be terminated:

10.2.1 by mutual agreement of JANSSEN and ACT II in a writing signed by the parties;

10.2.2 by written notice of JANSSEN or ACT II in the event of a material breach by the other party in the performance of any of its obligations hereunder, if the party not in default shall have given the defaulting party written notice specifying such default within 45 days after the occurrence of such breach and the defaulting party has not made substantial and diligent progress in remedying or correcting the default within 60 days after such notice is given, with such termination becoming effective at the end of such 60 days;

10.2.3 by written notice of JANSSEN or ACT II in the event that the other party makes an assignment for the benefit of its creditors, files a petition under bankruptcy or insolvency laws, a receiver or custodian is appointed for such party's business, proceedings are instituted against such party under bankruptcy or insolvency laws that have not been stayed within 90 days, all or substantially all or such party's business or assets become subject to attachment, garnishment or other process, or such a party becomes unable to pay its obligations as they become due;

10.2.4 by JANSSEN prior to any commercial Manufacturing upon giving thirty days prior written notice and following the commencement of the commercial manufacturing upon giving a six month prior written notice, provided that with respect to the latter the Agreement shall not be terminated by JANSSEN without cause during the first two calendar years following the commencement of the commercial Manufacturing, unless JANSSEN decides also to terminate the License Agreements;

102.5 by ACT II in accordance with the provisions of Articles 2.11

10.3 Upon termination of this Agreement for any reason whatsoever ACT II will cease the Manufacturing of the Products. Termination of this Agreement shall not affect the rights and obligations of the parties accrued prior to the termination hereof. Notwithstanding the termination of this Agreement, the confidentiality provisions of Article 3.3, the obligations set forth in Articles 7, 8, 9, and 12.9 shall continue and survive the termination hereof.

ARTICLE: 11 FORCE MAJEURE

Each party shall be relieved of its obligations to the extent that fulfillment of such obligations shall be prevented by acts beyond the reasonable control of such party affected, including, without limitation, acts of God, fire, explosion, flood, drought, war, riot, sabotage, embargo, strikes or other labor trouble, prohibitions against imports or exports of Products, impossibility of obtaining or shortages in supply of raw materials, or compliance with any order or regulation of any government entity acting under color of right. If such cause continues unabated for a period of thirty (30) days, both parties will promptly meet to discuss the possibilities to overcome such case of Force Majeure and the potential implications on the further performance under this Agreement.

ARTICLE: 12 MISCELLANEOUS

12.1 Status. Neither JANSSEN or ACT II shall make any representation or incur any obligation in the name of or in behalf of the other party, except as explicitly authorized hereunder. Nothing in this Agreement shall be deemed to establish a relationship of principal and agent between ACT II and JPI or JANSSEN US, nor any of their agents or employees for any purpose whatsoever. Nothing in this Agreement shall be deemed to constitute the parties as a partnership, association or other relationship.

12.2 Public Announcements. No public announcement with respect to the Product or the existence of this Agreement may be made by JANSSEN or ACT II without the prior written approval of the other party.

12.3 Modifications. Any amendment or supplement to this Agreement shall be effective only if contained in a writing signed by each of the parties hereto.

12.4 Assignments. Except as otherwise provided herein, this Agreement shall not be assignable by any party, without the other party's written consent, such consent not to be unreasonably withheld, except that such consent is not required in connection with the assignment of any parties' obligations to an affiliate of such party; provided, however, that any such assignment shall not relieve the parties hereto from any obligations under this Agreement.

12.5 Prior Agreements. The parties hereto acknowledge that this Agreement contains the entire agreement between the parties pertaining to the Manufacturing and supply of Product in Territory and terminates and supersedes all prior agreements, understandings, letters or other instruments whatsoever, whether written or oral, between the parties or any of their affiliates with respect to such matters.

12.6 Waiver. No waiver by JANSSEN or ACT II of any breach of this Agreement will constitute a waiver of any subsequent breach, and no exercise by either JANSSEN or ACT II of any right of termination will constitute a waiver of any right for recovery of any monies then due it hereunder or any other right or remedy such a party may have at law, in equity or otherwise.

12.7 Representations. Each party represents and warrants that it has the right to enter into this Agreement and that it is under no obligation to any third party, express or implied, conflicting with the terms and conditions of this Agreement.

12.8 Separability. Any term or provision of this Agreement which is invalid or unenforceable in any jurisdiction shall, as to such jurisdiction, be ineffective to the extent of such invalidity or unenforceability without rendering invalid or unenforceable the remaining terms and provisions of this agreement where affecting the validity or enforceability of any of the terms or provisions of this Agreement in any other jurisdiction.

12.9 Governing Law; Dispute Resolution.

12.9.1 In the event a dispute ("Dispute") arises between the parties arising out of or relating to this Agreement, the parties shall use all reasonable efforts to resolve the Dispute through direct discussions for a period of sixty (60) days, unless and to the extent this Agreement provides for other and shorter periods. The senior management of each party commits itself to respond to any such Dispute. Subsequent to such sixty (60) day period either party may, but shall not be required to resort to the binding arbitration procedures set out hereinafter in this Article 12.9.

12.9.2 If the parties are unable after exerting all reasonable efforts to resolve a Dispute between the parties, the Dispute shall be resolved through binding arbitration pursuant to the Commercial Arbitration Rules of the American Arbitration Association in accordance with the following provisions:

(a) If a Dispute arises between the parties, the place of arbitration shall be New York, New York.

(b) To the extent the parties can not immediately agree on a single arbitrator, the arbitration shall be conducted by a panel of three neutral arbitrators ("Arbitrators"). 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 demand for arbitration. The two arbitrators selected by the parties will appoint the third member within ten (10) days following their appointment.

(c) The language to be used in the arbitration shall be English.

(d) 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.

(e) The Arbitrators 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 Arbitrators shall have the right to require the parties to make or participate in such other written or oral submissions, presentations, or examinations as the Arbitrators shall deem necessary for the proper resolution of such Dispute, all of which shall be made or submitted directly to the Arbitrators and shall become part of the record in the proceeding.

(f) The specific pleading schedule for each proceeding shall be determined by the parties in consultation with the Arbitrators within fifteen business days after the date on which the Arbitration panel is constituted, but it shall in each case provide that the parties' respective initial submissions shall be filed simultaneously with the Arbitrators, as shall the parties' respective reply submissions.

(g) Unless the parties otherwise agree at the time a particular Dispute is submitted for arbitration, the Arbitrators shall be required as a

condition to their engagement to agree to render a decision within 30 days of the date on which the record in the proceeding is completed, but in no case more than 90 days after the date of the last hearing on the substantive issues.

(h) The parties shall use reasonable 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 Arbitrators to render its decision in accordance with the schedule set forth herein.

(i) All communications with the Arbitrators during the pendency of 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. The existence of the Dispute and the related proceedings shall be kept confidential in accordance with the provisions of Article 7.

(j) All decisions by the Arbitrators shall be done by majority vote. The arbitration award shall be rendered in writing and shall state the reasons for the award, and shall be final and binding upon the parties. In rendering their decision, the Arbitrators shall apply the substantive law of the state of New York, without regard to its conflict of law provisions, provided that the Arbitrators shall base their decision on the express terms and conditions of this Agreement.

(k) The Arbitrators are empowered to award any remedy allowed by law, including money damages and to grant final or interlocutory relief. Notwithstanding the foregoing punitive or multiple damages may not

be awarded and the express terms of this Agreement may not be altered.

(l) Each party shall bear its own expenses and attorneys' fees in connection with the arbitration.

