

**ALKERMES PUBLIC LIMITED COMPANY**  
**DIRECTORS' REPORT AND CONSOLIDATED FINANCIAL STATEMENTS**  
**For the Financial Year Ended December 31, 2016**

**ALKERMES PLC**  
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## DIRECTORS' REPORT

### For the Financial Year Ended December 31, 2016

The directors present their report and the consolidated financial statements and related notes of Alkermes PLC for the year ended December 31, 2016. Irish law requires the directors to prepare financial statements for each financial year that give a true and fair view of the consolidated and company's assets, liabilities and financial position as at the end of the financial year and of the profit or loss of the group for the financial year. Under that law, the Directors have prepared the consolidated financial statements in accordance with U.S. accounting standards, as defined in Section 279(1) of the Companies Act 2014, to the extent that the use of those principles in the preparation of the financial statements does not contravene any provision of the Companies Act or of any regulations made thereunder and the Parent Company financial statements in accordance with Generally Accepted Accounting Practice in Ireland (accounting standards issued by the Financial Reporting Council and promulgated by the Institute of Chartered Accountants in Ireland and Irish law).

#### NOTE REGARDING COMPANY AND PRODUCT REFERENCES

Use of the terms such as “us,” “we,” “our,” “Alkermes” or the “Company” in this Directors' Report is meant to refer to Alkermes plc and its consolidated subsidiaries. Except as otherwise suggested by the context, (a) references to “products” or “our products” in this Directors' Report include our marketed products, marketed products using our proprietary technologies, our product candidates, product candidates using our proprietary technologies, development products and development products 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 United States (“U.S.”) federal trademark registrations (“®”) and other trademarks (“™”), 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. (“Otsuka Pharm. Co.”); AMPYRA®, FAMPYRA®—Acorda Therapeutics, Inc. (“Acorda”); ANTABUSE®—Teva Women's Health, Inc.; AUBAGIO® and LEMTRADA®—Sanofi Societe Anonyme France; AVONEX®, PLEGRIDY®, TECFIDERA®, and TYSABRI®—Biogen MA Inc. (“Biogen”); BETASERON®—Bayer Pharma AG; BUNAVAIL™—BioDelivery Sciences; BYDUREON® and BYETTA®—Amylin Pharmaceuticals, LLC (“Amylin”); CAMPRAL®—Merck Sante; COPAXONE®—Teva Pharmaceutical Industries Ltd.; FOCALIN XR®, EXTAVIA®, GILENYA® and RITALIN LA®—Novartis AG; INVEGA SUSTENNA®, RISPERDAL CONSTA®, INVEGA TRINZA®, TREVICTA® 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; ZOXYDRO™—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 Directors' Report are the property of their respective owners. Solely for convenience, the trademarks and trade names in this Directors' 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.

## Principal Activities

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. Alkermes has 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 (“MS”). Headquartered in Dublin, Ireland, Alkermes has a research and development (“R&D”) facility and corporate offices in Waltham, Massachusetts; an R&D and manufacturing facility in Athlone, Ireland; and a manufacturing facility in Wilmington, Ohio.

## Business Overview

### 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 Directors’ 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:

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

### *Proprietary Products*

We develop and commercialize products designed to address the unmet needs of patients suffering from addiction and schizophrenia.

#### ***ARISTADA***

ARISTADA (aripiprazole lauroxil) is an extended-release intramuscular injectable suspension approved in the U.S. for the treatment of schizophrenia. 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 to deliver and maintain therapeutic levels of medication in the body. ARISTADA has three dosing options (441 mg, 662 mg and 882 mg) and is 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 countries 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 intramuscular injection every four weeks. We developed and exclusively manufacture VIVITROL. We 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 2015 U.S. National Survey on Drug Use and Health, an estimated 2.5 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. According to the 2015 U.S. National Survey on Drug Use and Health, an estimated 15 million people aged 18 or older were dependent on 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/TREVICTA and RISPERDAL CONSTA***

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

In May 2016, TREVICTA (paliperidone palmitate a 3-monthly injection), was approved in the EU for the maintenance treatment of schizophrenia in adult patients who are clinically stable on XEPLION. INVEGA TRINZA/TREVICTA use our proprietary technology and are 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 intramuscular injection every two weeks. RISPERDAL CONSTA microspheres are exclusively manufactured by us.

Revenues from Janssen accounted for approximately 36% and 40% of our consolidated revenues for the fiscal years ended December 31, 2016 and 2015, respectively. See “Collaborative Arrangements” later in this section for information about our relationship with Janssen.

#### *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) is believed to be 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 2016. AMPYRA and FAMPYRA incorporate our oral controlled-release technology. AMPYRA and FAMPYRA are manufactured by us.

#### *What is multiple sclerosis?*

Multiple sclerosis, or 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. AstraZeneca is responsible for the development and commercialization of BYDUREON worldwide. BYDUREON, a once-weekly formulation of exenatide, 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 R&D 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 R&D



efforts, we have devoted, and will continue to devote, significant resources to conducting pre-clinical work and clinical studies to advance the development of new pharmaceutical products. The discussion below highlights our key current R&D 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 later in “Principal Risks” of this report. Refer to the “Patents and Proprietary Rights” section of this report for information with respect to the intellectual property protection for our development products.

<u>Product Candidate</u>	<u>Target Indication(s)</u>	<u>Status</u>
<i>Aripiprazole Lauroxil Two-Month Dose</i> . . . . .	Schizophrenia	sNDA Review
<i>ALKS 5461</i> . . . . .	Major Depressive Disorder (“MDD”)	Phase 3
<i>ALKS 3831</i> . . . . .	Schizophrenia	Phase 3
<i>ALKS 8700</i> . . . . .	MS	Phase 3
<i>ALKS 6428</i> . . . . .	VIVITROL Seven-Day Taper Kit	Phase 3
<i>ALKS 4230</i> . . . . .	Cancer Immunotherapy	Phase 1

***Aripiprazole Lauroxil Two-Month Dose***

Aripiprazole lauroxil, an intramuscular injectable atypical antipsychotic, which is currently commercially available as ARISTADA, with once monthly and six-week dosing options, for the treatment of schizophrenia, is also 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 submitted a supplemental New Drug Application (“sNDA”) to the U.S. Food and Drug Administration (“FDA”) in August 2016 and the sNDA was accepted for filing by the FDA in October 2016 with a Prescription Drug User Fee Act (“PDUFA”) date in June 2017.

***ALKS 5461***

ALKS 5461 is a proprietary, once-daily, oral sublingual investigational medicine, with a novel mechanism of action, in development for the adjunctive treatment of Major Depressive Disorder (“MDD”) in patients with an inadequate response to standard antidepressant therapies. ALKS 5461 is composed of samidorphan in combination with buprenorphine. Samidorphan is a proprietary oral opioid modulator characterized by limited hepatic metabolism and durable pharmacologic activity in modulating brain opioid receptors. 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 2016, we announced the topline results of FORWARD-3 and FORWARD-4 from the FORWARD (Focused on Results With a Rethinking of Depression) pivotal program. Neither study met the prespecified primary efficacy endpoint, which compared ALKS 5461 to placebo on the change from baseline on the 10-item Montgomery—Åsberg Depression Rating Scale (“MADRS-10”) total scores. FORWARD-4, which tested two dose levels of ALKS 5461 (2mg/2mg and 0.5mg/0.5mg) compared to placebo, showed 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 2mg/2mg dose group on the MADRS-10 endpoint. Based on these analyses, we believe that FORWARD-4 provides supportive evidence of the efficacy of ALKS 5461 for the adjunctive treatment of MDD in patients with an inadequate response to standard antidepressant therapies. 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.



In October 2016, we announced positive topline results from FORWARD-5, a phase 3 randomized, double-blind, multicenter, placebo-controlled, sequential parallel comparison design study of ALKS 5461 in MDD from the FORWARD pivotal program. ALKS 5461 2mg/2mg met the prespecified primary endpoint of significantly reducing depression scores compared to placebo, as measured by the 6-item Montgomery—Asberg Depression Rating Scale (“MADRS-6”). ALKS 5461 2mg/2mg also demonstrated statistically significant reductions in MADRS-10 scores compared to placebo. The 1mg/1mg dose of ALKS 5461 showed improvement in depressive symptoms in the study, but did not separate significantly from placebo. FORWARD-5 was conducted in two sequential stages: Stage 1 was 5 weeks in duration, and Stage 2 was 6 weeks. In Stage 1, the average change from baseline depression scores was calculated for weeks 3 through 5. For Stage 2, the average change from baseline was calculated for weeks 3 through 6. The results of Stages 1 and 2 were then averaged. Depression scores were assessed using MADRS-6 and MADRS-10. MADRS-6, a subscale of the MADRS-10 assessment tool for depression, focuses on the core symptoms of depression. The most common adverse events for ALKS 5461 observed in the FORWARD efficacy studies included nausea, constipation and dizziness.

Based on the results of FORWARD-5, the supportive evidence from FORWARD-4 and the successful phase 2 study of ALKS 5461, we recently met with the FDA's Division of Psychiatric Products at a Type C meeting to discuss ALKS 5461. We will request a pre-NDA meeting with the FDA and plan to submit the New Drug Application (“NDA”) for ALKS 5461 in the second half of 2017.

### ***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 from olanzapine with favorable weight and metabolic properties and to have utility in the treatment of schizophrenia in patients with co-occurring alcohol use disorder.

In December 2015 and February 2016, we announced the initiation of ENLIGHTEN-1 and ENLIGHTEN-2, respectively, the two phase 3 studies from the ENLIGHTEN pivotal program for ALKS 3831. ENLIGHTEN-1 is a multicenter, randomized, double-blind study to evaluate the antipsychotic efficacy of ALKS 3831 compared to placebo over four weeks in patients experiencing acute exacerbation of schizophrenia. ENLIGHTEN-2 is designed to assess 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, metabolic and long-term safety profile of ALKS 3831. Results from ENLIGHTEN-1 are expected by the end of 2017 and results from ENLIGHTEN-2 are expected in mid-2018. We expect to use safety and efficacy data from the ENLIGHTEN pivotal program, if successful, to serve as the basis for an NDA to be submitted to the FDA.

In October 2016, we announced the initiation of a phase 1 metabolic study of ALKS 3831 to assess the effects of ALKS 3831 on whole body insulin sensitivity, lipid metabolism and other important metabolic parameters compared to olanzapine. Subjects will be randomized to receive ALKS 3831, olanzapine or placebo for 21 days. Results from the study are expected in mid-2017.

In January 2017, we announced plans to initiate a phase 3 study of ALKS 3831 in young adult patients. The study will assess the impact of ALKS 3831 on weight compared to treatment with olanzapine. The study is expected to initiate in the second quarter of 2017.

### ***ALKS 8700***

ALKS 8700 is a novel, proprietary, oral investigational 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.

We plan 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 the first quarter of 2017. We expect to complete ALKS 8700 registration studies and file the NDA in 2018.

### ***ALKS 6428***

ALKS 6428 is designed to help healthcare providers transition patients from physical dependence on opioids to initiation with VIVITROL. ALKS 6428 is an investigational regimen of ascending doses of oral naltrexone administered in conjunction with ancillary medications during a seven-day treatment period, prior to first VIVITROL injection. In February 2017, we announced that the study did not meet its primary endpoint, and no statistically significant difference between treatment groups was observed. Patients in each of the three treatment arms (ALKS 6428 plus tapering doses of buprenorphine, ALKS 6428 plus placebo, and placebo) performed equally well, with a similar percentage of patients successfully transitioning to initiation with VIVITROL. The company is continuing to analyze the full data set from the study.

A second phase 3 study of ALKS 6428 is ongoing in patients who want to transition from buprenorphine maintenance therapy to initiation with VIVITROL for the treatment of opioid dependence.

### ***ALKS 4230***

ALKS 4230 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. We filed an Investigational New Drug (“IND”) application with the FDA in the first quarter of 2016 and initiated a phase 1 clinical trial in May 2016. This phase 1 study is being conducted in two stages: a dose-escalation stage followed by a dose-expansion stage. The first stage of the study is designed to determine a maximum tolerated dose, and to identify the optimal dose range of ALKS 4230 based on measures of immunological-pharmacodynamic effects. Following the identification of the optimal dose range of ALKS 4230 in the first stage of the study, the dose-expansion stage of the study will evaluate ALKS 4230 in patients with selected solid tumor types. Initial results from the first stage of the phase 1 study are expected in 2017.

### ***ALKS 7119***

ALKS 7119 is a novel, proprietary, oral 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. In April 2016, we announced that early results of the single-ascending-dose study demonstrated a favorable tolerability profile and pharmacokinetic properties consistent with potential once-daily dosing.

Based on these early results, we initiated the multiple-ascending-dose study in healthy volunteers in July 2016. In October 2016, due to tolerability issues observed in a small number of subjects in the study, we ceased further development of ALKS 7119. The effects observed were not observed in the single-ascending dose study or anticipated based on pre-clinical models.

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

Please see “Results of Operations” for our R&D expenditures for the fiscal years ended December 31, 2016 and 2015.

### **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 Directors’ Report for information with respect to the intellectual property protection for these products.

#### *Janssen*

##### INVEGA SUSTENNA/XEPLION and INVEGA TRINZA/TREVICTA

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

Janssen may terminate the license agreement in whole or in part upon three months’ notice to 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 two 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 Canada, France, Germany, Italy, Japan, Spain and the United Kingdom, in each case, 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 pre-clinical 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, Biogen). 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 for the development of exendin products falling within the scope of our patents, including the once-weekly formulation of exenatide marketed as BYDUREON. In August 2012, Bristol-Myers Squibb Company (“Bristol-Myers”) acquired Amylin. From August 2012 through January 2014, Bristol-Myers and AstraZeneca jointly developed and commercialized Amylin’s exendin products, including BYDUREON, through their diabetes collaboration. In April 2013, Bristol-Myers completed its assumption of all global commercialization responsibility related to the marketing of BYDUREON from Amylin’s former collaborative partner, Eli Lilly & Company (“Lilly”). In February 2014, AstraZeneca acquired sole ownership from Bristol-Myers 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, except to the extent manufacturing rights have been transferred to Amylin, 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 licensed under this agreement. 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.

## **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 extended duration of 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 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 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 or development products, 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 Principal Risks 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, two VIVITROL lines and one ARISTADA line at commercial scale. Janssen has granted us an option, which we exercised, 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 and, in Russia and certain countries of the CIS, VIVITROL. Our Wilmington, Ohio facility has been inspected by U.S., European (including the Medicines and Healthcare Products Regulatory Agency), Chinese, Japanese, Brazilian, Turkish 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, Belarusian and Chinese regulatory authorities for compliance with required cGMP standards for continued commercial manufacturing.

### ***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 developing 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.

### **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 in Ireland (“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 of such technologies. 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 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 90 individuals. VIVITROL is sold directly to pharmaceutical wholesalers, specialty pharmacies and a specialty distributor. Product sales of VIVITROL during the year ended December 31, 2016 to AmerisourceBergen Corporation (“AmerisourceBergen”), McKesson Corporation, Cardinal Health and CVS Caremark Corporation represented approximately 19%, 18%, 13% and 12%, respectively, of total VIVITROL sales.