12.10 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 ACT II:

Alkermes Controlled Therapeutics Inc. II
64 Sidney Street
Cambridge
MA 02139-4136
U.S.A.
Telefax: +1-617-494-9263
attention: Chief Financial Officer

If to JANSSEN:

Janssen Pharmaceutica International, a division of Cilag AG
International,
CH-6300 Zug, Chollerstrasse 38,
Switzerland
Telefax: 041 748 3667

and

Janssen Pharmaceutica Inc.
1125 Trenton-Harbourton Road
Titusville
NJ 08560
U.S.A.
Telefax: +1-609-730-2323

Any such notice shall be deemed to have been received when it has been delivered in the ordinary course of post or received by telefax.

IN WITNESS WHEREOF, JPI, JANSSEN US AND ACT II have caused this instrument to be executed by their respective duly authorized officers, the date of execution to relate back to the day and year last below written.

Alkermes Controlled Therapeutics, Inc. II

This 8th day of August 1997

/s/ J. Duncan Higgons
(title) Vice President

By /s/ Michael Landine
(title) Vice President

JANSSEN PHARMACEUTICA
INTERNATIONAL represented by
CILAG AG INTERNATIONAL.

This 27th day of August 1997

/s/ illegible signature
(title)

By /s/ illegible signature
(title)

Janssen Pharmaceutica Inc.

This 3rd day of September 1997

(title)

By /s/ illegible signature
(title) President

Exhibit A

Specifications

Exhibit B

Equipment : capital items

Exhibit C

Minimum Quantities

1st Calendar year	**60 kg of bulk Product (microspheres - excluding vials) (on a pro rata basis taking into account actual date of the first commercial launch of the Final Product)**
2nd Calendar year	**100 kg of bulk Product**
3rd Calendar year and any subsequent calendar year	**160 kg of bulk Product**

Exhibit D

Manufacturing Fee

Amount purchased (vials) From	To	% of Licensed Net Selling Price	Amount purchased (vials) From	To	% of Licensed Net Selling Price
263,000	399,999	24.5 %	2,100,000	2,199,999	8.8 %
400,000	499,999	19.5 %	2,200,000	2,299,999	8.6 %
500,000	599,999	16.5 %	2,300,000	2,399,999	8.5 %
600,000	699,999	14.0 %	2,400,000	2,499,999	8.3 %
700,000	799,999	12.3 %	2,500,000	2,599,999	8.2 %
800,000	899,999	12.0 %	2,600,000	2,699,999	8.1 %
900,000	999,999	11.7 %	2,700,000	2,799,999	8.0 %
1,000,000	1,099,999	11.4 %	2,800,000	2,899,999	7.9 %
1,100,000	1,199,999	11.0 %	2,900,000	2,999,999	7.8 %
1,200,000	1,299,999	10.7 %	3,000,000	3,099,999	7.8 %
1,300,000	1,399,999	10.4 %	3,100,000	3,199,999	7.7 %
1,400,000	1,499,999	10.1 %	3,200,000	3,299,999	7.7 %
1,500,000	1,599,999	9.8 %	3,300,000	3,399,999	7.6 %
1,600,000	1,699,999	9.7 %	3,400,000	3,499,999	7.6 %
1,700,000	1,799,999	9.5 %	3,500,000	3,599,999	7.5 %
1,800,000	1,899,999	9.3 %	3,600,000	3,699,999	7.5 %
1,900,000	1,999,999	9.2 %	3,700,000	3,799,999	7.5 %
2,000,000	2,099,999	9.0 %	3,800,000	3,899,999	7.5 %
			3,900,000	4,000,000	7.5 %

Exhibit E

The Forecast Mechanism

Exhibit F

Specification of Compound

Exhibit G

Average Loss of Compounds further to Article 2.7

Exhibit H

Manufacturing Readiness Plan

Exhibit 10.4.2

ADDENDUM TO MANUFACTURING AND SUPPLY AGREEMENT

This Addendum to Manufacturing and Supply Agreement (this "Addendum"), dated as of the 1 day of August, 2001 (the "Effective Date") is by and between JPI PHARMACEUTICA INTERNATIONAL, a division of Cilag AG International Zug, a company duly organized and existing under the laws of Switzerland, having its principal office in CH- 6300 Zug, Kollerstrasse 38, Switzerland ("JPI") and JANSSEN PHARMACEUTICA Inc., 1125 Trenton-Harbourton Road, Titusville, NJ 08560, USA ("Janssen US" and, together with JPI, "Janssen") on the one hand and Alkermes Controlled Therapeutics Inc. II, a company organized and existing under the laws of the Commonwealth of Pennsylvania, having its principal office at 64 Sidney Street, Cambridge MA 02139-4136, USA ("ACTII") on the other hand.

WHEREAS, Janssen and ACTII have been collaborating for the development of a Risperidone depot formulation incorporating ACTII's proprietary technology concerning bioabsorbable polymer technologies and have entered into a Development Agreement and two License Agreements related thereto; and

WHEREAS, Janssen and ACTII entered into that certain Manufacturing and Supply Agreement, dated August 6, 1997 (the "Supply Agreement"), with-respect to the commercial manufacture and supply of such Risperidone depot formulation to Janssen; and

WHEREAS, Janssen and ACTII desire to enter into this Addendum regarding the expansion of ACTII's manufacturing facilities, and the financial responsibilities of each of the parties in connection with such expansion, in order to support the increased sales forecasts for such Risperidone depot formulation; and

WHEREAS, Janssen and ACTII further desire to enter into this Addendum to formally provide for a collaborative effort to develop the manufacturing facility and commercial supply of Product.

NOW, THEREFORE, in consideration of the mutual covenants and conditions set forth below, and intending to be legally bound hereby, the parties agree as follows:

ARTICLE 1 - DEFINITIONS

Section 1.1. Unless provided otherwise, any capitalized terms used in this Addendum and not defined herein or below, shall have the meaning set forth in the Supply Agreement.

1.1.1. "Regulatory Approval" shall mean either (i) the approval of a New Drug Application, or a comparable application, for the Product by the United States Food and Drug Administration ("FDA"), or (ii) regulatory approval in two (2) of the Major EU Member States (for the purpose hereof, "Major EU Member States" means Germany, UK, France, Spain and Italy), together in each case with satisfaction of any related regulatory and notification requirements of the FDA or such other regulatory authority.

ARTICLE 2 - EXPANSION PROJECT

Section 2.1. The Project. ACTII will retain the services of an engineering firm to develop plans to expand ACTII's manufacturing facility located in Wilmington, Ohio (the "Project"), including detailed timelines for completion of the Project. The Project shall include the following elements:

2.1.1. The expansion to the current facility will be a detached addition on the same campus as the original facility in Wilmington, Ohio (such detached addition, including the equipment to be fitted therein, are referred to herein as the "Expansion");

2.1.2. The Expansion will include the utilities for a second and third wet process line and a second filling line;

2.1.3. Only the equipment for the second wet process line will be installed as part of the Project; and

2.1.4. The Project is expected to be completed by early August 2003 and cost approximately twelve million dollars ($12,000,000), all according to the preliminary budget and timetable set forth on Schedule A attached hereto.

2.1.5. The underlying assumption of the terms agreed in this Addendum is that the Expansion will be dedicated to the manufacturing of the Product. Notwithstanding the above, ACTII shall have the right to manufacture other products in the Expansion, provided that ACTII shall notify Janssen at least ninety (90) days before any such other product is manufactured in the Expansion and shall discuss such intended manufacturing activities with the Global Supply Team. Any such notification and discussion shall be subject to ACTII's obligations of confidentiality (if any) to its collaborative partner for the product(s) to be manufactured in the Expansion. ACTII shall be entitled to proceed with such intended manufacturing activities, provided that the Global Supply Team is satisfied, in its reasonable judgment, that such activities will not affect the quality (including GMP guidelines), the supply chain or capacity requirements for the Product. In the event that ACTII proceeds with its intended manufacturing activities, ACTII and Janssen will negotiate in good faith the impact (if any) of such activities on the Minimum Revenues and/or the Guarantee provided in this Addendum and modify it accordingly.

Section 2.2. The Project Plan. Upon completion of the work by the engineering firm, which is expected to be completed prior to July 31, 2001, Janssen and ACTII shall meet to review the plans, budget and timetable for completion of the Project, determine the actions to be taken by each of the parties and to finalize the plans, budget and timetable for the Project (the "Project Plan"). The Project Plan, including the budget, must be amended by mutual agreement of the parties (after consultation with the Global Supply Team (defined in Section 5.2)) if the change impacts the timeline, capacity or budget with respect to the Product. At any time the parties amend the budget included in the Project Plan, a corresponding amendment to the Guarantee Cap (defined in Section 3.2) shall also be made.

Section 2.3. Contractors and Construction. Upon approval by both parties of the Project Plan, ACTII shall engage the services of any contractors necessary to begin and complete

actual construction of the Project and shall oversee such construction. ACTII shall cause the timetable for completion of the Project that is part of the Project Plan to be incorporated into all contracts and agreements with such contractors.

ARTICLE 3- FINANCIAL RESPONSIBILITY FOR THE PROJECT

Section 3.1. ACTII's Responsibility. ACTII shall be responsible for payment of all costs and expenses related to construction of the Project, including the design of and engineering services related to the Project, subject to the Guarantee and Minimum Revenues (each as defined in Sections 3.2 and 3.4, respectively).

Section 3.2. The Guarantee. In the event that Janssen terminates development of the Product prior to commercial launch or Janssen terminates the Project, Janssen will reimburse ACTII for all cumulative out-of-pocket expenses made or actually and irrevocably committed by ACTII for the Project through the date of ACTII's receipt of written notice of such termination (such reimbursement payment referred to herein as the "Guarantee"). The Guarantee shall not exceed twelve million dollars ($12,000,000) (the "Guarantee Cap"), unless the parties have mutually agreed to amend the budget and the Guarantee Cap pursuant to Section 2.2.

Section 3.3. Refund of the Guarantee. If Janssen pays to ACTII the Guarantee due to Janssen's termination of the Project and if the Expansion is utilized by ACTII for another· product with another corporate partner within three (3) years of Janssen's termination of the Project, then ACTII shall refund that portion of the Guarantee that is proportional to the actual utilization of the Expansion during the 3-year period which shall be paid to Janssen in installments over the months remaining in the 3-year period and so long as the utilization continues.

Section 3.4. Minimum Revenues. For a period often (10) calendar years, Janssen shall guarantee a certain minimum amount of revenues to ACTII from Janssen from the purchase of Product under the Supply Agreement (the "Minimum Revenues"), unless Janssen realizes the cumulative Minimum Revenues prior to the expansion of such 10-year period, all in accordance with this Section 3.4 and the subsections below.

3.4.1. Upon completion of the work by the engineering firm, which is expected to be completed prior to July 31, 2001, Janssen and ACTII shall meet to review the Project cost. If the aggregate Project cost is ten million dollars ($10,000,000) or more, but less than twelve million dollars ($12,000,000), the Minimum Revenues shall be:

Calendar Year of Minimum Revenues		**Scenario 1 : Detached Plant without filling line Capital Cost: $ 12.0 million Minimum Revenue for Alkermes $ million**
Year 1	$	11.0 m
Year 2	$	14.25 m
Year 3-10	$	15.75 m

3.4.2. If the aggregate Project cost is less than ten million dollars ($10,000,000) or greater than twelve million dollars ($12,000,000), then Janssen and ACTII shall re-calculate the Minimum Revenue amounts based on the Project cost and assumptions and preliminary Minimum Revenue amounts set forth below.

(a) The Minimum Revenues are intended to derive a minimum revenue that drives a net present value of zero (0) using a twelve and one-half percent (12.5%) discount rate for ACTII's manufacturing facility investment.

(b) For the purpose of calculating the Minimum Revenues under this Section 3.4, the Project cost shall not exceed twelve million dollars ($12,000,000), unless the parties have mutually agreed to amend the budget pursuant to Section 2.2.

(c) The Minimum Revenues under this Section 3.4.2 shall be calculated in substantially the same way as the Minimum Revenues under Section 3 .4.1 were calculated as shown on Schedule C.

3.4.3. First Calendar Year. The first calendar year in which Minimum Revenues shall be guaranteed, shall begin on the earlier of (a) the January 1 immediately following Regulatory Approval or (b) January 1, 2004, unless the parties agree otherwise.

3.4.4. Excess. If the aggregate amount of Product purchased by Janssen under the Supply Agreement in any one calendar year (an "Actual Purchase Amount") exceeds the Minimum Revenue amount for such calendar year, then such excess (the "Excess Credit") shall be credited against any future calendar year in which Janssen's Actual Purchase Amount is less than the Minimum Revenue amount for such calendar year.

3.4.5. Shortfall. If an Actual Purchase Amount is less than the Minimum Revenue amount for the relevant calendar year, then any available Excess Credit shall be added to the Actual Purchase Amount for such calendar year. If the sum of Actual Purchase Amount plus any such Excess Credit are less than the Minimum Revenue amount for such calendar year, then Janssen shall pay to ACTII the difference between the Minimum Revenue and the sum of the Actual Purchase Amount plus such Excess Credit (if any). A portion of an Excess Credit may be used if only a portion is necessary to bring the sum of the Actual Purchase Amount plus the Excess Credit up to the Minimum Revenue amount for the relevant calendar year, in which case the balance of the Excess Credit can be used for another future calendar year; provided, however, that the aggregate amount of Excess Credit may only be added to an Actual Purchase Amount once.

3.4.6. Reporting. Within seventy-five (75) days of the end of each calendar year after Regulatory Approval, ACTII shall prepare and deliver to Janssen a report showing (a) the Actual Purchase Amount and the Minimum Revenue amount for such calendar year, (b) any Excess Credit added to the Actual Purchase Amount, (c) any Excess Credit from a prior or the current calendar year available but not added to the Actual Purchase Amount, and (d) any amount due to ACTII under Section 3.4.5.

3.4.7. Prepayment. If (i) sales of Product are such that Janssen determines that the expanded facility will not be utilized or (ii) Janssen ceases to sell Product or terminates the

Supply Agreement after Regulatory Approval but before all Minimum Revenues have been achieved, then Janssen may, in its discretion, (a) prepay the Minimum Revenues in a lump sum that is the then net present value of the Minimum Revenues not yet achieved or (b) continue to pay any shortfall under Minimum Revenues over time as provided in this Section 3.4. If Janssen prepays the Minimum Revenues in a lump sum under this Section 3.4.7 and if the Expansion is utilized by ACTII for another product incorporating its bioabsorbable polymer technology with another corporate partner within three (3) years of such prepayment, then ACTII shall refund that portion of the lump sum payment that is proportional to the actual utilization of the Expansion during the 3-year period which shall be paid to Janssen in installments over the months remaining in the 3-year period and so long as the utilization continues.