Our sales force for ARISTADA in the U.S. consists of approximately 210 individuals. ARISTADA is primarily sold to pharmaceutical wholesalers. Product sales of ARISTADA during the year ended December 31, 2016 to Cardinal Health, McKesson Corporation and AmerisourceBergen represented approximately 45%, 23% and 21%, respectively, of total ARISTADA sales.

ICS AmerisourceBergen, a division of AmerisourceBergen, 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 under such agreements 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 products, we believe that our ability to successfully compete will depend on, among other things, the existence of competing or alternative products in the marketplace, including generic competition, and the relative price of those products; the efficacy, safety and reliability of our products compared to competing or alternative products; product acceptance by physicians, other health care providers and patients; our ability to comply with applicable laws, regulations and regulatory requirements with respect to the commercialization of our products, including any changes or increases to regulatory restrictions; protection of our proprietary rights; obtaining reimbursement for our products in approved indications; our ability to complete clinical development and obtain regulatory approvals for our products, and the timing and scope of regulatory approvals; our ability to provide a reliable supply of commercial quantities of a product to the market; and our ability to recruit, retain and develop skilled employees.

With respect to our proprietary injectable product platform, we are aware that there are other companies developing extended-release delivery systems for pharmaceutical products, including, but not limited to Luye Pharma Group Ltd. (“Luye Pharma”), which is developing risperidone formulated as extended release microspheres for intramuscular injection for the treatment of schizophrenia and/or schizoaffective disorders. In the treatment of schizophrenia, ARISTADA, INVEGA SUSTENNA/XEPLION and INVEGA TRINZA/TREVICTA 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 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 oral aripiprazole, REXULTI, LATUDA, risperidone, olanzapine, ziprasidone and clozapine.

In the treatment of alcohol dependence, VIVITROL competes with generic acamprosate calcium (also known as CAMPRAL) and generic disulfiram (also known as ANTABUSE) 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, PROBUPHINE (buprenorphine), marketed and sold by Braeburn Pharmaceuticals 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 products for the treatment of type 2 diabetes that, if approved by the FDA, would compete with BYDUREON.

While AMPYRA/FAMPYRA is 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, 2016, 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, that cover 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;
- U.S. Patent No. 9,193,685, having claims to pharmaceutical compositions that confer long-term stability, expiring in 2033;
- U.S. Patent No. 9,452,131, having claims to methods of treatment for schizophrenia, expiring in 2035; and
- U.S. Patent No. 9,526,726, having claims to kits comprising pharmaceutical compositions of aripiprazole lauroxil and instructions for intramuscular injection, expiring in 2035.

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 a significant number of patents and certain pending patent applications covering our microsphere technology throughout the world, 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 2026 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/TREVICTA***

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/TREVICTA. The latest of the patents subject to our license agreement with Janssen covering INVEGA SUSTENNA/XEPLION expire in 2019 in the U.S. and 2022 in the EU, and, in certain countries, such as Australia and South Korea, in 2023. The latest of the patents covering INVEGA TRINZA/TREVICTA expire in November 2017 in the U.S. and 2022 in the



EU. In addition, the latest of the patents not subject to our license agreement with Janssen covering INVEGA SUSTENNA/XEPLION expires in 2031 in the U.S.

***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 Note 15, *Commitments and Contingencies*, in the Notes to Consolidated Financial Statements.

***ALKS 5461 and ALKS 3831***

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

<u>U.S. Patent No.</u>	<u>Product Candidate(s) Covered</u>	<u>Expiration Date</u>
7,956,187 . . . . .	ALKS 5461	2021
	ALKS 3831	
8,252,929 . . . . .	ALKS 5461	2021
	ALKS 3831	
7,262,298 . . . . .	ALKS 5461	2025
	ALKS 3831	
8,680,112 . . . . .	ALKS 5461	2029
	ALKS 3831	
9,119,848 . . . . .	ALKS 5461	2031
	ALKS 3831	
9,126,977 . . . . .	ALKS 3831	2031
9,517,235 . . . . .	ALKS 3831	2031
8,778,960 . . . . .	ALKS 3831	2032
8,822,488 . . . . .	ALKS 5461	2032
9,498,474 . . . . .	ALKS 5461	2032

***ALKS 8700***

We have U.S. patents and patent applications, and a number of corresponding foreign counterparts, that cover 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.

***ALKS 4230***

We have U.S. patents and patent applications, and a number of corresponding foreign counterparts, that cover ALKS 4230. U.S. Patent No. 9,359,415, having claims to ligands that are modified by circular permutation as agonists and antagonists, expiring in 2033, covers ALKS 4230.

### *Protection of Proprietary Rights and Competitive Position*

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 “Principal Risks” later in this section.

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/XEPLION, INVEGA TRINZA/TREVICTA 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.

## **Employees**

As of February 3, 2017, we had approximately 1,750 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.

## **Review of the Performance of the Business**

### Overview

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 licensees. Our key marketed products are expected to generate significant revenues for us in the near- and medium-term and we believe are singular or competitively advantaged products in their classes. These key marketed products consist of INVEGA SUSTENNA/XEPLION, INVEGA TRINZA/TREVICTA and RISPERDAL CONSTA; AMPYRA/FAMPYRA; BYDUREON; VIVITROL; and ARISTADA. Revenues from these products accounted for 92% of our total revenues during the year ended December 31, 2016, as compared to 88% during the year ended December 31, 2015.

During the year ended December 31, 2016 we incurred an operating loss of \$208.7 million, which was primarily due to the continued significant investment in our R&D pipeline and commercial organization. During 2016, within R&D we:

- filed a sNDA for Aripiprazole Lauroxil Two-Month Dose;
- announced results from three phase 3 studies for ALKS 5461, met with the Division of Psychiatric Products at a Type C meeting and will request a pre-NDA meeting with the FDA and plan to submit the NDA for ALKS 5461 in the second half of 2017;
- continued the ENLIGHTEN phase 3 pivotal program for ALKS 3831, initiated in December 2015. We also announced the initiation of a phase 1 study of ALKS 3831 in October 2016;
- continued the two-year, multicenter, open-label phase 3 study designed to assess the safety of ALKS 8700, initiated in December 2015. We also announced our plan to initiate a randomized, head-to-head phase 3 study of the gastrointestinal tolerability of ALKS 8700 compared to TECFIDERA in the first half of 2017;
- completed, as of October 2016, enrollment of the phase 3 study evaluating the safety, tolerability and efficacy of ALKS 6428 in patients with opioid dependence, which was initiated in September 2015; and
- filed an IND with the FDA and initiated a phase 1 study of ALKS 4230 in May 2016.

In 2016, we had increases in net sales of VIVITROL of 45% when compared to 2015, and we had a full year of ARISTADA sales as ARISTADA was launched in October 2015. As a result of the

approval of ARISTADA, and our continued investment in VIVITROL, selling, general and administrative expenses increased by 20% in 2016, when compared to 2015, most of which was driven by increases in headcount and increased marketing activity related to these two products.

## Results of Operations

### 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' net 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, 2016 and 2015:

(In millions)	Year Ended December 31,		Change Favorable/ (Unfavorable)
	2016	2015	
Manufacturing and royalty revenues:			
INVEGA SUSTENNA/XEPLION & INVEGA			
TRINZA/TREVICTA . . . . .	\$184.2	\$149.7	\$ 34.5
AMPYRA/FAMPYRA . . . . .	114.2	104.7	9.5
RISPERDAL CONSTA . . . . .	87.2	100.7	(13.5)
BYDUREON . . . . .	45.6	46.1	(0.5)
RITALIN LA & FOCALIN XR . . . . .	—	9.3	(9.3)
Other . . . . .	56.0	64.8	(8.8)
Manufacturing and royalty revenues . . . . .	<u>\$487.2</u>	<u>\$475.3</u>	<u>\$ 11.9</u>

Under our INVEGA SUSTENNA/XEPLION and INVEGA TRINZA/TREVICTA agreement with Janssen, we earn royalties on end-market net sales of INVEGA SUSTENNA/XEPLION and INVEGA TRINZA/TREVICTA 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 of 7.5% of Janssen's unit net sales price of RISPERDAL CONSTA and royalty revenues of 2.5% of end-market sales.

The increase in INVEGA SUSTENNA/XEPLION and INVEGA TRINZA/TREVICTA royalty revenues in each period was due to an increase in Janssen's end-market sales of INVEGA SUSTENNA/XEPLION and INVEGA TRINZA/TREVICTA. Janssen's end-market sales of INVEGA SUSTENNA/XEPLION and INVEGA TRINZA/TREVICTA were \$2.2 billion and \$1.8 billion during the years ended December 31, 2016 and 2015, respectively.

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 net sales of RISPERDAL CONSTA were \$893.0 million and \$970.0 million during the years ended December 31, 2016 and 2015, respectively. The decline in Janssen's end-market net sales led to a decrease in our royalty revenues of 8% in 2016, as compared to 2015. The manufacturing revenue we earned on shipments of RISPERDAL CONSTA to Janssen also declined by 15% in 2016, as compared to 2015 which was primarily due to a 13% decrease in the number of units shipped to Janssen.

We expect revenues from our long-acting, atypical antipsychotic franchise to continue to grow as INVEGA SUSTENNA/XEPLION grows and INVEGA TRINZA/TREVICTA 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, INVEGA TRINZA/TREVICTA and RISPERDAL CONSTA. Increased competition may lead to reduced unit sales of INVEGA SUSTENNA/XEPLION, INVEGA TRINZA/TREVICTA and RISPERDAL CONSTA, as well as increasing pricing pressure. The latest of the patents subject to our license agreement with Janssen covering INVEGA SUSTENNA/XEPLION expire in 2019 in the U.S. and 2022 in the EU, and, in certain countries, such as Australia and South Korea, in 2023. The latest of the patents covering INVEGA TRINZA/TREVICTA expire in November 2017 in the U.S. and 2022 in the EU. In addition, the latest of the patents not subject to our license agreement with Janssen covering INVEGA SUSTENNA/XEPLION expires in 2031 in the U.S. RISPERDAL CONSTA is covered by a patent until 2021 in the EU and 2023 in the U.S. As such, we do not anticipate generic versions in the near-term for any 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 net sales of FAMPYRA by Biogen.

The increase in AMPYRA/FAMPYRA revenues in 2016, as compared to 2015 was due to a 10% increase in manufacturing revenue and an 8% increase in royalty revenue. The increase in manufacturing revenue was primarily due to a 12% increase in product shipped to Acorda and Biogen. The increase in royalty revenue was due to an increase in the end-market net sales of AMPYRA/FAMPYRA as end-market net sales of the products were \$573.9 million and \$520.7 million in the years ended December 31, 2016 and 2015, respectively. 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. AMPYRA is subject to an IPR proceeding and Paragraph IV litigation. For a discussion of legal proceedings related to the patents covering AMPYRA, see Note 15, *Commitments and Contingencies*, in the accompanying “Notes to Consolidated Financial Statements.” 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.

Under our BYDUREON license agreement with AstraZeneca, we earned royalties on end-market net sales of BYDUREON of 8% in the years ended December 31, 2016 and 2015. The decrease in BYDUREON royalty revenues in 2016 as compared to 2015 was due to the amount of end-market net sales of BYDUREON. AstraZeneca’s end-market net sales of BYDUREON were \$576.3 million and \$580.0 million in 2016 and 2015, respectively. BYDUREON is covered by a patent until 2026 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.

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 “Currency Exchange Rate Risk” later in this section 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., primarily to wholesalers, specialty distributors and specialty pharmacies. The following table presents the adjustments deducted from product sales, gross to arrive

at product sales, net for sales of VIVITROL and ARISTADA in the U.S. during the years ended December 31, 2016 and 2015:

(In millions)	Year Ended December 31, 2016		Year Ended December 31, 2015	
	Amount	% of Sales	Amount	% of Sales
Product sales, gross . . . . .	\$ 444.6	100.0%	\$227.0	100.0%
Adjustments to product sales, gross:				
Medicaid rebates . . . . .	(94.2)	(21.2)%	(32.2)	(14.2)%
Product discounts . . . . .	(35.1)	(7.9)%	(13.2)	(5.8)%
Chargebacks . . . . .	(31.5)	(7.1)%	(17.8)	(7.8)%
Co-pay assistance . . . . .	(8.5)	(1.9)%	(6.5)	(2.9)%
Other . . . . .	(19.2)	(4.3)%	(8.3)	(3.7)%
Total adjustments . . . . .	(188.5)	(42.4)%	(78.0)	(34.4)%
Product sales, net . . . . .	<u>\$ 256.1</u>	<u>57.6%</u>	<u>\$149.0</u>	<u>65.6%</u>

The increase in product sales, gross in 2016, as compared to 2015, was primarily due to a 70% increase in VIVITROL gross sales, and a full year of ARISTADA sales. The increase in VIVITROL gross sales was primarily due to a 66% increase in the number of VIVITROL units sold and a 3% increase in the price of VIVITROL. The increase in Medicaid rebates as a percentage of sales in 2016, as compared to 2015, was primarily due to an increase in the amount of VIVITROL sold under the Medicaid Drug Rebate Program. Our product sales, net for VIVITROL and ARISTADA in 2016 were \$209.0 million and \$47.1 million, respectively, as compared to \$144.4 million and \$4.6 million in 2015, respectively. 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 and increased pricing pressure may lead to reduced unit sales of VIVITROL. 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 and increased pricing pressure may lead to reduced unit sales of ARISTADA. ARISTADA is covered by a patent that will expire in the U.S. in 2035, and, as such, we do not anticipate any generic versions of this product in the near-term.

## Costs and Expenses

### Cost of Goods Manufactured and Sold

(In millions)	Year Ended December 31,		Change Favorable/ (Unfavorable)
	2016	2015	
Cost of goods manufactured and sold . . . . .	<u>\$132.1</u>	<u>\$139.0</u>	<u>\$6.9</u>

The decrease in cost of goods manufactured and sold in 2016, as compared to 2015, was primarily due to the Gainesville Transaction. During the year ended December 31, 2015, the Gainesville facility had cost of goods manufactured of \$10.2 million. In addition, cost of goods manufactured at our Athlone facility decreased by \$8.2 million, which was primarily due to a reduction in manufacturing activity due to the restructuring program initiated in April 2013. These decreases were partially offset

by a \$11.4 million increase in cost of goods manufactured and sold related to products produced at our Wilmington, Ohio manufacturing facility, which was primarily due to the increase in VIVITROL sales and a full year of ARISTADA 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:

(In millions)	Year Ended December 31,		Change Favorable/ (Unfavorable)
	2016	2015	
External R&D Expenses:			
Key development programs:			
ALKS 3831 . . . . .	\$ 71.0	\$ 26.1	\$(44.9)
ALKS 5461 . . . . .	46.2	108.4	62.2
ARISTADA and ARISTADA line extensions . . .	36.3	38.1	1.8
ALKS 8700 . . . . .	26.9	17.9	(9.0)
ALKS 6428 . . . . .	16.3	7.0	(9.3)
Other external R&D expenses . . . . .	47.2	19.5	(27.7)
Total external R&D expenses . . . . .	<u>243.9</u>	<u>217.0</u>	<u>(26.9)</u>
Internal R&D expenses:			
Employee-related . . . . .	110.1	97.5	(12.6)
Occupancy . . . . .	9.0	8.1	(0.9)
Depreciation . . . . .	7.9	6.2	(1.7)
Other . . . . .	16.2	15.6	(0.6)
Total internal R&D expenses . . . . .	<u>143.2</u>	<u>127.4</u>	<u>(15.8)</u>
Research and development expenses . . . . .	<u>\$387.1</u>	<u>\$344.4</u>	<u>\$(42.7)</u>

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

The increase in the expenses related to ALKS 3831 in 2016, as compared to 2015, was primarily due to the ENLIGHTEN-1 and ENLIGHTEN-2 pivotal trials, which were initiated in December 2015 and February 2016, respectively. The decrease in expenses related to ALKS 5461 in 2016, as compared to 2015 was primarily due to the timing of the three core phase 3 studies related to the program. We announced the results of the FORWARD-3 and FORWARD-4 studies in January 2016 and topline results from FORWARD-5 were announced in October 2016. The ALKS 5461 pivotal clinical development program was initiated in March 2014. The decrease in expenses related to ARISTADA and ARISTADA line extensions in 2016, as compared to 2015, was primarily due to the timing of the

phase 1 clinical study of extended dosing intervals of aripiprazole lauroxil in patients with schizophrenia. 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. Based on the results of this study, we submitted a sNDA to the FDA in August 2016. The increase in expenses related to ALKS 6428 was primarily due to the initiation of the phase 3 study evaluating the safety, tolerability and efficacy of ALKS 6428 in patients with opioid dependence in September 2015. The increase in expenses related to ALKS 8700 was primarily due to the timing of study activity. We initiated the two-year, multicenter, open-label phase 3 study designed to assess the safety of ALKS 8700 in December 2015, following the completion of a phase 1 study of ALKS 8700 initiated in 2014.