ARTICLE 4- SECOND FILLING LINE AND FUTURE EXPANSIONS

Section 4.1. Second Filling Line. The parties may mutually determine that a second filling line needs to be added to the manufacturing facility. If such a determination is made, it is anticipated that the cost of adding a second filling line will be approximately eleven million dollars ($11,000,000). Janssen and ACTII shall amend the Guarantee Cap and the Minimum Revenues to take into account such additional cost, taking into consideration the assumptions set forth in Section 3.4 (including the subsections) and the subsections below.

4.1.1. Upon completion of the work by the engineering firm with regard to the Project, including the second filling line, Janssen and ACTII shall meet to review the Project cost. If the aggregate Project cost is twenty-one million dollars ($21,000,000) or more, but less than twenty-three million dollars ($23,000,000), the Minimum Revenues, if a second filling line is included, shall be:

Calendar Year of Minimum Revenues		Scenario 2: Detached Plant filling line Capital Cost: $ 22 million Minimum Revenue for Alkermes $ million
Year 1	$	12.0 m
Year 2	$	18.0 m
Year 3-10	$	19.0 m

4.1.2. If the aggregate Project cost, including a second filling line, is less than twenty-one million dollars ($21,000,000), or greater than twenty-three million dollars ($23,000,000), then Janssen and ACTII shall re-calculate the Minimum Revenue amounts based on the Project cost, including the second filling line, and assumptions and preliminary Minimum Revenue amounts set forth below.

(a) The Minimum Revenues are intended to derive a minimum revenue that drives a net present value of zero (0) using a twelve and one-half percent (12.5%) discount rate for ACTII's manufacturing facility investment.

(b) For the purpose of calculating the Minimum Revenues under this Section 4.1.2, the Project cost shall not exceed twenty-three million dollars ($23,000,000), unless the parties have mutually agreed to amend the budget pursuant to Section 2.2.

(c) The Minimum Revenues under this Section 4.1.2 shall be calculated in substantially the same way as the Minimum Revenues under Section 4.1.1 were calculated as shown on Schedule C.

Section 4.2. Reimbursement of Incremental Capital Cost. In the event that the parties determine to include a second filling line (the "2nd Line") in the Project, Janssen shall reimburse ACTII for the financial cost of the incremental capital associated with the 2nd Line. To that end, Janssen shall pay to ACTII, on a quarterly basis, an amount equal to the Prime Rate times the capital expenses associated with the 2nd Line in excess of the capital expenses associated with the Project excluding the 2nd Line. For purposes hereof, "Prime Rate" shall be the prime rate as reported in the eastern edition of The Wall Street Journal on the first day of the relevant calendar quarter on which The Wall Street Journal is published. Janssen's obligation under this Section 4.2 shall terminate upon the occurrence of both of the following two conditions: (a) Product delivered by ACTII to Janssen under the Supply Agreement meets or exceeds five million (5,000,000) vials in any twelve (12)-month period and (b) Janssen's twenty-four (24)-month supply forecast for Product to be delivered by ACTII under the Supply Agreement exceeds the vial filling capacity of the existing filling line in any twelve (12)-month period in such twenty-four (24)-month forecast.

Section 4.3. Future Expansions. If the Global Supply Team determines that an additional process line is required, then such additional line will be included in the Project under conditions to be negotiated by Janssen and ACTII at the time of such determination.

ARTICLE 5 - MANAGEMENT OF PROJECT AND COMMERCIAL SUPPLY

Section 5.1. Collaborative Efforts. Both parties acknowledge and agree that the management of the commercial supply chain of Product is of critical importance, as is (i) the timely expansion of the capacity for the manufacturing of the bulk Product and the vial filling, (ii) the transition of the current activities to a continuous commercial manufacturing and supply process and (iii) the eventual commercial supply and logistics chain. Therefore, the parties shall actively collaborate with each other, including a free exchange of expertise and knowledge, with the following goals: (a) the timelines of expansion and supply are respected, (b) a robust manufacturing and supply process is developed, (c) Product will comply with all relevant quality and regulatory requirements and (d) a continued supply of Product in accordance with current forecasts is achieved.

Section 5.2. Global Supply Team. ACTII shall be responsible for the operation and management of the Project and the manufacture and supply of Product. Notwithstanding the foregoing, a Global Supply Team shall be established under this Section 5.2 whose goal will be to enhance and facilitate the collaborative effort described in Section 5.1.

5.2.1. Formation and Make-Up. Within thirty (30) days after the Effective Date, the parties shall form the Global Supply Team. The Global Supply Team shall consist of an

equal number of representatives of each party. The Global Supply Team may delegate its responsibilities and authority to one or more Sub-Teams. The members of the Global Supply Team and any Sub-Teams shall have expertise in the functional disciplines that either party believes should be represented at the team or sub-team. The representatives of a party may be changed from time to time at the discretion of that party upon written notification by the party making such change to the other.

5.2.2. Oversight of the Project and Commercial Supply. The Global Supply Team shall be responsible for recommending actions to ACTII and Alkermes management following periodic reviews of the Project and the commercial supply process. Within fifteen (15) days after the receipt of the Project Plan, or any amendment or supplement to the Project Plan, the Global Supply Team or the appropriate Sub-Team shall meet to evaluate the Project Plan, amendment or supplement and recommend actions. The Global Supply Team or the appropriate Sub-Team shall periodically review the Project Plan and the progress of the activities called for under the plan. ACTII and Alkermes management shall keep the Global Supply Team and any Sub-Teams informed on a periodic basis of issues and decisions affecting the commercial supply chain and the construction of the Project and shall consult with it on such issues before making decisions whenever possible.

5.2.3. Meetings. The Global Supply Team and any Sub-Teams shall meet from time to time as determined by the team members. It is expected that the teams shall meet in person at least once in each calendar quarter. The location of team meetings shall alternate between ACTII's and Janssen's offices unless otherwise agreed by the parties, with the first meeting being held at ACTII's Ohio office. Consultants and non-member employees of the parties may attend team meetings as required to further the team's goals. Minutes of all meetings setting forth decisions of the Global Supply Team or Sub-Team will be prepared and circulated by the party hosting the meeting within thirty (30) days of such meeting. Such minutes will become official when agreed to by all team members. Each party will bear all expenses associated with attendance of its employees and consultants at such meetings. If the team members all agree, a meeting may be held by means of telephone conference or similar communications equipment by means of which all persons participating in the meeting can hear each other.

5.2.4. Decisions. Recommendations of the Global Supply Team or Sub-Teams shall be made by unanimous vote, with the representatives of each party having one collective vote. If the Global Supply Team or a Sub-Team is unable to reach a unanimous vote on any issue, then the issue shall be referred to the President of Alkermes (or successor position) and the Senior Vice President of Manufacturing of Janssen (or successor position) for further discussion and resolution. These individuals shall, as soon as practicable, attempt in good faith to resolve the dispute and, thereby, make the recommendation on behalf of the Global Supply Team or Sub-Team. These individuals may obtain the advice of other employees as they deem necessary or advisable in order to make the recommendation. If such issue (a) is not resolved within thirty (30) days after it has been referred to such persons for resolution, (b) would cause a serious interruption of the manufacturing and supply chain and (c) is related to the Logistic Systems, Quality System, Control of Change, Validation, timelines of the Project Plan or commercialization ramp-up, the issue shall be resolved in accordance with the views of the Senior Vice President of Manufacturing of Janssen. Any issue related to the budget for the

Project shall be discussed in good faith to determine the appropriate modification or outcome and shall be agreed to by the parties in good faith. Also, in the event ACTII is reasonably of the opinion that Janssen's standpoint on any of the above issues could adversely affect its obligations under the Supply Agreement, it will raise such issue and the parties will duly consider it and its ramifications in resolving the issue at hand. In the event Janssen nevertheless decides to proceed in accordance with its standpoint, the parties will in good faith discuss the modifications that may be warranted in relation to the other obligations with respect to which ACTII had raised concerns.

Section 5.3. Janssen Representative at the Project. In order to implement the collaborative effort set forth under Section 5.1, Janssen will have the right to have one or more Janssen representatives visit the Project and/or the entire manufacturing facility in Wilmington, Ohio for short or extended periods of time. Any such visits shall be at Janssen's expense; provided that ACTII shall provide some accommodation at the site upon reasonable request and provided that there is no disruption to the course of business at the site. In the event that there is any dispute under this Section 5.3 or either party has a concern related to the Janssen representative(s) at the manufacturing facility, the Global Supply Team shall attempt to resolve such dispute or address such concern.

Section 5.4. Janssen Support. At ACTII's request, Janssen shall reasonably assist ACTII in its contacts with manufacturing and supply contractors and shall support ACTII in connection with its vendor relations.

ARTICLE 6 - MISCELLANEOUS

Section 6.1. Change in Control of Alkermes, Inc. or ACTII. For purposes of this Section 6.1, "Change in Control" shall mean the acquisition, directly or indirectly, by any person, entity or "group" (within the meaning of Section 13(d)(3) or 14(d)(2) of the Securities Exchange Act of 1934, as amended (the "Exchange Act")) (excluding Alkermes, Inc., its subsidiaries, and any employee benefit plan of Alkermes, Inc. or its subsidiaries which acquires beneficial ownership of voting securities of Alkermes, Inc.) of beneficial ownership (within the meaning of Rule 13d-3 promulgated under the Exchange Act) of more than 40% of the combined voting power of Alkermes, Inc.'s or ACTII's then outstanding voting securities entitled to vote generally in the election of directors. In the event of a Change in Control of Alkermes, Inc. or ACTII, Alkermes, Inc. and ACTII will use reasonable efforts to notify Janssen as soon as possible, legally and in accordance with any confidentiality obligations related to the Change in Control transaction, in advance of any Change of Control, and upon the announcement thereof. As soon as possible after giving such notice, ACTII (or any successor) and Janssen will meet to discuss what effect, if any, the Change in Control will have on ACTII's (or any successor's) performance under the Supply Agreement, including this Addendum. The parties shall then determine what, if any, actions need be taken in light of the effects of the Change in Control. ACTII and/or Alkermes shall use reasonable efforts to (a) cooperate with Janssen to provide continuity of supply of Product, (b) cause the assignment of all of the obligations of ACTII under the Supply Agreement to any successor entity upon consummation of such Change in Control and, (c) ensure the confidentiality of the proprietary technology of Janssen vis- á-vis the controlling entity of ACTII upon consummation of such Change in Control, including the use of "fire walls", if appropriate or reasonably requested by Janssen. Promptly following the consummation of the

Change of Control, Act II (or any successor) shall provide to Janssen a written confirmation that AGTII (or any successor) shall comply with all obligations under the Supply Agreement, including this Addendum.

Section 6.2. Bankruptcy provisions. In the event ACTII or Alkermes, Inc. files a petition in bankruptcy, insolvency or reorganization for the benefit of its creditors or if a receiver or trustee is appointed as provided for in Section 10.2.3 of the Supply Agreement, ACTII shall, unless and until the Supply Agreement would be rejected by the bankruptcy trustee in accordance with the relevant bankruptcy codes, continue to perform all its obligations under the Supply Agreement, including this Addendum, unless and until Janssen elects to terminate the Supply Agreement in accordance with Section 10.2.3 of the Supply Agreement. By October 31, 2001, ACTII shall submit to a neutral escrow agent mutually agreeable to the parties, such as DSI Technology Escrow Services, Inc. (the "Escrow Agent"), to hold in escrow all of the standard operating procedures and batch records, which shall contain detailed descriptions of all steps and operations involved in the approved Manufacturing Process (the "Escrow Documents"). ACTII shall update the Escrow Documents annually. In the event that Janssen terminates the Agreement under Section 10.2.3 of the Supply Agreement, Janssen shall be free to access the Escrow Documents. Janssen, ACTII and the Escrow Agent shall execute an escrow agreement which will control the deposit, possession and release of the Escrow Documents and any conflict between this Addendum and such escrow agreement shall be controlled by the escrow agreement. Janssen, as a licensee of intellectual property rights granted under the License Agreement dated February 13, 1996, by and between Janssen US and ACT II and the License dated February 21, 1996, by and between JPI and ACT II, shall in addition to any rights or remedies expressly provided herein, retain any and all of its rights under the bankruptcy code to resort to other remedies as may now or hereafter exist at law or in equity in such event.

Section 6.3. Amendments to the Supply Agreement. To the extent that the provisions of this Addendum are in conflict with Sections 2.2 and 2.9 of the Supply Agreement, Sections 2.2 and 2.9 shall be deemed to be amended by this Addendum. The provision regarding Minimum Revenues in this Addendum shall supersede the provisions for minimum number of Product to be purchased by Janssen pursuant to Section 2.11 of the Supply Agreement for the ten (10) calendar years following Regulatory Approval of Product. Except as provided in the foregoing two sentences, all of the provisions of the Supply Agreement shall remain in full force and effect.

Section 6.4. Prior Agreements. The parties hereto acknowledge that this Addendum and the Supply Agreement contain the entire agreement between the parties pertaining to the manufacture and supply of Product in Territory and terminates and supersedes all prior agreements, understandings, letters or other instruments whatsoever, whether written or oral, between the parties or any of their affiliates with respect to such matters.

IN WITNESS WHEREOF, JPI, Janssen US and ACTII have caused this Addendum to Manufacturing and Supply Agreement to be executed by their respective duly authorized officers on the date first set forth above.

JANSSEN PHARMACEUTICA
INTERNATIONAL represented by CILAG AG
INTERNATIONAL

By: /s/ Erik Rombouts
Name: Erik Rombouts
Title: Vice President

JANSSEN PHARMACEUTICA INC.

By: /s/ David Y. Norton
Name: David Y. Norton
Title: President

ALKERMES CONTROLLED THERAPEUTICS INC. II

By: /s/ Robert A. Breyer
Name: Robert A. Breyer
Title:

Schedule A
Preliminary Timetable and Budget

		Plant expansion With 2nd wet process train		Plant expansion with 2nd process train and 2nd filling line	
Quarter	Key event	Capital Expenditures	Cumulative	Capital Expenditures	Cumulative
4Q/00		$ 0.1 m	$ 0.1 m	$ 0.1 m	$ 0.1 m
1Q/01	Phase 3 topline results	$ 0.6 m	$ 0.7 m	$ 1.0 m	$ 1.1 m
2Q/01	Tox results	$ 1.2m	$ 1.9m	$ 2.1 m	$ 3.2m
3Q/01	NDA ready	$ 2.4 m	$ 4.3 m	$ 5.3 m	$ 8.5 m
4Q/01		$ 2.4 m	$ 6.7 m	$ 4.1 m	$ 12.6 m
1Q/02		$ 1.2m	$ 7.8m	$ 2.4m	$ 15.0 m
2Q/02		$ 1.2 m	$ 9.0 m	$ 2.3 m	$ 17.3 m
3Q/02	Regulatory Approval	$ 0.6m	$ 9.6m	$ 1.2m	$ 18.4m
4Q/02		$ 1.2 m	$ 10.8 m	$ 2.3 m	$ 20.7 m
1Q/03		$ 1.2 m	$ 12.0 m	$ 2.3 m	$ 23.0 m
		$ 12.0 m		**$ 23.0 m**	