The increase in other external R&D expenses was primarily due to a \$10.0 million non-refundable, upfront payment made as partial consideration of a grant to us of rights and licenses pursuant to a collaboration and license option agreement with Reset Therapeutics, Inc., as well as an increase in external expenses related to our early-stage, pre-clinical development activity. The increase in employee-related expenses was primarily due to an increase in headcount. Our R&D-related headcount increased by 20% in 2016, as compared to 2015.

For additional detail on the status of our key development programs, refer to “Key Development Programs” earlier in this section.

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

(In millions)	Year Ended December 31,		Change Favorable/ (Unfavorable)
	2016	2015	
Selling, general and administrative . . . . .	<u>\$374.1</u>	<u>\$311.6</u>	<u>\$(62.5)</u>

The increase in selling, general and administrative (“SG&A”) expense in 2016, as compared to 2015, was primarily due to a \$28.9 million increase in employee-related expenses and a \$27.1 million increase in marketing and professional services expenses. The increase in employee-related expenses was primarily due to a 15% increase in our SG&A-related headcount during 2016. The increase in marketing and professional services expenses was primarily due to additional brand investments in both VIVITROL and ARISTADA in 2016, as well as an increase in patient access support services, such as reimbursement and transition assistance, for both of these products.

***Amortization of Acquired Intangible Assets***

(In millions)	Year Ended December 31,		Change Favorable/ (Unfavorable)
	2016	2015	
Amortization of acquired intangible assets . . . . .	<u>\$61.0</u>	<u>\$57.7</u>	<u>\$(3.3)</u>

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, 2016 is expected to be approximately \$60.0 million, \$60.0 million, \$55.0 million, \$50.0 million and \$45.0 million in the years ending December 31, 2017 through 2021, respectively.

***Other (Expense) Income, Net***

(In millions)	Year Ended December 31,		Change Favorable/ (Unfavorable)
	2016	2015	
Interest income . . . . .	\$ 3.8	\$ 3.3	\$ 0.5
Interest expense . . . . .	(14.9)	(13.2)	(1.7)
Change in the fair value of contingent consideration . . . . .	7.9	(2.3)	10.2
Gain on the Gainesville Transaction . . . . .	—	9.6	(9.6)
Gain on the sale of property, plant and equipment	—	2.9	(2.9)
Other (expense), net . . . . .	(2.5)	—	(2.5)
Total other (expense) income, net . . . . .	<u>\$ (5.7)</u>	<u>\$ 0.3</u>	<u>\$(6.0)</u>

The increase in interest expense in 2016, as compared to 2015, was due to the amendment of Term Loan B-1 in October 2016, pursuant to which, among other things, the due date of Term Loan B-1 was extended from September 25, 2019 to September 25, 2021 (the “Refinancing”). The interest rate under Term Loan B-1 was unchanged and remains at LIBOR plus 2.75% with a LIBOR floor of 0.75%. We incurred a charge of \$2.1 million in connection with the Refinancing, which is included in interest expense.

In April 2015, we completed the Gainesville Transaction and received \$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 the IV/IM and parenteral forms of Meloxicam and any other product with the same active ingredient as Meloxicam IV/IM that is discovered or identified using certain of our intellectual property to which Recro was provided a right of use, through license or transfer, pursuant to the Gainesville Transaction (the “Meloxicam Products”), and up to \$120.0 million in milestone payments upon the achievement of certain regulatory and sales milestones related to the Meloxicam Products. We determined the fair value of the contingent consideration through three valuation approaches, which are described in greater detail in Note 3, *Divestitures*, in the accompanying “Notes to Consolidated Financial Statements”. At each reporting date, we 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, and will continue to do so until the milestones and/or royalties included in the contingent consideration have been settled.

During the years ended December 31, 2016 and 2015, we determined that the fair value of the contingent consideration increased by \$7.9 million and decreased by \$2.3 million, respectively. The increase in contingent consideration in 2016 was primarily due to the change in the structure of the development milestones and a shorter time to payment on the milestones and royalties included in the contingent consideration. The decrease in contingent consideration recorded in 2015 was primarily due to a delay in the timing of future clinical events.



*(Benefit) Provision for Income Taxes*

(In millions)	Year Ended December 31,		Change Favorable/ (Unfavorable)
	2016	2015	
(Benefit) provision for income taxes . . . . .	<u>\$ (5.9)</u>	<u>\$ 3.2</u>	<u>\$ 9.1</u>

The income tax benefit for the year ended December 31, 2016 was primarily due to U.S. federal research credits. The favorable change in the income taxes in the year ended December 31, 2016, as compared to 2015, was due to a reduction in income earned in the U.S. The income tax provision for the year ended December 31, 2015 was primarily due to U.S. 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 \$133.7 million at December 31, 2016.

At December 31, 2016, we maintained a valuation allowance of \$4.8 million against certain U.S. state deferred tax assets and \$137.1 million against certain Irish deferred tax assets as we determined that it is more-likely-than-not that these net deferred tax assets will not be realized. If we demonstrate consistent profitability in the future, the evaluation of the recoverability of these deferred tax assets may change and the remaining valuation allowance may be released in part or in whole.

As of December 31, 2016, we had \$1.1 billion of Irish NOL carryforwards, \$8.0 million of U.S. federal NOL carryforwards and \$7.4 million of U.S. state NOL carryforwards, \$53.1 million of federal R&D credits, \$9.0 million of alternative minimum tax credits and \$9.4 million of U.S. state tax credits which either expire on various dates through 2036 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 ordinary shares. 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.

**Liquidity and Capital Resources**

Our financial condition is summarized as follows:

(In millions)	December 31, 2016	December 31, 2015
Cash and cash equivalents . . . . .	\$186.4	\$181.1
Investments—short-term . . . . .	310.9	353.6
Investments—long-term . . . . .	121.9	264.1
Total cash and investments . . . . .	<u>\$619.2</u>	<u>\$798.8</u>
Outstanding borrowings—current and long-term . . . . .	<u>\$283.7</u>	<u>\$349.9</u>

At December 31, 2016, our investments consisted of the following:

(In millions)	Amortized Cost	Gross Unrealized		Estimated Fair Value
		Gains	Losses	
Investments—short-term . . . . .	\$310.9	\$0.1	\$(0.1)	\$310.9
Investments—long-term available-for-sale . . . . .	119.0	—	(0.5)	118.5
Investments—long-term held-to-maturity . . . . .	3.4	—	—	3.4
Total . . . . .	<u>\$433.3</u>	<u>\$0.1</u>	<u>\$(0.6)</u>	<u>\$432.8</u>

*Sources and Uses of Cash*

We used \$63.8 million and \$40.4 million of cash from operations during the years ended December 31, 2016 and 2015, 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 twelve months following the date from which our financial statements were issued. Subject to market conditions, interest rates and other factors, we may pursue opportunities to obtain additional financing in the future, including debt and equity offerings, corporate collaborations, bank borrowings, arrangements relating to assets or other financing methods or structures.

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, 2016, 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, 2016 and 2015:

(In millions)	Year Ended	Year Ended
	December 31, 2016	December 31, 2015
Cash and cash equivalents, beginning of period . .	\$181.1	\$224.1
Cash used in operating activities . . . . .	(63.8)	(40.4)
Cash provided by (used in) investing activities .	127.2	(43.5)
Cash (used in) provided by financing activities .	(58.1)	40.9
Cash and cash equivalents, end of period . . . . .	<u>\$186.4</u>	<u>\$181.1</u>

*Operating Activities*

The \$23.4 million increase in cash used in operating activities in 2016, as compared to 2015, was primarily due to a \$57.8 million increase in the amount of cash paid to our employees and a \$76.2 million increase in the amount of cash paid to our suppliers, partially offset by a \$98.2 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.

#### *Investing Activities*

Cash provided by our investing activities increased by \$170.7 million in 2016, as compared to 2015, which was primarily due to the increase in net sales of investments of \$226.8 million, which were primarily used to fund operations in 2016. The increase in cash provided by our investing activities was partially offset by the \$50.0 million in cash we received in 2015 from the Gainesville Transaction, as previously discussed.

In 2016, our capital spending decreased slightly when compared to 2015, which was primarily due to the timing of our capital projects, primarily for the construction of facilities and equipment at our Wilmington, Ohio location for the manufacture of products currently in development and existing proprietary products. Amounts included as construction in progress at December 31, 2016 primarily include capital expenditures at our manufacturing facility in Wilmington, Ohio. We expect to spend approximately \$75.0 million during the year ended December 31, 2017 for capital expenditures. We continue to evaluate our manufacturing capacity based on expectations of demand for our products and will continue to record such amounts within construction in progress until such time as the underlying assets are placed into service, or we determine we have sufficient existing capacity and the assets are no longer required, at which time we would recognize an impairment charge. We continue to periodically evaluate whether facts and circumstances indicate that the carrying value of these long-lived assets to be held and used may not be recoverable.

#### *Financing Activities*

The increase in cash used in financing activities in 2016, as compared to 2015, was primarily due to a \$60.9 million principal payment for a term loan which matured in September 2016, which had an original principal balance of \$75.0 million, bore interest at LIBOR plus 2.75%, with no LIBOR floor. In addition, there was a \$12.2 million decrease in cash received from employee stock option exercises.

#### ***Borrowings***

At December 31, 2016, our borrowings consisted of \$287.3 million outstanding under Term Loan B-1. 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, 2016:

<u>Contractual Obligations</u>	<u>Total</u>	<u>Less Than One Year (2017)</u>	<u>One to Three Years (2018 - 2019)</u>	<u>Three to Five Years (2020 - 2021)</u>	<u>More than Five Years (After 2021)</u>
			(In thousands)		
Term Loan B-1—Principal . . . . .	\$287,250	\$ 3,000	\$ 6,000	\$278,250	\$ —
Term Loan B-1—Interest . . . . .	56,333	10,014	19,714	26,605	—
Operating lease obligations . . . . .	24,817	6,055	12,367	5,729	666
Purchase obligations . . . . .	431,950	431,950	—	—	—
Total contractual cash obligations . . . . .	<u>\$800,350</u>	<u>\$451,019</u>	<u>\$38,081</u>	<u>\$310,584</u>	<u>\$666</u>

As interest on Term Loan B-1 is based on a one, three or six month LIBOR rate of our choosing, we assumed LIBOR to be 0.75%, which is the LIBOR rate floor under the terms of Term Loan B-1 as

the one-month LIBOR rate at December 31, 2016 was 0.72%. 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, 2016, we had \$4.7 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, 2016, 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.

#### **Financial Risk Management**

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 60% of our investments at December 31, 2016 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, 2016, our borrowings consisted of \$287.3 million outstanding under our Term Loan B-1. Term Loan B-1 bears interest at a LIBOR rate of our choosing (one, three or six months), plus 2.75% with a LIBOR floor of 0.75%. As the one-month LIBOR rate was 0.72% at December 31, 2016, 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, 2017. A

10% increase in the one-month LIBOR rate would increase the amount of interest we owe under this agreement during the year ending December 31, 2017 by approximately \$0.1 million.

### **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, 2016, 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 \$18.3 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, 2016, 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 \$6.4 million.

### **Principal Risks**

*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 Directors' Report. 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, product candidates using our proprietary technologies, development products and development products 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 products from which we receive manufacturing and/or royalty revenue 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 certain of our products. Janssen is responsible for the commercialization of RISPERDAL CONSTA, INVEGA SUSTENNA/XEPLION, and INVEGA TRINZA/TREVICTA, and, in Russia and the CIS, VIVITROL. 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, ARISTADA competes directly with RISPERDAL CONSTA, INVEGA SUSTENNA/XEPLION and INVEGA TRINZA/TREVICTA, products 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 licensee'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/TREVICTA by Janssen, upon continued sales of AMPYRA/FAMPYRA by Acorda and its sublicensee, Biogen, and upon our continued sales of VIVITROL. 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 or proceedings before the U.S. Patent and Trademark Office's (the "USPTO") Patent Trial and Appeal Board (the "PTAB"), including so-called "Paragraph IV" litigation, inter partes reviews ("IPR") 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 less experience in the commercialization of long-acting atypical antipsychotics than our competitors.***

We launched ARISTADA in October 2015 into a highly competitive market with companies larger than us and with more experience than us marketing and selling competing long-acting injectable atypical antipsychotic products for the treatment of schizophrenia.

We have less experience commercializing ARISTADA in a competitive market of this type. If we are not able to continue to attract and retain qualified personnel to serve in our sales and marketing organization, to maintain an effective distribution network and reimbursement for ARISTADA, or to otherwise effectively and efficiently support our commercialization activities, we may not be able to successfully commercialize 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 certain of our other development products. 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. 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 providers, 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.

In addition, 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/TREVICTA 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 sublicensees could materially and adversely affect sales of products from which we receive revenue, and 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 providers to demonstrate ongoing cGMP or other regulatory compliance could require us to withdraw or recall products and interrupt clinical and 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 other 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, or deductible amounts, 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, including but not limited to price control initiatives, discounts and other pricing-related actions. For example, in 2016, the State of California proposed a ballot initiative that, if passed, would have prohibited state agencies from entering into purchasing agreements with drug manufacturers unless the net cost of the drug was equal to less than that paid by the Veterans Administration. We expect similar state drug pricing initiatives in 2017. In addition, 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.

In 2017, we may face uncertainties as a result of likely federal and administrative efforts to repeal, substantially modify or invalidate some or all of the provisions of the Patient Protection and Affordable Care Act (the “PPACA”) and potential reforms and changes to government negotiation or regulation of drug pricing. There is no assurance that the PPACA, as currently enacted or as amended in the future, or such reforms and changes, will not adversely affect our business and financial results, and we cannot predict how future federal or state legislative or administrative changes relating to healthcare reform will affect our business.