Schedule B
Sales Forecasts as of the Effective Date
As of June 2001

		2002	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012
Sales of Microspheres (US$ millions)		**$ 33.6**	**$336.5**	**$665.8**	**$ 879.7**	**$1,028.6**	**$1,173.8**	**$1,249.2**	**$1,214.1**	**$1,180.1**	**$1,118.2**	**$1,023.7**
Sales Forecast Vials-000's	25.0 mg	213	1,639	3,204	4,463	5,308	6,149	6,554	6,255	5,973	5,600	5,262
June 19 Approved Forecast	37.5 mg	119	1,168	2,305	3,223	3,798	4,335	4,611	4,501	4,393	4,163	3,954
	50.0 mg	192	1,748	3,418	5,007	6,117	7,123	7,683	7,634	7,571	7,117	6,704
	Total	524	4,554	8,927	12,693	15,223	17,607	18,849	18,390	17,937	16,881	15,920
Purchase Forecast Vials-000's	25.0 mg	555	1,965	3,466	4,639	5,483	6,233	6,492	6,196	5,895	5,530	4,165
	37.5 mg	362	1,405	2,496	3,343	3,910	4,392	4,588	4,479	4,345	4,120	3,130
Inventory Level 2.5 months	50.0 mg	556	2,096	3,749	5,238	6,327	7,240	7,673	7,621	7,476	7,031	5,307
	Total	1,473	5,465	9,711	13,220	15,720	17,866	18,753	18,296	17,717	16,681	12,603

Schedule C
Calculation of Minimum Revenues

Alkermes Capital Expenditures:												
Current Plant:	$ 9,000											
New Plant + 2nd Process Line:	$ 12,000											
Total Capital Expenditures:	$ 21,000											
			2002	**2003**	**2004**	**2005**	**2006**	**2007**	**2008**	**2009**	**2010**	**2011**
Minimum Revenues:			**$ 0**	**$ 11,000**	**$ 14,500**	**$ 15,750**	**$ 15,750**	**$ 15,750**	**$ 15,750**	**$ 15,750**	**$ 15,746**	**$ 15,750**
NPV Calculation:												
Manufacture by Alkermes		**2001**	**2002**	**2003**	**2004**	**2005**	**2006**	**2007**	**2008**	**2009**	**2010**	**2011**
(+) Mfg Profit			$ 6,189	$ 3,845	$ 4,178	$ 5,014	$ 5,014	$ 5,014	$ 5,014	$ 5,014	$ 5,010	$ 4,898
(-) Capital		$15,600	$4,200	$ 1,200	$ 0							
(-) Tax	**30** %		$ 1,857	$ 1,154	$ 1,253	$ 1,504	$ 1,504	$ 1,504	$ 1,504	$ 1,504	$ 1,503	$ 1,469
(+) Deprec			$ 900	$ 900	$ 2,400	$ 2,400	$ 2,400	$ 2,400	$ 2,400	$ 2,400	$ 2,400	$ 2,400
Cash Flow		$ 15,600	$ 7,633	$ 2,392	$ 5,325	$ 5,910	$ 5,910	$ 5,910	$ 5,910	$ 5,910	$ 5,907	***$ 0***

Disc Rate	**NPV=**
12.5%	$63

Alkermes Capital Expenditures:											
Current Plant:	**$ 9,000**										
New Plant + 2nd Process Line + 2nd Fill Line:	**$22,000**										
Total Capital Expenditures:	**$31,000**										
			2002	**2003**	**2004**	**2005**	**2006**	**2007**	**2008**	**2009**	**2010**	**2011**
Minimum Revenues:			$ 0	**$11,000**	**$14,500**	**$19,000**	**$19,000**	**$19,000**	**$19,000**	**$19,000**	**$19,000**	**$19,000**
NPV Calculation:												
Manufacture by Alkermes		**2001**	**2002**	**2003**	**2004**	**2005**	**2006**	**2007**	**2008**	**2009**	**2010**	**2011**
(+) Mfg Profit			$ -6,189	$ 3,845	$ 2,928	$ 6,564	$ 6,564	$ 6,564	$ 6,564	$ 6,564	$ 6,564	$ 6,452
(-) Capital		$21,100	$ 7,700	$ 2,200	$ 0							
(-) Tax	**30 %**		$ -1,857	$ 1,154	$ 878	$ 1,969	$ 1,969	$ 1,969	$ 1,969	$ 1,969	$ 1,969	$ 1,935
(+) Deprec			$ 900	$ 900	$ 3,650	$ 3,650	$ 3,650	$ 3,650	$ 3,650	$ 3,650	$ 3,650	$ 3,650
Cash Flow		$ 21,100	$11,133	$ 1,392	$ 5,700	$ 8,245	$ 8,245	$ 8,245	$ 8,245	$ 8,245	$ 8,245	$ 8,166

Disc Rate	**NPV=**
12.5%	$85

Exhibit 10.4.3

Alkermes Controlled Therapeutics Inc. II
64 Sidney Street
Cambridge, MA 02139 USA

February 1, 2002

JPI Pharmaceutica International,
a division of Cilag AG International Zug
CH-6300 Zug
Kollerstrasse 38
Switzerland

Janssen Pharmaceutica Inc.
11125 Trenton-Harbourton Road
Titusville, NJ 08560 USA

Re: Exhibits to Manufacturing and Supply Agreement, dated August 6, 1997

Gentlemen:

Pursuant to that certain Manufacturing and Supply Agreement (the "Agreement"), dated August 6, 1997, among Alkermes Controlled Therapeutics Inc. II ("ACT II"), JPI Pharmaceutica International, a division of Cilag AG International Zug, a company organized under the laws of Switzerland ("JPI"), and Janssen Pharmaceutica Inc. ("Janssen US") (JPI and Janssen US collectively referred to herein as "Janssen"), as supplemented by that certain Addendum to Manufacturing and Supply Agreement (the "Addendum"), dated August 1, 2001, among ACT II, JPI and Janssen, certain exhibits referred to in the Agreement would be agreed to by the parties in the future. Those exhibits are Exhibits A, B, E, F, G and H. This letter sets forth the agreement by the parties as to such Exhibits.

1. Exhibit A (Specifications) shall be in the form attached hereto as Exhibit A.

2. Exhibit B (Equipment: Capital Items) is, at the current time, intentionally left blank because there are no capital items owned by Janssen.

3. Exhibit E (Forecast mechanism) shall be in the form attached hereto as Exhibit E.

4. Exhibit F (Specification of Compound) shall be in the form attached hereto as Exhibit F.

5. Exhibit G (Average Loss of Compound further to Article 2.7) shall be in the form attached hereto as Exhibit G.

6. Exhibit H (Manufacturing Readiness Plan) shall cease to apply from December 1, 2001 in view of the commencement of the commercial manufacture of Product.

To the extent that the provisions of Exhibit E are in conflict with Sections 2.3, 2.4, 2.11 or 4.1 of the Agreement, such Sections shall be deemed to be amended by Exhibit E. To the extent that the provisions of Exhibit G are in conflict with Sections 2.7 or 4.2 of the Agreement, such Sections shall be deemed to be amended by Exhibit G.

If you are in agreement with the foregoing, please have this letter agreement executed by a duly authorized officer and return one fully executed copy to me.

Sincerely,
ALKERMES CONTROLLED
THERAPEUTICS INC. II

By: /s/ Michael Landine
Name: Michael Landine
Title: Vice President

Agreed to:

JPI PHARMACEUTICA INTERNATIONAL,
A DIVISION OF CILAG AG INTERNATIONAL ZUG

By: /s/ Erik Rombouts
Name: Erik Rombouts
Title: Vice President Alliance Management

/s/ Heinz Schmid
Heinz Schmid
General Manager

JANSSEN PHARMACEUTICA INC.

By: /s/ Alex Gorsky
Name: Alex Gorsky
Title: President

Exhibit A
Specifications

The specifications for "RISPERDAL CONSTA(tm)" as found in NDA # 21-346 submitted by Janssen on August 31, 2001, all applicable MAA filings, all applicable supplements to the filings and all subsequent revisions to these specifications.

Exhibit E
Forecast Mechanism

1. **Effective Time of this Exhibit.** This Exhibit E (Forecast Mechanism) shall only be ineffect until December 31, 2002 at which time the parties shall review and modify (if needed) the forecast mechanism, which shall then be in effect for the remainder of the term of the Agreement, unless the parties agree otherwise.

2. **Definitions.** For purposes of this Exhibit E, the following terms shall have the following meanings. Any capitalized term not defined below shall have the meaning set forth in the Manufacturing and Supply Agreement to which this Exhibit is appended (the "Agreement").

   (a) "Batch" shall mean the quantity produced from one operation of the emulsion phase of the manufacturing process.

   (b) "Dose" shall mean the amount of active ingredient included in each Vial of Product. There shall only be three Dose sizes: 25 mg, 37.5 mg and 50 mg.

   (c) For purposes of this Exhibit E only, "Janssen" shall include any designee of Janssen.

   (d) "Region" shall mean the geographic region in which certain Vials are to be distributed and sold. There shall only be two Regions: (i) the United States and (ii) the rest of the world.

   (e) "Vial" shall mean the primary container filled with finished Product in a single dosage form. Vials will be the final Product to be shipped by ACT II to Janssen for final packaging into a kit before distribution and sale.

3. **Full Batches.** ACT II shall Manufacture Product and prepare Vials for shipment only in Batches and not in less than a full Batch size.

4. **Forecasts.** On or before the 25th calendar day of each month, Janssen will provide to ACT II a rolling forecast of Product for the eighteen (18) months following the month in which such forecast is submitted. Each forecast shall include the quantity of Vials forecasted in Batch quantity amounts based on the estimated Vials per Batch set forth below. The forecast shall also state the quantities of Vials by Dose and Region and the estimated Batch quantities (by Dose and Region) needed to produce such Vials based on the estimated Vials per Batch set forth below.

Dose Size:	25 mg	37.5 mg	50 mg
Estimated Yield of Vials per Batch	136,000	92,000	69,000

5. **Binding Forecasts; Semi-Firm Forecasts.** Months one through and including four (the "Firm Months") of each forecast shall be binding on Janssen and shall constitute a firm order. Months five through and including nine (the "Semi-Firm Months") of each forecast shall not be binding, but shall be semi-firm, meaning that in any subsequent forecast, Janssen may only increase the Batches forecasted in the Semi-Firm Months within the limits set forth below, provided, however, that ACT II shall use commercially reasonable efforts to meet Janssen's requirements for Product. For the avoidance of doubt, Janssen shall be entitled to decrease its forecast for the Semi-Firm Months in an unlimited fashion. Months ten through eighteen of each forecast shall be neither binding nor semi-firm, but shall be good faith estimates of Janssen's anticipated requirements for Product.

Previously Forecasted Batch Quantity	Allowable Monthly Increase	Allowable Monthly Forecasted Batch Quantity
0	2	2
1	1	2
2	1	3
3	1	4
4	0	4

6. **Purchase Orders.** JPI and Janssen US may issue to ACT II formal purchase orders for the Regions they are responsible for; provided that the aggregate of purchase orders submitted by JPI and Janssen US shall not exceed the amount forecasted for the applicable period, unless specifically allowed hereunder or agreed by the parties. Even in the absence of one or more purchase orders, ACT II may Manufacture and prepare for shipment the quantity of Vials, in Doses and for the Regions, called for in the forecast for any Firm Month.

7. **Monthly Forecast Maximum; Manufacturing Shut-Downs.** No forecast may require the Manufacture of more than one (1) Batch per week. ACT II will be allowed up to two (2) manufacturing shut-downs each year and each manufacturing shut-down shall last not longer than two (2) weeks. ACT II shall provide to Janssen the schedule for manufacturing shut-downs at the beginning of each calendar year. The parties will work together to schedule delivery of Product in accordance with both the forecasts and scheduled shut-downs.

8. **Diligence to Meet Forecast.** ACT II will use commercially reasonable efforts to Manufacture and prepare for shipment Product in the Vial quantities, in the Doses, for the Regions and in the time periods forecasted by Janssen.

9. **Shortfalls.** There shall be a shortfall at any time that the cumulative amount of Vials for any Dose or Region actually prepared for shipment in any six (6) month period falls below eighty percent (80%) of the amount of Vials forecasted by Janssen for such Dose or Region for such six (6) month period (the difference between the amount of such Vials prepared for shipment and eighty percent (80%) of the forecasted amount of such Vials

shall be the "Shortfall"). Notwithstanding the foregoing, there shall not be a Shortfall if Janssen submits a forecast in which the amount of Vials for a Firm Month are greater than what was forecasted in the same Firm Month in a previous forecast or the amount of Vials for a Firm Month or a Semi-Firm Month are greater than the allowable increase over what was forecasted in the same Semi-Firm Month in a previous forecast. In the event of a Shortfall, Janssen shall notify ACT II that a Shortfall has occurred, stating in what Dose or Region the Shortfall occurred and requesting that ACT II cure such Shortfall. Upon receipt of such notice from Janssen, ACT II will use commercially reasonable efforts to Manufacture and prepare for shipment an amount of Vials in the particular Dose or Region in order to cure such Shortfall in the month following receipt of such notice.

10. **No Breach.** ACT II shall not be considered to be in breach of its obligations to supply the requested quantities of Product under the Agreement (including the provisions in this Exhibit E) if:

(a) there is any Shortfall during the initial five (5) months of commercial Manufacture of Product under the Agreement;

(b) there is a Shortfall after the initial five (5) months of commercial Manufacture of Product under the Agreement, Janssen requests that ACT II cure such Shortfall and ACT II uses or is using Commercially Reasonable Efforts to cure such Shortfall, all in accordance with Section 9 hereof; or

(c) a delay in the Manufacture of Product, preparation for shipment or actual delivery of Vials is caused by Janssen (for example, due to a failure or delay in the supply of bulk Compound, testing of Product by Janssen, validation by Janssen of shipping containers, receipt of test results, protocols, reports or approvals from Janssen required under the Quality Agreement for Manufacture or shipment of Product, receipt of delivery instructions from Janssen, release of Product by Janssen, etc.);

provided that, in each case, ACT II is using commercially reasonable efforts to Manufacture and prepare for shipment Vials in accordance with the forecast.

11. **Inventory; Shelf Life of Product Delivered.** ACT II may, at its option, Manufacture and hold Product in inventory. All Product, including any Product that may have been held in inventory, delivered by ACT II to Janssen in accordance with Section 4.1 of the Agreement shall have a remaining shelf life of at least eighteen (18) months at the time it is so delivered by ACT II, unless otherwise agreed on an ad hoc basis. Notwithstanding the foregoing, ACT II shall not be held responsible for, and Janssen shall be obligated to purchase (if otherwise meeting Specifications), Product whose remaining shelf-life is less than eighteen (18) months at the time of such delivery, if the delivery of Product has been delayed by more than 4 months from the time that the Product was filled into Vials if such delay is caused by Janssen (for example, due to a failure or delay in the testing of

Product by Janssen, validation by Janssen of shipping containers, receipt of test results, protocols, reports or approvals from Janssen required under the Quality Agreement for shipment of Product, receipt of delivery instructions from Janssen, release of Product by Janssen, etc.). This Section 11 shall be reviewed and modified (if needed) by the parties at the end of calendar year 2002.