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 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, licensors, 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 and an increasing number of IPRs and administrative proceedings in the pharmaceutical industry regarding patents and other intellectual property rights. A patent holder might file an IPR, interference and/or infringement action against us claiming that certain claims of one or more of our issued patents are invalid or that the manufacture, use, offer for sale, sale or import of our products infringed one or more of such party's patents. We may have to expend considerable time, effort and resources to defend such actions. In addition, we may need to enforce our intellectual property rights against third parties who infringe our patents and other intellectual property or challenge our patents, patent applications 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 trial proceedings, such as IPRs, 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 and proceedings could adversely affect our business and the validity and scope of our patents 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 amendment to our credit agreement, dated as of October 12, 2016, we extended our \$288.0 million term loan with an interest rate at LIBOR plus 2.75% with a LIBOR floor of 0.75% by two years to September 25, 2021 (“Term Loan B-1”).

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 Term Loan B-1 include a number of restrictive covenants that, among other things, and 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 (see “—Our revenues may be lower than expected as a result of failure by the marketplace to accept our products or for other factors” for factors that may affect the market acceptance of our products approved for sale).

***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 pre-clinical 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 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, phase 3 efficacy studies of ALKS 3831 are 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 in later clinical trials to obtain necessary regulatory approvals.

If a product 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 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 in Note 15, *Commitments and Contingencies*, of the Notes to Consolidated Financial Statements in this Directors' 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 with the United States District Court for the District of Columbia (the "DC Court") against the FDA requesting, among other things, that the DC Court vacate FDA's approval of the ARISTADA NDA. We successfully intervened in, and received the DC Court's approval to become a party to, this action.

On July 28, 2016, the DC Court issued an opinion in favor of us and the FDA, affirming in all respects FDA's decision to approve ARISTADA for the treatment of schizophrenia, and denying the action filed by Otsuka for declaratory and injunctive relief. Otsuka has filed an appeal of the DC Court's decision with the U.S. Court of Appeals for the District of Columbia Circuit ("DC Circuit") asking the DC Circuit to reverse the DC Court's decision, vacate FDA's approval of the ARISTADA NDA and remand the case to the DC Court for consideration of any appropriate equitable remedy for Otsuka's lost exclusivity. The DC Circuit's appellate hearing for this matter occurred on December 12, 2016.

If Otsuka's action is successful, the DC Circuit could remand the case to the DC Court and the DC 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 attempt 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, including, but not limited to, Luye Pharma, which is developing risperidone formulated as extended release microspheres for intramuscular injection for the treatment of schizophrenia and/or schizoaffective disorders. In the treatment of schizophrenia, ARISTADA, RISPERDAL CONSTA, INVEGA SUSTENNA/XEPLION, and INVEGA TRINZA/TREVICTA currently 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 oral aripiprazole, REXULTI, LATUDA, risperidone, olanzapine, ziprasidone and clozapine.

In the treatment of alcohol dependence, VIVITROL competes with generic acamprosate calcium (also known as CAMPRAL) and generic disulfiram (also known as ANTABUSE) 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, PROBUPHINE (buprenorphine), marketed and sold by Braeburn Pharmaceuticals 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 products for the treatment of type 2 diabetes that, if approved by the FDA, would compete with BYDUREON.

While AMPYRA/FAMPYRA is 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. 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, 2016, our accumulated deficit was \$947.9 million, which was primarily the result of net losses incurred from 1987, the year Alkermes, Inc., was founded, through December 31, 2016, 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 partners' ability to manufacture economically, our marketed products. 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 manufacturers;
- 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, and/or 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, XEPLION and TREVICTA 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. Our efforts to mitigate the impact of fluctuating currency exchange rates may not be successful. As a result, currency fluctuations among our reporting currency, USD, and the currencies in which we do business will affect our results of operations, often in unpredictable ways. Refer to “Currency Exchange Rate Risk” earlier in this document for additional information relating to our foreign currency exchange rate risk.

***We may not be able to attract and 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, 2016, we have \$318.2 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 the drug technology business (“EDT”) of Elan Corporation, plc may limit our ability to use our tax attributes to offset taxable income, if any, generated from such business combination.***

On September 16, 2011, the business of Alkermes, Inc. and EDT were combined under Alkermes plc (this combination is referred to as the “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. If this rule was to apply to the Business Combination, among other things, Alkermes, Inc. would have been restricted in its ability to use 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. 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, 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.

### **Likely Future Developments**

We expect to invest in R&D expenditures associated with internal initiatives in conjunction with external acquisitive investments and to focus these investments on products that we believe will offer the greatest potential for near and long-term growth. We plan to invest in areas in which we can benefit from our core competencies and global infrastructure. We plan to allocate resources to support the product lines that are faster-growing, higher-margin businesses in which we have or can develop a global competitive advantage. In fiscal year 2017, we plan to continue to analyze our business portfolio, which may lead to the acquisition or divestiture of businesses.



## Accounting Records

The directors are responsible for ensuring that the Company keeps adequate accounting records and appropriate accounting systems. To achieve this, the directors have appointed a Chief Financial Officer who makes regular reports to the Board of Directors and ensures compliance with the requirements of Sections 281 to 285 of the Companies Act, 2014. The Chief Financial Officer makes regular reports to the Audit and Risk Committee of the Board of Directors. The Audit and Risk Committee, in turn, briefs the full Board of Directors on significant financial matters arising from reports of the Chief Financial Officer and the external auditor.

The measures taken by the directors to secure compliance with the Company's obligation to keep adequate accounting records are the use of appropriate systems and procedures and employment of competent persons. The accounting records are kept at Connaught House, 1 Burlington Road, Dublin 4, Republic of Ireland.

## Corporate Governance

The Company's corporate governance policies and procedures are available on the investors page of the Company's website, [www.alkermes.com](http://www.alkermes.com).

## Events Since the End of the Financial Year

None.

## Directors and Secretary

The names of the persons who were directors or secretary at any time during the year ended December 31, 2016 or since December 31, 2016 are set out below.

<u>Directors</u>	<u>Date of Service as a Director or Secretary</u>
David W. Anstice . . . . .	(Reappointed May 25, 2016)
Floyd E. Bloom . . . . .	(Reappointed May 27, 2015)
Robert A. Breyer . . . . .	(Reappointed May 25, 2016)
Wendy L. Dixon . . . . .	(Reappointed May 25, 2016)
Paul J. Mitchell . . . . .	(Reappointed May 28, 2014)
Richard F. Pops . . . . .	(Reappointed May 28, 2014)
Nancy L. Snyderman . . . . .	(Appointed May 25, 2016)
Nancy J. Wysenski . . . . .	(Reappointed May 27, 2015)
<u>Secretary</u>	
Kathryn L. Biberstein . . . . .	(Appointed September 16, 2011)

## Acquisition or Disposal of Own Shares

<u>Own shares held by the Company (par value, \$0.01 per share)</u> <u>(Value in thousands)</u>	<u>Number</u>	<u>Value</u>
January 1, 2016 . . . . .	1,427,952	\$58,661
Acquired during the year . . . . .	332,815	13,978
December 31, 2016 . . . . .	<u>1,760,767</u>	<u>\$72,639</u>

The shares acquired during the year were received by the Company for the purchase of employee stock options or to satisfy minimum tax withholding obligations related to employee share based awards.

## 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.

## Directors' and Secretary's Interests in Shares

No director, the secretary or any member of their immediate families had any interest in shares or debentures of any subsidiary. Directors' remuneration is set forth in Note 21, *Directors' Remuneration*, of the consolidated financial statements. The interests of the directors and secretary in office at December 31, 2016 and 2015 in the ordinary share capital of Alkermes plc are shown in the table below.

	Ordinary Shares <sup>(1)</sup> At December 31, 2016			Ordinary Shares <sup>(1)</sup> At January 1, 2016		
	Shares	Options	Restricted Share Units	Shares	Options	Restricted Share Units
<b>Directors</b>						
David W. Anstice . . . . .	15,000	217,600	—	10,000	196,000	—
Floyd E. Bloom . . . . .	128,881	197,600	—	108,881	196,000	—
Robert A. Breyer . . . . .	15,156	133,000	—	37,156	114,400	—
Wendy L. Dixon . . . . .	1,600	172,600	—	1,600	151,000	—
Paul J. Mitchell . . . . .	8,000	197,600	—	8,000	196,000	—
Richard F. Pops . . . . .	608,962	3,245,000	139,750	553,497	3,158,750	134,625
Nancy L. Snyderman . . . . .	—	43,600	—	—	—	—
Nancy J. Wysenski . . . . .	—	128,850	—	—	107,250	—
<b>Company Secretary</b>						
Kathryn L. Biberstein . . . . .	132,687	767,370	45,000	95,379	720,679	42,500

(1) All interests declared are in the ordinary shares of \$0.01 par value of Alkermes plc.

## Political Donations

No political contributions that require disclosure under S26(1) Electoral Act 1997 (as amended) were made during the financial year 2016.

## Subsidiary Companies and Branches

Information regarding our subsidiaries is provided in Note 23, *Subsidiaries*, to the consolidated financial statements. The Company does not operate any branches outside of the State.

## Going Concern

The board has formed a judgment at the time of approving the financial statements that there is a reasonable expectation that the Company have adequate resources to continue in operational existence for the foreseeable future. In arriving at this conclusion the board has taken account of current and anticipated trading performance, together with the current and anticipated levels of net debt and the availability of the committed borrowing facilities. For this reason, the going concern basis continues to be adopted in the preparation of the Company financial statements.

## **AGM**

The Annual General Meeting of the Company will take place at Connaught House, 1 Burlington Road, Dublin 4, Republic of Ireland on May 27, 2017. The notice of meeting and a description of the business to be transacted is available on the Company's website at [www.alkermes.com](http://www.alkermes.com).

## **Audit committee**

The Company has established an audit committee.

## **Statutory Auditors**

The statutory auditors, PricewaterhouseCoopers (PwC) have indicated their willingness to continue in office and a resolution that they be re-appointed will be proposed at the Annual General Meeting.

## **Disclosure of information to auditors**

The directors in office at the date of this report have each confirmed that:

- As far as he/she is aware, there is no relevant audit information of which the company's auditor is unaware; and
- He/she has taken all the steps that he/she ought to have taken as a director in order to make himself/herself aware of any relevant audit information and to establish that the company's auditor is aware of that information.

## **Directors' compliance statement**

The directors acknowledge that they are responsible for securing the company's compliance with its relevant obligations. The directors confirm that they have:

1. Drawn up a compliance policy statement setting out the company's policies respecting compliance by the company with its relevant obligations.
2. Put in place appropriate arrangements or structures that are designed to secure material compliance with the company's relevant obligations.
3. Conducted a review, during the financial year ended 31 December 2016, of the arrangements and structures, referred to at 2 above.

On behalf of the Directors

/s/ RICHARD F. POPS  
Richard F. Pops  
*Chairman*

/s/ PAUL J. MITCHELL  
Paul J. Mitchell  
*Director*

April 7, 2017

**ALKERMES PLC**  
**STATEMENT OF DIRECTORS' RESPONSIBILITIES**

The directors are responsible for preparing the directors' report and the financial statements in accordance with Irish law.

Irish law requires the directors to prepare financial statements for each financial year that give a true and fair view of the consolidated and Company's assets, liabilities and financial position and of the profit or loss of the group for the financial year. Under that law the directors have prepared the financial statements in accordance with U.S. accounting standards, as defined in Section 279(1) of the Companies Act 2014, to the extent that the use of those principles in the preparation of the financial statements does not contravene any provision of the Companies Act or of any regulations made thereunder and the Parent Company financial statements in accordance with Generally Accepted Accounting Practice in Ireland (accounting standards issued by the Financial Reporting Council and promulgated by the Institute of Chartered Accountants in Ireland and Irish law).

Under Irish law, the directors shall not approve the financial statements unless they are satisfied that they give a true and fair view of the company's assets, liabilities and financial position as at the end of the financial year and the profit or loss of the company for the financial year.

In preparing these financial statements, the directors are required to:

- select suitable accounting policies and then apply them consistently;
- make judgments and estimates that are reasonable and prudent;
- state that the consolidated financial statements of Alkermes PLC and its subsidiaries (the Group) comply with accounting principles generally accepted in the United States of America (U.S. GAAP) to the extent that it does not contravene Irish Company Law and that the standalone entity balance sheet of Alkermes PLC (the Company) comply with accounting standards issued by the Financial Reporting Council and promulgated by the institute of Chartered Accountants in Ireland and Irish Law; and
- prepare the financial statements on the going concern basis unless it is inappropriate to presume that the company will continue in business.

The directors are responsible for keeping adequate accounting records that are sufficient to:

- correctly record and explain the transactions of the company;
- enable, at any time, the assets, liabilities, financial position and profit or loss of the company to be determined with reasonable accuracy; and
- enable the directors to ensure that the financial statements comply with the Companies Act 2014 and enable those financial statements to be audited.

The directors are also responsible for safeguarding the assets of the company and hence for taking reasonable steps for the prevention and detection of fraud and other irregularities.

The directors are responsible for the maintenance and integrity of the corporate and financial information included on the Company's website ([www.alkermes.com](http://www.alkermes.com)). Legislation in the Republic of Ireland concerning the preparation and dissemination of financial statements may differ from legislation in other jurisdictions.



## ***Independent auditors' report to the members of Alkermes plc***

### **Report on the financial statements**

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#### **Our opinion**

In our opinion:

- Alkermes plc's group and parent company financial statements (the "financial statements") give a true and fair view of the group's and parent company's assets, liabilities and financial position as at 31 December 2016 and of the group's loss and cash flows for the year then ended;
  - the group financial statements have been properly prepared, in accordance with accounting principles generally accepted in the United States of America ("US GAAP"), as defined in Section 279 of the Companies Act 2014, to the extent that the use of those principles in the preparation of the group financial statements does not contravene any provision of the Companies Act 2014 or of any regulations made thereunder;
  - the parent company balance sheet has been properly prepared in accordance with Generally Accepted Accounting Practice in Ireland; and
  - the financial statements have been properly prepared in accordance with the requirements of the Companies Act 2014.
- 

#### **What we have audited**

The financial statements comprise:

- the consolidated and parent company balance sheets as at 31 December 2016;
- the consolidated profit and loss account for the year then ended;
- the consolidated statement of cash flows for the year then ended;
- the consolidated statement of comprehensive loss for the year then ended;
- the group and parent company reconciliation of movements in shareholders' funds for the year then ended; and
- the notes to the financial statements, which include a summary of significant accounting policies and other explanatory information.

The financial reporting framework that has been applied in the preparation of the group financial statements is Irish law and US GAAP, as defined in Section 279 of the Companies Act 2014, to the extent that the use of those principles in the preparation of the financial statements does not contravene any provision of the Companies Act 2014 or of any regulations made thereunder.

The financial reporting framework that has been applied in the preparation of the parent company financial statements is Irish law and accounting standards issued by the Financial Reporting Council and promulgated by the Institute of Chartered Accountants in Ireland (Generally Accepted Accounting Practice in Ireland), including FRS 102 "The Financial Reporting Standard applicable in the United Kingdom and the Republic of Ireland".

In applying the financial reporting framework, the directors have made a number of subjective judgements, for example in respect of significant accounting estimates. In making such estimates, they have made assumptions and considered future events.

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#### **Matters on which we are required to report by the Companies Act 2014**

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- We have obtained all the information and explanations which we consider necessary for the purposes of our audit.
- In our opinion, the accounting records of the parent company were sufficient to permit the parent company financial statements to be readily and properly audited.
- The parent company balance sheet is in agreement with the accounting records.
- In our opinion the information given in the Directors' Report is consistent with the financial statements.