Exhibit F
Specification of Compound

The specifications for "Risperidone Drug Substance" as found in NDA # 21-346 submitted by Janssen on August 31, 2001, all applicable MAA filings, all applicable supplements to the filings and all subsequent revisions to these specifications.

Exhibit G
Average Loss of Compound

1. **Effective Time of this Exhibit.** This Exhibit G (Average Loss of Compound) shall only be in effect until December 31, 2002 at which time the parties shall review and modify (if needed) the assumptions or calculations set forth herein. Thereafter, this Exhibit G will be reviewed and modified (if needed) to reflect actual performance on an annual basis.

2. **Timing of Penalty/Yield Calculation and Payment, if any.** On or before January 31of each calendar year, ACT II shall calculate whether any penalty is due pursuant to the yield calculation set forth in this Exhibit G and, if due, shall pay such penalty to Janssen. In any event, ACT II shall submit to Janssen its yield calculation, either with any such penalty payment or without payment if no penalty is due.

3. **Calculation of a Penalty, if any, for Unacceptable Yield.** The calculation of how much penalty is due, if any, for unacceptable yield shall be as follows:

Penalty = $10,000 X [Input — Output]
(No payment by either party if a negative answer)

where

Output = A + B + 10.125 +C and Input = [D X 8.1] + [E X 4.05]

where

A = [(F X G) / 1,000,000] + [(H X I) / 1,000,000] + [(J X K) / 1,000,000], where F equals the number of vials of dose size 25 mg that were actually shipped by ACT II in the previous calendar year; G equals the Compound Usage per Vial (mg) for the 25 mg dose size pursuant to the chart under Section 4(a)(i) of this Exhibit G; H equals the number of vials of dose size 37.5 mg that were actually shipped by ACT II in the previous calendar year; I equals the Compound Usage per Vial (mg) for the 37.5 mg dose size pursuant to the chart under Section 4(a)(i) of this Exhibit G; J equals the number of vials of dose size 50 mg that were actually shipped by ACT II in the previous calendar year; and K equals the Compound Usage per Vial (mg) for the 50 mg dose size pursuant to the chart under Section 4(a)(i) of this Exhibit G.

B = 10%XA

C = the documented loss in kilograms due to filling if more than 1 dose size was filled from a singe batch.

D = the total number of batches actually shipped by ACT II in the previous calendar year.

E = the total number of actual failed batches in the previous calendar year.

Certain factors in the calculation set forth above shall be reviewed and modified, if necessary, on an annual basis, all as set forth below in Section 4 of this Exhibit G.

4. **Explanation of Calculation of Penalty.**

(a) **Explanation of Output Calculation.**

(i) The following chart shows the current standard number of vials from each batch of Product for each dose size (the "Standard Batch Vial Yield"). Based on such number of vials per dose size and the amount of Compound (bulk active drug product) used for each batch, the Compound usage for each vial (the "Compound Usage/Vial") is calculated and then also shown in the chart. The "Standard Batch Vial Yield" and corresponding "Compound Usage/Vial" will be re-calculated on an annual basis based on the performance of the prior calendar year. The corresponding numbers in this chart will then be adjusted (on an annual basis). The "Compound Usage/Batch" shall not change unless the Specifications, including the Manufacturing processes, change.

Dose Size	**25**	**37.5**	**50**
Standard Batch Vial Yield (000's)	136	92	69
Compound Usage / Batch (kg)	8.1	8.1	8.1
Compound Usage / Vial (mg)	59.6	88.0	117.4

(ii) Certain "Buffers" are added to the Output calculation.

(1) There is expected to be a successful batch yield variability of 10% of the Compound that will be used in Manufacturing.

(2) The parties have agreed to share in the anticipated batch failures based on the previous calendar year performance. The number of failed batches to be shared will be adjusted on an annual basis. For the initial fifteen month period, the failed batch sharing allotment shall be 10.125 kg of Compound, which is based on 2.5 failed batches times the 4.05 kg allotment of Compound per failed batch.

(3) The parties acknowledge that there will be losses of Product during the filling process in the event that ACT II must fill more than one dose size in a single batch. Therefore, such loss can be added to

the Output calculation provided that ACT II can document the actual loss resulting from the filling process.

(b) **Explanation of Input calculation.** The total number of batches actually shipped by ACT II in a calendar year shall not include work in process or batches that were Manufactured but held in inventory (and not shipped) by ACT II.

(c) **Example.** The following example of a calculation under this Exhibit G is provided for clarification purposes only.

(i) Assumption of Facts:

20 batches manufactured by Alkermes
19 batches shipped to Janssen (1 failed batch)
1 batch split into 2 dose sizes (documented loss is 1 kg)

(ii) Output.

(1) Calculation of A.

Sum total vials per dose size actually shipped (19 batches):

- 25 mg dose: 748,000 vials
- 37.5 mg dose: 506,000 vials
- 50 mg dose: 552,000 vials

Multiply vials per dose by the Compound Usage per Vial:

- 25 mg dose: [748,000 vials X 59.6 mg/vial] / 1,000,000 = 44.58 kg
- 37.5 mg dose: [506,000 vials X 88.0 mg/vial] / 1,000,000 = 44.53 kg
- 50 mg dose: [552,000 vials X 117.4 mg/vial] / 1,000,000 = 64.81 kg

Total: 44.58 + 44.53 + 64.81 = 153.92 kg

(2) Calculation of B (Successful batch variability).

10% X 153.92 = 15.39 kg

(3) Calculation of.C (Documented Filling Loss) = 1.00 kg

(4) Output = 153.92 + 15.39 + 10.125 + 1.00 = 180.435 kg

(iii) Input = [19 X 8.1] + [1 X 4.05] = 157.95 kg

(iv) Penalty = $10,000 X [157.95 — 180.435] = -$224,850
NO penalty since the result is a negative number

Exhibit H
Manufacturing Readiness Plan

EXHIBIT 21.1

SUBSIDIARIES

Name	Jurisdiction
Alkermes Ireland Holdings Limited	Ireland
Alkermes Pharma Ireland Limited	Ireland
Alkermes Finance Ireland Limited	Ireland
Daravita Pharma Ireland Limited	Ireland
Alkermes Finance Ireland (No. 3) Limited	Ireland
Alkermes Science Four Limited	Ireland
Alkermes Science Five Limited	Ireland
Alkermes Science Six Limited	Bermuda
Daravita 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

EXHIBIT 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We hereby consent to the incorporation by reference in the Registration Statements on Form S-3 (No. 333-192256) and Form S-8 (Nos. 333-179545, 333-184621 and 333-200777) of Alkermes plc of our report dated February 25, 2016 relating to the financial statements and the effectiveness of internal control over financial reporting, which appears in this Form 10-K.

/s/ PricewaterhouseCoopers

Boston, Massachusetts
February 25, 2016

EXHIBIT 31.1

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)

February 25, 2016

EXHIBIT 31.2

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 Officer)

February 25, 2016

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

In connection with the Annual Report of Alkermes plc (the "Company") on Form 10-K for the period ended December 31, 2015 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 Officer)

February 25, 2016