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## **Matter on which we are required to report by exception**

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### **Directors' remuneration and transactions**

Under the Companies Act 2014 we are required to report to you if, in our opinion, the disclosures of directors' remuneration and transactions specified by sections 305 to 312 of that Act have not been made. We have no exceptions to report arising from this responsibility.

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## **Responsibilities for the financial statements and the audit**

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### **Our responsibilities and those of the directors**

As explained more fully in the Directors' Responsibilities Statement set out on page 50, the directors are responsible for the preparation of the financial statements and for being satisfied that they give a true and fair view.

Our responsibility is to audit and express an opinion on the financial statements in accordance with Irish law and International Standards on Auditing (UK and Ireland). Those standards require us to comply with the Auditing Practices Board's Ethical Standards for Auditors.

This report, including the opinions, has been prepared for and only for the company's members as a body in accordance with section 391 of the Companies Act 2014 and for no other purpose. We do not, in giving these opinions, accept or assume responsibility for any other purpose or to any other person to whom this report is shown or into whose hands it may come save where expressly agreed by our prior consent in writing.

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### **What an audit of financial statements involves**

We conducted our audit in accordance with International Standards on Auditing (UK and Ireland). An audit involves obtaining evidence about the amounts and disclosures in the financial statements sufficient to give reasonable assurance that the financial statements are free from material misstatement, whether caused by fraud or error. This includes an assessment of:

- whether the accounting policies are appropriate to the group's and the parent company's circumstances and have been consistently applied and adequately disclosed;
- the reasonableness of significant accounting estimates made by the directors; and
- the overall presentation of the financial statements.

We primarily focus our work in these areas by assessing the directors' judgements against available evidence, forming our own judgements, and evaluating the disclosures in the financial statements.

We test and examine information, using sampling and other auditing techniques, to the extent we consider necessary to provide a reasonable basis for us to draw conclusions. We obtain audit evidence through testing the effectiveness of controls, substantive procedures or a combination of both.

In addition, we read all the financial and non-financial information in the directors' report and consolidated financial statements to identify material inconsistencies with the audited financial statements and to identify any information that is apparently materially incorrect based on, or materially inconsistent with, the knowledge acquired by us in the course of performing the audit. If we become aware of any apparent material misstatements or inconsistencies we consider the implications for our report.

**Alisa Hayden**  
**for and on behalf of PricewaterhouseCoopers**  
**Chartered Accountants and Statutory Audit Firm**  
**Dublin**  
**7 April 2017**



**ALKERMES PLC**  
**CONSOLIDATED PROFIT AND LOSS ACCOUNT**

	<u>Note</u>	<u>Year Ended December 31,</u>	
		<u>2016</u>	<u>2015</u>
<u>(In thousands, except per share amounts)</u>			
Manufacturing and royalty turnover . . . . .		\$ 487,247	\$ 475,288
Product sales, net . . . . .		256,146	149,028
Research and development turnover . . . . .		2,301	4,019
Total turnover . . . . .		<u>745,694</u>	<u>628,335</u>
Cost of sales . . . . .		<u>132,122</u>	<u>138,989</u>
Gross profit . . . . .		613,572	489,346
Research and development expense . . . . .		387,148	344,404
Selling, general and administrative expense . . . . .		374,130	311,558
Amortization of acquired intangible assets . . . . .	8	<u>60,959</u>	<u>57,685</u>
Operating loss . . . . .		<u>(208,665)</u>	<u>(224,301)</u>
Interest income . . . . .		3,752	3,330
Interest expense . . . . .	9	(14,889)	(13,247)
Change in the fair value of contingent consideration . . . . .	3	7,900	(2,300)
Gain on the Gainesville Transaction . . . . .	3	—	9,636
Gain on sale of property, plant and equipment . . . . .		—	2,862
Other (expense) income, net . . . . .		<u>(2,485)</u>	<u>15</u>
Total other (expense) income, net . . . . .		<u>(5,722)</u>	<u>296</u>
Loss on ordinary activities, before income taxes . . . . .		(214,387)	(224,005)
Income tax benefit (provision) . . . . .	14	<u>5,943</u>	<u>(3,158)</u>
Loss on ordinary activities, after tax . . . . .		<u>\$(208,444)</u>	<u>\$(227,163)</u>
<b>LOSS PER ORDINARY SHARE:</b>			
Basic and diluted . . . . .	10	<u>\$ (1.38)</u>	<u>\$ (1.52)</u>
<b>WEIGHTED AVERAGE NUMBER OF ORDINARY SHARES</b>			
<b>OUTSTANDING:</b>			
Basic and diluted . . . . .	10	<u>151,484</u>	<u>149,206</u>

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

**ALKERMES PLC**  
**CONSOLIDATED STATEMENT OF COMPREHENSIVE LOSS**

	Year Ended December 31,	
	2016	2015
	(In thousands, except per share amounts)	
NET LOSS . . . . .	\$(208,444)	\$(227,163)
Unrealized losses on marketable securities:		
Holding gains (losses), net of tax . . . . .	522	(661)
Unrealized losses on marketable securities . . . . .	522	(661)
COMPREHENSIVE LOSS . . . . .	\$(207,922)	\$(227,824)

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

**ALKERMES PLC**  
**CONSOLIDATED BALANCE SHEET**

	<u>Note</u>	<u>December 31,</u> <u>2016</u>	<u>December 31,</u> <u>2015</u>
		(In thousands)	
<b>ASSETS</b>			
<i>Fixed Assets</i>			
Intangible assets—Goodwill . . . . .	8	\$ 92,873	\$ 92,873
Intangible assets—Intellectual property . . . . .	8	318,227	379,186
Associated undertakings . . . . .	8	15,831	1,631
Tangible fixed assets . . . . .	7	<u>264,785</u>	<u>254,819</u>
Total fixed assets . . . . .		<u>691,716</u>	<u>728,509</u>
<i>Current Assets</i>			
Stock . . . . .	6	62,998	38,411
Debtors . . . . .	16	352,544	289,975
Investments . . . . .	4	432,787	617,740
Cash at bank and in-hand . . . . .		<u>186,378</u>	<u>181,109</u>
Total current assets . . . . .		<u>1,034,707</u>	<u>1,127,235</u>
<b>TOTAL ASSETS</b> . . . . .		<u><u>\$1,726,423</u></u>	<u><u>\$1,855,744</u></u>
<b>LIABILITIES</b>			
<i>Capital and Reserves</i>			
Called-up share capital presented as equity . . . . .	11	\$ 1,539	\$ 1,518
Share premium . . . . .		525,665	504,867
Profit and loss account . . . . .		409,395	616,009
Treasury shares . . . . .	11	(72,639)	(58,661)
Other reserves . . . . .		<u>345,521</u>	<u>250,542</u>
Total equity . . . . .		<u>1,209,481</u>	<u>1,314,275</u>
<i>Creditors</i>			
Debt . . . . .	9	283,666	349,944
Creditors . . . . .	17	<u>233,276</u>	<u>191,525</u>
Total for creditors . . . . .		<u>516,942</u>	<u>541,469</u>
<b>TOTAL LIABILITIES</b> . . . . .		<u><u>\$1,726,423</u></u>	<u><u>\$1,855,744</u></u>

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

The Consolidated Financial Statements were approved by the Board of Directors on April 7, 2017 and signed on its behalf by:

/s/ RICHARD F. POPS  
Richard F. Pops  
*Chairman*

/s/ PAUL J. MITCHELL  
Paul J. Mitchell  
*Director*

**ALKERMES PLC**  
**CONSOLIDATED STATEMENT OF CASH FLOWS**

	Year Ended	
	December 31, 2016	December 31, 2015
	(In thousands)	
<b>CASH FLOWS FROM OPERATING ACTIVITIES:</b>		
Loss after tax	\$(208,444)	\$(227,163)
Adjustments to reconcile net loss after tax to cash flows from operating activities:		
Share-based compensation expense	94,396	97,341
Depreciation and amortization	94,256	85,596
Deferred income taxes	(9,689)	(37,580)
Excess tax benefit from share-based compensation	(4,229)	(28,576)
Change in the fair value of contingent consideration	(7,900)	2,300
Loss on debt refinancing	2,075	—
Gain on the Gainesville Transaction	—	(9,636)
Gain on sale of property, plant and equipment	—	(3,272)
Other non-cash charges	2,936	(1,351)
Changes in assets and liabilities:		
Receivables	(35,616)	(16,455)
Inventory	(26,381)	3,687
Prepaid expenses and other assets	(15,014)	15,931
Accounts payable and accrued expenses	45,870	76,155
Deferred revenue	(649)	(629)
Other long-term liabilities	4,587	3,292
Cash flows (used in) operating activities	(63,802)	(40,360)
<b>CASH FLOWS FROM INVESTING ACTIVITIES:</b>		
Additions to property, plant and equipment	(43,657)	(52,877)
Proceeds from the sale of equipment	194	535
Investment in Reset Therapeutics, Inc.	(15,000)	—
Net proceeds from the Gainesville Transaction	—	49,966
Purchases of investments	(375,099)	(508,683)
Sales and maturities of investments	560,805	467,573
Cash flows provided by (used in) investing activities	127,243	(43,486)
<b>CASH FLOWS FROM FINANCING ACTIVITIES:</b>		
Proceeds from the issuance of ordinary shares for share-based compensation arrangements	20,308	44,969
Excess tax benefit from share-based compensation	4,229	28,576
Employee taxes paid related to net share settlement of equity awards	(13,468)	(25,904)
Payment made in connection with debt refinancing	(3,428)	—
Principal payments of long-term debt	(65,813)	(6,750)
Cash flows (used in) provided by financing activities	(58,172)	40,891
<b>NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS</b>	5,269	(42,955)
<b>CASH AND CASH EQUIVALENTS—Beginning of period</b>	181,109	224,064
<b>CASH AND CASH EQUIVALENTS—End of period</b>	186,378	\$ 181,109
<b>SUPPLEMENTAL CASH FLOW DISCLOSURE:</b>		
Cash paid for interest	\$ 12,458	\$ 12,323
Cash paid for taxes	\$ 5,531	\$ 705
Non-cash investing and financing activities:		
Purchased capital expenditures included in accounts payable and accrued expenses	\$ 5,766	\$ 6,054
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**  
**CONSOLIDATED RECONCILIATION OF MOVEMENT IN SHAREHOLDERS' FUNDS**

	Share Capital	Share Premium	Profit and Loss Account <small>(In thousands)</small>	Treasury Shares	Other Reserves	Total
BALANCE—January 1, 2015	\$1,482	\$459,229	\$ 814,596	\$(32,052)	\$153,582	\$1,396,837
Net loss	—	—	(227,163)	—	—	(227,163)
Other comprehensive loss	—	—	—	—	(659)	(659)
Share-based payment reserve	—	—	—	—	97,619	97,619
Shares issued under employee stock plans	35	44,934	—	—	—	44,969
Receipt of Alkermes' shares for the purchase of share options or to satisfy minimum tax withholding obligations related to share based awards	1	704	—	(26,609)	—	(25,904)
Excess tax benefit from share-based compensation	—	—	28,576	—	—	28,576
BALANCE—December 31, 2015	\$1,518	\$504,867	\$ 616,009	\$(58,661)	\$250,542	\$1,314,275
Net loss	—	—	(208,444)	—	—	(208,444)
Other comprehensive loss	—	—	—	—	521	521
Share-based payment reserve	—	—	—	—	94,458	94,458
Shares issued under employee stock plans	20	20,288	—	—	—	20,308
Receipt of Alkermes' shares for the purchase of share options or to satisfy minimum tax withholding obligations related to share based awards	1	510	—	(13,978)	—	(13,467)
Excess tax benefit from share-based compensation	—	—	1,830	—	—	1,830
BALANCE—December 31, 2016	\$1,539	\$525,665	\$ 409,395	\$(72,639)	\$345,521	\$1,209,481

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

**ALKERMES PLC**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**1. DESCRIPTION OF BUSINESS**

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.

**2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES AND STATEMENT OF COMPLIANCE**

*Basis of Preparation*

Irish law requires the directors to prepare financial statements for each financial year that give a true and fair view of the consolidated and company’s assets, liabilities and financial position as at the end of the financial year and of the profit or loss of the group for the financial year. Under that law, the Directors have prepared the consolidated financial statements in accordance with accounting standards generally accepted in the United States (“U.S. GAAP”), as defined in Section 279(1) of the Companies Act 2014, to the extent that the use of those principles in the preparation of the financial statements does not contravene any provision of the Companies Act or of any regulations made thereunder and the Parent Company financial statements in accordance with Generally Accepted Accounting Practice in Ireland (accounting standards issued by the Financial Reporting Council and promulgated by the Institute of Chartered Accountants in Ireland and Irish law).

The Consolidated Financial Statements are prepared in accordance with Irish Company Law, to present to the shareholders of Alkermes plc and file with the Companies Registration Office in Ireland. Accordingly, these Consolidated Financial Statements include disclosures required by the Companies Act 2014 of Ireland in addition to those required under U.S. GAAP.

The preparation of the Consolidated Financial Statements in conformity with U.S. GAAP accepted accounting principles requires management to use judgment in making estimates and assumptions based on the relevant information available at the end of each period. These estimates and assumptions have a significant effect on reported amounts of assets and liabilities, revenue and expenses as well as the disclosure of contingent assets and liabilities because they result primarily from the need to make estimates and assumptions on matters that are inherently uncertain. Actual results may differ from estimates.

*Statements of Compliance*

The entity financial statements have been prepared on the going concern basis and in accordance with Irish GAAP (accounting standards issued by the Financial Reporting Council of the UK and promulgated by the Institute of Chartered Accountants in Ireland and the Companies Act 2014). The entity financial statements comply with Financial Reporting Standard 102, ‘The Financial Reporting Standard applicable in the UK and Republic of Ireland’ (“FRS 102”) and the Companies Act 2014.



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

**2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES AND STATEMENT OF COMPLIANCE (Continued)**

*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.; 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 of Alkermes Gainesville LLC, which represent the entities sold, for the period from January 1, 2015 through April 10, 2015; and the year ended December 31, 2014.

During the year ended December 31, 2016, Eagle Holdings USA, a subsidiary of Alkermes plc, was merged with and into its parent company, Alkermes U.S. Holdings, Inc.

*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 at Bank and In-Hand*

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.

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

**2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES AND STATEMENT OF COMPLIANCE (Continued)**

*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, 2016, 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,” 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.”

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” 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, 2016 and 2015 included U.S. treasury securities and a fixed term deposit account;

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

**2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES AND STATEMENT OF COMPLIANCE (Continued)**

- *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, 2016 and 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, 2016 and 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 at bank and in-hand, debtors and creditors approximate fair value due to their short-term nature.

***Stock***

Stock is stated at the lower of cost and net realizable value. Cost is determined using the first-in, first-out method. Included in stock 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 stock 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 profit and loss account.

***Tangible Fixed Assets***

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

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

***Business Acquisitions and Divestitures***

The Company’s consolidated financial statements include the operations of an acquired business after the completion of the acquisition. The Company accounts for acquired businesses using the acquisition method of accounting. The acquisition method of accounting for acquired businesses

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

**2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES AND STATEMENT OF COMPLIANCE (Continued)**

requires, among other things, that assets acquired and liabilities assumed be recognized at their estimated fair values as of the acquisition date, and that the fair value of acquired in-process research and development be recorded on the balance sheet. Also, transaction costs are expensed as incurred. Any excess of the purchase price over the assigned values of the net assets acquired is recorded as goodwill. Contingent consideration, if any, is included within the acquisition cost and is recognized at its fair value on the acquisition date. A liability resulting from contingent consideration is re-measured to fair value at each reporting date until the contingency is resolved. Changes in the fair value of the contingent consideration are recognized in earnings.

The Company's consolidated financial statements include gains and losses from divested businesses. The Company accounts for the deconsolidation of a subsidiary, or derecognition of a group of assets, by recognizing a gain or loss in net income attributable to the Company, measured as the difference between the fair value of any consideration received and the carrying amount of the former subsidiary's assets and liabilities, or the carrying amount of the group of assets. If consideration received for the divested business includes contingent consideration, the Company elects, for the components of the contingent consideration that are not derivative instruments, such as future regulatory milestones, sales milestones and royalties, to include them in the contingent consideration portion of the arrangement at fair value. The Company has elected the fair value option for the subsequent accounting of the contingent consideration. The Company will continue to revalue the contingent consideration at each reporting date until each milestone and/or royalty have been achieved or ceased, with any changes in the fair value of the contingent consideration recognized in earnings.

***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. 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.

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

**2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES AND STATEMENT OF COMPLIANCE (Continued)**

*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 one level below an operating segment or a component to which goodwill is assigned when initially recorded.

Irish Company Law requires that goodwill and other fixed assets be written-off over a time period which does not exceed their useful life. Consistent with U.S. GAAP, goodwill is not amortized over an arbitrary period, 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'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.

In situations where the Company has significant influence, but not control, of an entity, it applies the equity method of accounting. Under the equity method of accounting, the Company's share of the investee's underlying net income or loss is recorded within "Other (expense) income, net" in the accompanying consolidated statements of operations. Refer to Note 8, *Goodwill and Intangible Assets*, for further discussion of the Company's equity method investments.

*Impairment of Long-Lived Assets*

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

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

**2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES AND STATEMENT OF COMPLIANCE (Continued)**

used, or a significant adverse change that would indicate that the carrying amount of an asset or group of assets is not recoverable. Determination of recoverability is based on an estimate of undiscounted future cash flows resulting from the use of the asset and its eventual disposition. In the event that such cash flows are not expected to be sufficient to recover the carrying amount of the assets, the assets are written-down to their estimated fair values. Long-lived assets to be disposed of are carried at fair value less costs to sell them.

***Turnover 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®/TREVICTA® 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 net product sales.

*Manufacturing turnover*—The Company recognizes manufacturing turnover from the sale of products it manufactures for resale by its collaborative partners. Manufacturing turnover is 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 turnover 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 turnover and estimated manufacturing turnover is reconciled and adjusted for in the period in which they become known, which is generally within the quarter. The difference between actual and estimated manufacturing turnover has not been material.

*Royalty turnover*—The Company recognizes royalty turnover 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 turnover 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 turnover and estimated royalty turnover are reconciled and adjusted for in the period in which they become known, which is generally within the quarter. The difference between actual and estimated royalty turnover has not been material.



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

**2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES AND STATEMENT OF COMPLIANCE (Continued)**

*Research and development turnover*—R&D turnover 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, net 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 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. To date, the difference between actual and estimated Medicaid rebates has not been material;
- *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, the difference between actual and estimated chargebacks has not been material;

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

**2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES AND STATEMENT OF COMPLIANCE (Continued)**

- *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, the difference between actual and estimated product discounts has not been material;
- *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, the difference between actual and estimated co-pay assistance has not been material; 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, 2016, the product return reserve was estimated to be approximately 1.6% and 1.5% of gross product sales for VIVITROL and ARISTADA, respectively, collectively amounting to \$13.5 million.

Other

The Company recognizes turnover 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 collectability 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 (expense) income, net" in the accompanying consolidated profit and loss account. During the years ended December 31, 2016 and 2015, the Company recorded a gain on foreign currency translation of \$0.1 million and \$1.4 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

ALKERMES PLC

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

**2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES AND STATEMENT OF COMPLIANCE (Continued)**

customers exceeding 10% of the total in each category as of December 31, 2016 and 2015 and for the years ended December 31, 2016 and 2015:

<u>Customer</u>	<u>Year Ended December 31, 2016</u>		<u>Year Ended December 31, 2015</u>	
	<u>Receivables</u>	<u>Revenue</u>	<u>Receivables</u>	<u>Revenue</u>
Janssen . . . . .	33%	36%	44%	40%
Acorda . . . . .	17%	15%	—	17%

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.

***Geographic Information***

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

<u>(In thousands)</u>	<u>Year Ended December 31, 2016</u>	<u>Year Ended December 31, 2015</u>
Turnover by region:		
U.S. . . . .	\$557,312	\$448,639
Ireland . . . . .	4,407	3,902
Rest of world . . . . .	183,975	175,794
Assets by region:		
Current assets:		
U.S. . . . .	\$382,168	\$360,154
Ireland . . . . .	407,761	394,281
Rest of world . . . . .	749	527
Long-term assets:		
U.S.:		
Intangible assets . . . . .	\$ —	\$ —
Goodwill . . . . .	—	—
Other . . . . .	236,175	294,158
Ireland:		
Intangible assets . . . . .	\$318,227	\$379,186
Goodwill . . . . .	92,873	92,873
Other . . . . .	288,470	334,565

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

**2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES AND STATEMENT OF COMPLIANCE (Continued)**

*Research and Development Expenses*

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

*Selling, General and Administrative Expenses*

Selling, general and administrative (“SG&A”) 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, 2016 and 2015, advertising costs totaled \$24.0 million and \$10.6 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

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

**2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES AND STATEMENT OF COMPLIANCE (Continued)**

disclosed below reflect different expected behavior among certain groups of employees. Expected stock volatility factors are based on a weighted average of implied volatilities from traded options on the Company's ordinary shares and historical share price volatility of the Company's ordinary shares, which is determined based on a review of the weighted average of historical daily price changes of the Company's ordinary shares. The risk-free interest rate for periods commensurate with the expected term of the share option is based on the U.S. treasury yield curve in effect at the time of 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:

	<u>Year Ended December 31, 2015</u>	<u>Year Ended December 31, 2015</u>
Expected option term . . . . .	5 - 7 years	5 - 7 years
Expected stock volatility . . . . .	39% - 53%	38% - 46%
Risk-free interest rate . . . . .	0.95% - 2.14%	1.29% - 2.02%
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 ordinary shares 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

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

**2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES AND STATEMENT OF COMPLIANCE (Continued)**

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***

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

***Loss Per Share***

Basic loss per share is calculated based upon net loss available to holders of ordinary shares divided by the weighted average number of ordinary shares outstanding. For the calculation of diluted loss 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



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

**2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES AND STATEMENT OF COMPLIANCE (Continued)**

matches 100% of employee contributions up to the first 5% of employee pay, up to IRS limits. Employee and Company contributions are fully vested when made. During the years ended December 31, 2016 and 2015, the Company contributed \$8.1 million and \$6.6 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, 2016 and 2015, the Company contributed \$3.2 million and \$3.0 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 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. Numerous updates have been issued subsequent to the initial guidance that provide clarification on a number of specific issues as well as requiring additional disclosures. Entities have the option of using either a full retrospective or a modified retrospective approach for the adoption of the new standard, and this guidance becomes effective for the Company in its year ending December 31, 2018. The Company is still assessing the impact of the new guidance on its consolidated financial statements, as well as evaluating the disclosure requirements under the new standard. The Company expects to adopt the new standard using the modified retrospective method.

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

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

**2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES AND STATEMENT OF COMPLIANCE (Continued)**

outstanding as of the beginning of the earliest annual period presented in the financial statements. The Company adopted this guidance on January 1, 2016, and this guidance does not have an impact on its consolidated financial statements.

In August 2014, the FASB issued guidance related to an entity's ability to continue as a going concern. This standard requires management to evaluate, for each annual and interim reporting period, whether there are conditions and events, considered in the aggregate, that raise substantial doubt about an entity's ability to continue as a going concern within one year after the date the financial statements are issued or are available to be issued. If substantial doubt is raised, additional disclosures around management's plan to alleviate these doubts are required. This update became effective for all annual periods and interim reporting periods ending after December 15, 2016. The adoption of this standard did not have any impact on the Company's current disclosures in the financial statements.

In January 2015, the FASB issued guidance that simplifies income statement presentation by eliminating the concept of extraordinary items. The Company adopted this guidance on January 1, 2016, and this guidance does not have an impact on its consolidated financial statements.

In January 2016, the FASB issued guidance that enhances the reporting model for financial instruments through addressing certain aspects of recognition, measurement, presentation and disclosure of financial instruments. The amendments in this update include: requiring equity securities to be measured at fair value with changes in fair value recognized through the income statement; simplifying the impairment assessment of equity instruments without readily determinable fair values by requiring a qualitative assessment to identify impairment; eliminating the requirement to disclose the fair value of financial instruments measured at amortized cost for entities that are not public business entities; eliminating the requirement for public business entities to disclose the method(s) and significant assumptions used to estimate the fair value that is required to be disclosed for financial instruments measured at amortized cost on the balance sheet; requiring public business entities to use the exit price notion when measuring the fair value of financial instruments for disclosure purposes; requiring an entity to present separately in other comprehensive income the portion of the total change in the fair value of a liability resulting from a change in the instrument-specific credit risk when the entity has elected to measure the liability at fair value in accordance with the fair value option for financial instruments; requiring separate presentation of financial assets and financial liabilities by measurement category and form of financial asset; and clarifying that an entity should evaluate the need for a valuation allowance on a deferred tax asset related to available-for-sale securities in combination with the entity's other deferred tax assets. This guidance becomes effective for the Company in its year ending December 31, 2018, and the Company is currently assessing the impact that this standard will have on its consolidated financial statements.

In February 2016, the FASB issued guidance to increase transparency and comparability among organizations by recognizing lease assets and lease liabilities on the balance sheet and disclosing key information about leasing arrangements. The main difference between previous GAAP and this guidance is the recognition of lease assets and lease liabilities by lessees for those leases classified as operating leases under previous GAAP. This guidance becomes effective for the Company in its year ending December 31, 2019, and the Company is currently assessing the impact that this standard will have on its consolidated financial statements.

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

**2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES AND STATEMENT OF COMPLIANCE (Continued)**

In March 2016, the FASB issued guidance as part of its simplification initiative to eliminate the requirement to retroactively adopt the equity method of accounting when an investment qualifies for the use of the equity method as a result of an increase in the level of ownership interest or degree of influence. This guidance becomes effective for the Company in its year ending December 31, 2017, and the Company does not currently expect this guidance to have an impact on its consolidated financial statements.

In March 2016, the FASB issued guidance as part of its simplification initiative that involves several aspects of the accounting for share-based payment transactions. The amendments in this update established that: all excess tax benefits and tax deficiencies be recognized as income tax expense or benefit in the income statement; excess tax benefits be classified as an operating activity in the statement of cash flows; the entity make an entity-wide accounting policy election to either estimate the number of awards that are expected to vest, which is current GAAP, or account for forfeitures as they occur; the threshold to qualify for equity classification permits withholding up to the maximum statutory tax rates in the applicable jurisdictions; and cash paid by an employer when directly withholding shares for tax withholding purposes be classified as a financing activity in the statement of cash flows. This guidance becomes effective for the Company in the first quarter of 2017. The Company has assessed the impact this standard will have on its consolidated financial statements and has determined that upon adoption of the new standard, a cumulative-effect adjustment of approximately \$61.5 million will be recorded within retained earnings, related to the recognition of net deferred tax assets on certain U.S. tax credit and net operating loss (“NOL”) carryforwards.

In August 2016, the FASB issued guidance to address diversity in practice in how certain cash receipts and cash payments are presented and classified in the statement of cash flows. This guidance becomes effective for the Company in its year ending December 31, 2018, and the Company is currently assessing the impact that this standard will have on its consolidated financial statements.

In October 2016, the FASB issued guidance to simplify and improve accounting on transfers of assets between affiliated entities. The updated guidance eliminates the prohibition for all intra-entity asset transfers, except for inventory. This guidance becomes effective for the Company in the first quarter of 2018, and the Company is currently assessing the impact that this standard will have on its consolidated financial statements.

In November 2016, the FASB issued guidance to clarify the definition of a business with the objective of adding guidance to assist entities with evaluating whether transactions should be accounted for as acquisitions (or disposals) of assets or businesses. This guidance becomes effective for the Company in its year ending December 31, 2018, and the Company is currently assessing the impact that this standard will have on its consolidated financial statements.

**3. DIVESTITURE**

On April 10, 2015, the Company completed the sale of its 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, a Pennsylvania corporation listed on the NASDAQ 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 the Company and the Purchasers.

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

**3. DIVESTITURE (Continued)**

In accordance with the terms of the Purchase Agreement, at the closing of the Disposition, the Purchasers made an initial cash payment to the Company of \$50.0 million, a \$4.0 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. The Company is also eligible to receive low double-digit royalties on net sales of IV/IM and parenteral forms of Meloxicam and any other product with the same active ingredient as Meloxicam IV/IM that is discovered or identified using certain of the Company's intellectual property to which Recro was provided a right of use, through license or transfer, pursuant to the Gainesville Transaction (together, the "Meloxicam Products") and up to \$125.0 million in milestone payments upon the achievement of certain regulatory and sales milestones related to the Meloxicam Products, including, pursuant to the First Amendment to the Purchase Agreement, at Recro's election, either scenario (i) \$10.0 million upon the submission of an NDA filing for the first Meloxicam Product and \$30.0 million upon regulatory approval of an NDA for the first Meloxicam Product or scenario (ii) an aggregate of \$45.0 million upon regulatory approval of an NDA for the first Meloxicam Product.

The gain on the Gainesville Transaction was determined as follows:

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

The Company recorded the gain on the Gainesville Transaction within the accompanying consolidated statement of operations and comprehensive loss. 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 would not have a major effect on its operations and financial results. Accordingly, the operations from the Gainesville Transaction were 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.

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

**3. DIVESTITURE (Continued)**

At December 31, 2016, the Company determined the value of the Gainesville Transaction's contingent consideration using the following valuation approaches:

- The fair value of the 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 year and two years, respectively, and used a discount rate of 2.8% and 3.6%, respectively, for each of these events. The Company then assessed the likelihood of Recro opting to pay us under scenario (i) or scenario (ii) to arrive at a probability weighted present value for these regulatory milestones;
- 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 16.0%, 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 10.6% to 12.3%.

At December 31, 2016, the Company determined that the value of the Gainesville Transaction's contingent consideration was \$63.2 million. The Company recorded the increase of \$7.9 million and decrease of \$2.3 million in the value of the contingent consideration during the years ended December 31, 2016 and 2015, respectively, within "Change in the fair value of contingent consideration" in the accompanying consolidated statements of operations and comprehensive loss.

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, 2016, the Company determined that the value of these warrants had decreased to \$1.4 million and were 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, 2016:

	<b>Year Ended December 31, 2016</b>
Closing stock price at December 31, 2016 . . . . .	\$ 8.06
Warrant strike price . . . . .	\$19.46
Expected term (years) . . . . .	5.27
Risk-free interest rate . . . . .	1.93%
Volatility . . . . .	80.0%

The decrease in the fair value of the warrants of \$0.4 million and \$0.3 million during the year ended December 31, 2016 and 2015, respectively, was recorded within "Other (expense) income, net" in the accompanying consolidated profit and loss account.

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

**4. INVESTMENTS**

Investments consist of the following:

	<u>Amortized Cost</u>	<u>Gross Unrealized</u>		<u>Estimated Fair Value</u>
		<u>Gains</u>	<u>Losses</u>	
		(In thousands)		
<b>December 31, 2016</b>				
Short-term investments:				
Available-for-sale securities:				
U.S. government and agency debt securities . . . . .	\$177,203	\$ 96	\$ (51)	\$177,248
Corporate debt securities . . . . .	128,119	47	(53)	128,113
International government agency debt securities . . . . .	5,511	—	(16)	5,495
Total short-term investments . . . . .	<u>310,833</u>	<u>143</u>	<u>(120)</u>	<u>310,856</u>
Long-term investments:				
Available-for-sale securities:				
U.S. government and agency debt securities . . . . .	81,839	—	(391)	81,448
Corporate debt securities . . . . .	31,223	—	(89)	31,134
International government agency debt securities . . . . .	5,992	—	(18)	5,974
	<u>119,054</u>	<u>—</u>	<u>(498)</u>	<u>118,556</u>
Held-to-maturity securities:				
Fixed term deposit account . . . . .	1,667	—	(7)	1,660
Certificates of deposit . . . . .	1,715	—	—	1,715
	<u>3,382</u>	<u>—</u>	<u>(7)</u>	<u>3,375</u>
Total long-term investments . . . . .	<u>122,436</u>	<u>—</u>	<u>(505)</u>	<u>121,931</u>
Total investments . . . . .	<u>\$433,269</u>	<u>\$143</u>	<u>\$ (625)</u>	<u>\$432,787</u>
<b>December 31, 2015</b>				
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 . . . . .	<u>353,957</u>	<u>71</u>	<u>(359)</u>	<u>353,669</u>
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
	<u>261,636</u>	<u>—</u>	<u>(946)</u>	<u>260,690</u>
Held-to-maturity securities:				
Fixed term deposit account . . . . .	1,666	—	—	1,666
Certificates of deposit . . . . .	1,715	—	—	1,715
	<u>3,381</u>	<u>—</u>	<u>—</u>	<u>3,381</u>
Total long-term investments . . . . .	<u>265,017</u>	<u>—</u>	<u>(946)</u>	<u>264,071</u>
Total investments . . . . .	<u>\$618,974</u>	<u>\$ 71</u>	<u>\$(1,305)</u>	<u>\$617,740</u>



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

**4. INVESTMENTS (Continued)**

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

(In thousands)	Year Ended December 31,	
	2016	2015
Proceeds from the sales and maturities of marketable securities . . . . .	\$560,805	\$467,573
Realized gains . . . . .	\$ 206	\$ 111
Realized losses . . . . .	\$ 28	\$ 3

The Company's available-for-sale and held-to-maturity securities at December 31, 2016 had contractual maturities in the following periods:

(In thousands)	Available-for-sale		Held-to-maturity	
	Amortized Cost	Estimated Fair Value	Amortized Cost	Estimated Fair Value
Within 1 year . . . . .	\$282,361	\$282,344	\$1,715	\$1,715
After 1 year through 5 years . . . . .	147,526	147,068	1,667	1,660
Total . . . . .	\$429,887	\$429,412	\$3,382	\$3,375

At December 31, 2016, the Company believed that the unrealized losses on its available-for-sale investments were temporary. The investments with unrealized losses consisted primarily of corporate debt securities. In making the determination that the decline in fair value of these securities was temporary, the Company considered various factors, including, but not limited to: the length of time each security was in an unrealized loss position; the extent to which fair value was less than cost; financial condition and near-term prospects of the issuers; and the Company's intent not to sell these securities and the assessment that it is more likely than not that the Company would not be required to sell these securities before the recovery of their amortized cost basis.

The Company's investment in Civitas Therapeutics, Inc. ("Civitas") was zero at December 31, 2016 and 2015. In October 2014, Civitas was acquired by Acorda for \$525.0 million. As a result of this transaction, the Company received \$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.

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

**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, 2016	Level 1	Level 2	Level 3
<b>Assets:</b>				
Cash equivalents . . . . .	\$ 1,660	\$ 1,660	\$ —	\$ —
U.S. government and agency debt securities . . . . .	258,696	156,370	102,326	—
Corporate debt securities . . . . .	159,247	—	159,247	—
International government agency debt securities . . . . .	11,469	—	11,469	—
Contingent consideration . . . . .	63,200	—	—	63,200
Common stock warrants . . . . .	1,392	—	—	1,392
Total . . . . .	<u>\$495,664</u>	<u>\$158,030</u>	<u>\$273,042</u>	<u>\$64,592</u>

(In thousands)	December 31, 2015	Level 1	Level 2	Level 3
<b>Assets:</b>				
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 . . . . .	<u>\$673,146</u>	<u>\$216,122</u>	<u>\$399,903</u>	<u>\$57,121</u>

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

There were no transfers of any securities from Level 1 to Level 2 or from Level 2 to Level 1 during the year ended December 31, 2016. 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, 2016:

(In thousands)	Fair Value
Balance, January 1, 2016 . . . . .	\$57,121
Change in the fair value of contingent consideration . . . . .	7,900
Decrease in the fair value of warrants . . . . .	(429)
Balance, December 31, 2016 . . . . .	<u>\$64,592</u>

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

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

**5. FAIR VALUE (Continued)**

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 at December 31, 2016 consisted of a \$300.0 million term loan, bearing interest at LIBOR plus 2.75% with a LIBOR floor of 0.75% and matures on September 25, 2021 ("Term Loan B-1"). The estimated fair value of Term Loan B-1, which was based on quoted market price indications (Level 2 in the fair value hierarchy) and which may not be representative of actual values that could have been or will be realized in the future, was as follows at December 31, 2016:

(In thousands)	<u>Carrying Value</u>	<u>Estimated Fair Value</u>
Term Loan B-1 . . . . .	\$283,666	\$289,045

**6. STOCK**

Stock consists of the following:

(In thousands)	<u>December 31, 2016</u>	<u>December 31, 2015</u>
Raw materials . . . . .	\$19,413	\$16,445
Work in process . . . . .	21,811	12,423
Finished goods(1) . . . . .	<u>21,774</u>	<u>9,543</u>
Total stock . . . . .	<u>\$62,998</u>	<u>\$38,411</u>

(1) At December 31, 2016 and 2015, the Company had \$7.1 million and \$3.0 million, respectively, of finished goods stock located at its third-party warehouse and shipping service provider.

The estimated replacement cost of stocks did not differ significantly from the amounts shown above. The Company performs periodic assessments to determine the existence of obsolete, slow-moving and non-saleable stock and records provisions to reduce such stock to net-realizable value. At December 31, 2016 and 2015, the Company had a provision for stock obsolescence of \$2.6 million and \$3.7 million, respectively.

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

**7. TANGIBLE FIXED ASSETS**

Tangible fixed assets consists of the following:

	<u>Land and Buildings</u>	<u>Furniture, Fixtures and Equipment</u>	<u>Leasehold Improvements</u>	<u>Construction in Progress</u>	<u>Total</u>
	(In thousands)				
<b>Cost:</b>					
At January 1, 2015 . . . . .	\$157,321	\$ 225,834	\$12,971	\$ 39,774	\$ 435,900
Additions at cost . . . . .	4,078	31,900	3,626	15,846	55,450
Transfers . . . . .	243	2,879	—	(3,122)	—
Disposals . . . . .	(18,932)	(41,895)	—	(956)	(61,783)
At December 31, 2015 . . . . .	<u>\$142,710</u>	<u>\$ 218,718</u>	<u>\$16,597</u>	<u>\$ 51,542</u>	<u>\$ 429,567</u>
Additions at cost . . . . .	7,173	32,150	2,644	1,402	43,369
Transfers . . . . .	8,901	2,789	—	(11,690)	—
Disposals . . . . .	—	(2,220)	—	—	(2,220)
At December 31, 2016 . . . . .	<u>\$158,784</u>	<u>\$ 251,437</u>	<u>\$19,241</u>	<u>\$ 41,254</u>	<u>\$ 470,716</u>
<b>Accumulated Depreciation:</b>					
At January 1, 2015 . . . . .	\$(46,007)	\$(118,446)	\$(5,707)	\$ —	\$(170,160)
Charged during the year . . . . .	(5,130)	(21,294)	(1,487)	—	(27,911)
Disposals . . . . .	2,478	20,845	—	—	23,323
At December 31, 2015 . . . . .	<u>\$(48,659)</u>	<u>\$(118,895)</u>	<u>\$(7,194)</u>	<u>\$ —</u>	<u>\$(174,748)</u>
Charged during the year . . . . .	(5,240)	(25,925)	(2,133)	—	(33,298)
Disposals . . . . .	—	2,115	—	—	2,115
At December 31, 2016 . . . . .	<u>\$(53,899)</u>	<u>\$(142,705)</u>	<u>\$(9,327)</u>	<u>\$ —</u>	<u>\$(205,931)</u>
<b>Net Book Amount:</b>					
At December 31, 2016 . . . . .	<u>\$104,885</u>	<u>\$ 108,732</u>	<u>\$ 9,914</u>	<u>\$ 41,254</u>	<u>\$ 264,785</u>
At December 31, 2015 . . . . .	<u>\$ 94,051</u>	<u>\$ 99,823</u>	<u>\$ 9,403</u>	<u>\$ 51,542</u>	<u>\$ 254,819</u>

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. Refer to Note 3, *Divestiture* for additional details regarding this transaction. 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.

Depreciation expense was \$33.3 million and \$27.9 million for the years ended December 31, 2016 and 2015, respectively. Also, during the years ended December 31, 2016 and 2015, the Company wrote off furniture, fixtures and equipment that had a carrying value of \$0.9 million and \$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

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

**7. TANGIBLE FIXED ASSETS (Continued)**

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, INTANGIBLE ASSETS AND ASSOCIATED UNDERTAKINGS**

Goodwill and intangible assets consist of the following:

(In thousands)	Intangible Assets—Intellectual Property				
	Goodwill	Collaboration Agreements	NanoCrystal Technology	OCR Technology	Total
<b>Cost:</b>					
At January 1, 2015 . . . . .	\$94,212	\$ 499,700	\$ 74,600	\$ 66,300	\$ 640,600
Disposals during the year . . . . .	(1,339)	(34,110)	—	(23,740)	(57,850)
At December 31, 2015 . . . . .	<u>\$92,873</u>	<u>\$ 465,590</u>	<u>\$ 74,600</u>	<u>\$ 42,560</u>	<u>\$ 582,750</u>
At December 31, 2016 . . . . .	<u>\$92,873</u>	<u>\$ 465,590</u>	<u>\$ 74,600</u>	<u>\$ 42,560</u>	<u>\$ 582,750</u>
<b>Accumulated Depreciation:</b>					
At January 1, 2015 . . . . .	\$ —	\$(127,393)	\$(13,243)	\$(20,552)	\$(161,188)
Expensed during the year . . . . .	—	(47,473)	(5,051)	(5,161)	(57,685)
Disposals . . . . .	—	6,648	—	8,661	15,309
At December 31, 2015 . . . . .	<u>—</u>	<u>(168,218)</u>	<u>(18,294)</u>	<u>(17,052)</u>	<u>(203,564)</u>
Expensed during the year . . . . .	—	(50,100)	(6,090)	(4,769)	(60,959)
At December 31, 2016 . . . . .	<u>\$ —</u>	<u>\$(218,318)</u>	<u>\$(24,384)</u>	<u>\$(21,821)</u>	<u>\$(264,523)</u>
<b>Net Book Amount:</b>					
At December 31, 2016 . . . . .	<u>\$92,873</u>	<u>\$ 247,272</u>	<u>\$ 50,216</u>	<u>\$ 20,739</u>	<u>\$ 318,227</u>
At December 31, 2015 . . . . .	<u>\$92,873</u>	<u>\$ 297,372</u>	<u>\$ 56,306</u>	<u>\$ 25,508</u>	<u>\$ 379,186</u>

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. Refer to Note 3, *Divestiture* for additional details regarding this transaction.

The Company recorded \$61.0 million and \$57.7 million of amortization expense related to its finite-lived intangible assets during the years ended December 31, 2016 and 2015, respectively. Based on the Company's most recent analysis, amortization of intangible assets included within its consolidated balance sheets at December 31, 2016 is expected to be approximately \$60.0 million, \$60.0 million, \$55.0 million, \$50.0 million and \$45.0 million in the years ending December 31, 2017 through 2021, 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

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

**8. GOODWILL, INTANGIBLE ASSETS AND ASSOCIATED UNDERTAKINGS (Continued)**

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.

During the three months ended December 31, 2016, the Company performed its annual goodwill impairment test. The Company decided to perform the quantitative two-step goodwill impairment test due to the length of time since it had last performed such a test. The Company worked with a third-party valuation firm and established fair value for the purpose of impairment testing by using an average of the income approach and the market approach. The income approach employs a discounted cash flow model that takes into account (i) assumptions that market participants would use in their estimates of fair value, (ii) current period actual results, and (iii) budgeted results for future periods that have been vetted by senior management. The discounted cash flow model incorporates the same fundamental pricing concepts used to calculate fair value in an acquisition due diligence process and a discount rate that takes into consideration the Company's estimated cost of capital adjusted for the uncertainty inherent in an acquisition. The market approach employs market multiples for comparable publicly traded companies in the pharmaceutical and biotechnology industries obtained from industry sources, taking into consideration the nature, scope and size of the acquired reporting unit. In the market approach, estimates of fair value are established using an average of both revenue and EBITDA multiples, adjusted for the reporting unit's performance relative to peer companies. The Company determined that the fair value of its reporting unit was substantially in excess of its respective carrying value and there was no impairment in the value of this asset as of October 31, 2016.

*Associated Undertakings*

In February 2016, the Company entered into a collaboration and license option agreement with Reset Therapeutics, Inc. ("Reset"), a related party. The Company made an upfront, non-refundable payment of \$10.0 million in partial consideration of the grant to the Company of the rights and licenses included in such agreement, which was included in R&D expense in the three months ended March 31, 2016, and simultaneously made a \$15.0 million investment in exchange for shares of Reset's Series B Preferred Stock. The Company is accounting for its investment in Reset under the equity method based on its percentage of ownership, its seat on the board of directors and its belief that it can exert significant influence over the operating and financial policies of Reset. During the year ended December 31, 2016, the Company recorded a reduction in its investment in Reset of \$1.7 million, which represents the Company's proportional share of Reset's net loss for the period. The Company's \$13.3 million investment at December 31, 2016 is included within "Fixed assets—Associated undertaking" in the accompanying consolidated balance sheet.

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



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

**8. GOODWILL, INTANGIBLE ASSETS AND ASSOCIATED UNDERTAKINGS (Continued)**

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, 2016 and 2015, the Company had made payments of, and its investment is equal to, \$2.5 million (€2.1 million) and \$1.6 million (€1.3 million), respectively, which is included within “Intangible assets—Associated undertaking” in the accompanying consolidated balance sheets. During the years ended December 31, 2016 and 2015, the Company recorded a reduction in its investment in Fountain of \$0.4 million and \$0.2 million respectively, which represented the Company’s proportionate share of Fountain’s net loss for this period.

**9. LONG-TERM DEBT**

Long-term debt consists of the following:

(In thousands)	December 31,	
	2016	2015
Term Loan B-1, due September 25, 2021 . . . . .	\$283,666	\$287,207
Term Loan B-2, due September 25, 2016 . . . . .	—	62,737
Total . . . . .	283,666	349,944
Less: current portion . . . . .	(3,000)	(65,737)
Long-term debt . . . . .	\$280,666	\$284,207

***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. In October 2016, the Company amended Term Loan B-1, which, among other things, extended the due date from September 25, 2019 to September 25, 2021 (the “Refinancing”).

The Refinancing involved multiple lenders who were considered members of a loan syndicate. In determining whether the Refinancing was to be accounted for as a debt extinguishment or a debt modification, the Company considered whether creditors remained the same or changed and whether the changes in debt terms were substantial. A change in the debt terms was considered to be substantial if the present value of the remaining cash flows under the new terms of Term Loan B-1 are at least 10% different from the present value of the remaining cash flows under the original terms of Term Loan B-1 (commonly referred to as the “10% Test”). The Company performed a separate 10% Test for each individual creditor participating in the loan syndication. The loans of any creditors no longer participating in the loan syndication were accounted for as a debt extinguishment.

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 amortized in equal quarterly amounts of 1.25% of the original principal amount of the loan, with the balance payable at maturity. In September 2016, Term Loan B-2 matured and the Company repaid the outstanding principal balance of \$60.9 million in its entirety.

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

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

Term Loan B-1 is guaranteed by certain subsidiaries of the Company (the “Guarantors”) and is secured by a first priority lien on substantially all of the assets and properties of the Company and the Guarantors (subject to certain exceptions and limitations).

Scheduled maturities with respect to Term Loan B-1 are as follows (in thousands):

<u>Year Ended:</u>	
2017 .....	\$ 3,000
2018 .....	3,000
2019 .....	3,000
2020 .....	3,000
2021 .....	<u>275,250</u>
Total .....	<u>\$287,250</u>

Beginning on January 1, 2014, the Company became subject to mandatory prepayments of principal if certain excess cash flow thresholds, as defined in Term Loan B-1, were met.

Term Loan B-1 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. Term Loan B-1 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. Term Loan B-1 also contains customary affirmative covenants and events of default. The Company was in compliance with its debt covenants at December 31, 2016.

The Refinancing resulted in a \$2.1 million charge in the three months ended December 31, 2016, which was included in “Interest expense” in the accompanying consolidated statement of operations and comprehensive loss.

At December 31, 2016, the Company’s balance of unamortized deferred financing costs and unamortized original issue discount costs were \$1.3 million and \$2.3 million, respectively. These costs are being amortized to interest expense over the estimated repayment period of Term Loan B-1 using the effective interest method. During the years ended December 31, 2016 and 2015, the Company had amortization expense of \$0.9 million related to deferred financing costs and original issue discount.

**10. LOSS PER SHARE**

Basic loss per ordinary share is calculated based upon net loss available to holders of ordinary shares divided by the weighted average number of shares outstanding. For the years ended December 31, 2016 and 2015, as the Company was in a net loss position, the diluted loss per share did not assume conversion or exercise of stock options or awards as they would have an anti-dilutive effect on loss per share.

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

**10. LOSS PER SHARE (Continued)**

The following potential ordinary equivalent shares were not included in the net loss per ordinary share calculation because the effect would have been anti-dilutive:

(In thousands)	Year Ended December 31,	
	2016	2015
Stock options . . . . .	10,166	9,179
Restricted stock units . . . . .	1,320	1,351
Total . . . . .	11,486	10,530

**11. SHARE CAPITAL**

*Share Capital*

(In thousands, except per share amounts)	December 31,	
	2016	2015
Authorized:		
40,000 ordinary shares of €1 par value . . . . .	\$ 40,000	\$ 40,000
50,000,000 preferred shares of \$0.01 par value . . . . .	500,000	500,000
450,000,000 ordinary shares of \$0.01 par value . . . . .	4,500,000	4,500,000
Share Capital . . . . .	\$5,040,000	\$5,040,000

Issued Ordinary Shares (par value, \$0.01 per share) (Value in thousands)	Number	Value
Balance at January 1, 2015 . . . . .	148,545,150	\$1,482
Issuance of ordinary shares under employee stock plans . . . . .	3,583,791	36
Balance at December 31, 2015 . . . . .	152,128,941	\$1,518
Issuance of ordinary shares under employee stock plans . . . . .	2,062,340	21
Balance at December 31, 2016 . . . . .	154,191,281	\$1,539

*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, 2016, 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, 2016 and 2015, the Company did not acquire any ordinary shares under the repurchase program.

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

**11. SHARE CAPITAL (Continued)**

*Treasury Shares*

<u>Treasury Shares (par value, \$0.01 per share)</u> <u>(Value in thousands)</u>	<u>Number</u>	<u>Value</u>
Balance at January 1, 2015 . . . . .	1,006,631	\$32,052
Acquired during the year . . . . .	421,321	26,609
Balance at December 31, 2015 . . . . .	<u>1,427,952</u>	<u>\$58,661</u>
Acquired during the year . . . . .	332,815	13,978
Balance at December 31, 2016 . . . . .	<u>1,760,767</u>	<u>\$72,639</u>

The shares acquired during the year were received by the Company for the purchase of employee stock options or to satisfy minimum tax withholding obligations related to employee share based awards.

**12. 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:

<u>(In thousands)</u>	<u>Year Ended</u>	
	<u>December 31,</u> <u>2016</u>	<u>December 31,</u> <u>2015</u>
Cost of goods manufactured and sold . . . . .	\$ 8,633	\$ 8,880
Research and development . . . . .	24,023	24,201
Selling, general and administrative . . . . .	<u>61,740</u>	<u>64,260</u>
Total share-based compensation expense . . . . .	<u>\$94,396</u>	<u>\$97,341</u>

During the years ended December 31, 2016 and 2015, \$1.1 million of share-based compensation expense was capitalized and recorded as "Stock" 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.

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

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

At December 31, 2016, there were 11.3 million 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.

*Stock Options*

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

	<b>Number of Shares</b>	<b>Weighted Average Exercise Price</b>
Outstanding, January 1, 2016 . . . . .	12,978,806	\$31.86
Granted . . . . .	2,750,800	\$36.16
Exercised . . . . .	(1,155,030)	\$18.02
Forfeited . . . . .	(311,788)	\$56.73
Expired . . . . .	(60,621)	\$55.64
Outstanding, December 31, 2016 . . . . .	<u>14,202,167</u>	\$33.17
Exercisable, December 31, 2016 . . . . .	<u>8,878,873</u>	\$24.73

The weighted average grant date fair value of stock options granted during the years ended December 31, 2016 and 2015 was \$17.11 and \$28.88, respectively. The aggregate intrinsic value of stock options exercised during the years ended December 31, 2016 and 2015 was \$35.0 million and \$127.7 million, respectively.

At December 31, 2016, there were 5.2 million stock options expected to vest with a weighted average exercise price of \$47.24 per share, a weighted average contractual remaining life of 8.5 years and an aggregate intrinsic value of \$64.6 million. At December 31, 2016, the aggregate intrinsic value of stock options exercisable was \$281.5 million with a weighted average remaining contractual term of 4.9 years. The number of stock options expected to vest was 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, 2016, there was \$52.0 million of unrecognized compensation cost related to unvested stock options, which is expected to be recognized over a weighted average period of 1.9 years. Cash received from option exercises under the Company's award plans during the years ended December 31, 2016 and 2015 was \$20.3 million and \$45.0 million, respectively, related to these awards.

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

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

*Time-Vested Restricted Stock Units*

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

	<b>Number of Shares</b>	<b>Weighted Average Grant Date Fair Value</b>
Unvested, January 1, 2016 . . . . .	1,545,632	\$50.38
Granted . . . . .	1,264,425	\$32.27
Vested . . . . .	(636,901)	\$40.86
Forfeited . . . . .	(98,740)	\$43.46
Unvested, December 31, 2016 . . . . .	<u>2,074,416</u>	\$42.60

The weighted average grant date fair value of time-vested RSUs granted during the years ended December 31, 2016 and 2015 were \$32.27 and \$71.16, respectively. The total fair value of time-vested RSUs that vested during the years ended December 31, 2016 and 2015 were \$26.0 million and \$21.3 million, respectively.

At December 31, 2016, there was \$36.3 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 initial portion of these awards vested in October 2015 upon the approval of ARISTADA by the FDA. The remaining fifty percent of the award vested in October, 2016, on the one-year anniversary of the vesting date of the initial portion. In the years ended December 31, 2016 and 2015, the Company recognized cost of goods manufactured and sold of \$1.0 million and \$2.5 million; R&D expense of \$3.1 million and \$3.1 million; and SG&A expense of \$5.6 million and \$8.3 million, respectively, related to these awards.

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

	<b>Number of Shares</b>	<b>Weighted Average Grant Date Fair Value</b>
Unvested, January 1, 2016 . . . . .	280,665	\$47.17
Granted . . . . .	—	—
Vested . . . . .	(270,409)	\$47.17
Forfeited . . . . .	(10,256)	\$47.16
Unvested, December 31, 2016 . . . . .	<u>—</u>	—



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

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

The grant date fair value of the performance-vesting RSUs was equal to the market value of the Company's ordinary shares on the date of grant.

**13. COLLABORATIVE ARRANGEMENTS**

The Company has entered into various agreements related to its activities to research, develop, manufacture and commercialize product candidates and utilize its technology platforms. The collaboration revenue the Company has earned in the years ended December 31, 2016 and 2015 was as follows:

	Year Ended December 31,	
	2016	2015
	(In thousands)	
<b>MANUFACTURING AND ROYALTY TURNOVER:</b>		
Significant collaborative arrangements . . . . .	\$431,302	\$401,236
All other collaborative arrangements . . . . .	55,945	74,052
Total manufacturing and royalty turnover . . . . .	\$487,247	\$475,288
<b>RESEARCH AND DEVELOPMENT TURNOVER:</b>		
Significant collaborative arrangements . . . . .	\$ 403	\$ 582
All other collaborative arrangements . . . . .	1,898	3,437
Total research and development turnover . . . . .	\$ 2,301	\$ 4,019

The Company's significant collaborative arrangements are described below:

***Janssen***

**INVEGA SUSTENNA/XEPLION and INVEGA TRINZA/TREVICTA**

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/TREVICTA 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/TREVICTA net sales in each country where the license is in effect, with the exact royalty percentage determined based on worldwide net sales. The tiered royalty payments consist of a patent royalty and a know-how royalty, both of which are determined on a country-by-country basis. The patent royalty, which equals 1.5% of net sales, is payable until the expiration of the last of the patents claiming the product in such country. The know-how royalty is a tiered royalty of 3.5%, 5.5% and 7.5% on aggregate worldwide net sales of below \$250 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

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

**13. COLLABORATIVE ARRANGEMENTS (Continued)**

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/TREVICTA of \$184.2 million and \$149.7 million during the years ended December 31, 2016 and 2015, 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 two 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.

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%.

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

**13. COLLABORATIVE ARRANGEMENTS (Continued)**

Under its agreements with Janssen, the Company recognized manufacturing revenues related to RISPERDAL CONSTA of \$64.9 million and \$76.5 million during the years ended December 31, 2016 and 2015, respectively. Under its agreements with Janssen, the Company recognized royalty revenues related to RISPERDAL CONSTA of \$22.3 million and \$24.2 million during the years ended December 31, 2016 and 2015, respectively.

*Acorda*

Under an amended and restated license agreement, the Company granted Acorda an exclusive worldwide license to use and sell and, solely in accordance with its supply agreement, to make or have made AMPYRA/FAMPYRA. Under its license agreement with Acorda, the Company receives certain commercial and development milestone payments, license revenues and a royalty of approximately 10% based on net sales of AMPYRA/FAMPYRA by Acorda or its sub-licensee, Biogen. 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 pre-clinical 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.

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

**13. COLLABORATIVE ARRANGEMENTS (Continued)**

Under its commercial manufacturing supply agreement with Acorda, the Company manufactures and supplies AMPYRA/FAMPYRA for Acorda (and its sub-licensee, Biogen). 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 a 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,

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

**13. COLLABORATIVE ARRANGEMENTS (Continued)**

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

During the years ended December 31, 2016 and 2015, the Company recognized \$114.2 million and \$104.7 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 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 net 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, except to the extent manufacturing rights have been transferred to Amylin; 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 a \$7.0 million milestone payment related to the first commercial sale of BYDUREON in the EU and a \$7.0 million milestone payment related to the first commercial sale of BYDUREON in the U.S.

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 licensed under this agreement. Upon

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

**13. COLLABORATIVE ARRANGEMENTS (Continued)**

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, 2016 and 2015, the Company recognized \$45.6 million and \$46.1 million, respectively, of revenues from its arrangements with respect to BYDUREON.

**14. INCOME TAXES**

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

(In thousands)	Year Ended	
	December 31, 2016	December 31, 2015
Current income tax provision:		
U.S. federal . . . . .	\$ 3,163	\$ 29,959
U.S. state . . . . .	480	1,615
Ireland . . . . .	—	77
Rest of world . . . . .	103	94
Deferred income tax (benefit):		
U.S. federal . . . . .	(9,278)	(18,336)
Ireland . . . . .	(269)	(9,647)
U.S. state . . . . .	(142)	(604)
Total tax (benefit) provision . . . . .	\$(5,943)	\$ 3,158

The current income tax provision for the years ended December 31, 2016 and 2015 was primarily due to U.S. federal and state taxes on income earned by the Company in the U.S. The favorable change in the current income taxes in the year ended December 31, 2016, as compared to 2015, was due to a reduction in income earned in the U.S. A \$4.2 million and \$28.6 million benefit was recorded to additional paid-in capital in the years ended December 31, 2016 and 2015, respectively, with a corresponding reduction to current taxes payable. This was 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, 2016 was primarily due to current year temporary differences in the U.S. the deferred income tax benefit for the year ended December 31, 2015 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.

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 \$133.7 million at December 31, 2016.



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

**14. INCOME TAXES (Continued)**

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

(In thousands)	Year Ended	
	December 31, 2016	December 31, 2015
Ireland . . . . .	\$(212,198)	\$(289,105)
U.S. . . . .	(18,935)	38,398
Rest of world . . . . .	16,746	26,702
Loss before provision for income taxes . . . . .	\$(214,387)	\$(224,005)

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

(In thousands)	December 31, 2016	December 31, 2015
Deferred tax assets:		
Irish NOL carryforwards . . . . .	\$ 156,147	\$ 128,635
Share-based compensation . . . . .	52,479	42,519
Other . . . . .	19,841	19,891
Less: valuation allowance . . . . .	(141,859)	(106,746)
Total deferred tax assets . . . . .	86,608	84,299
Deferred tax liabilities:		
Intangible assets . . . . .	(20,805)	(26,935)
Property, plant and equipment . . . . .	(17,541)	(15,217)
Other . . . . .	(826)	(1,761)
Total deferred tax liabilities . . . . .	(39,172)	(43,913)
Net deferred tax assets . . . . .	\$ 47,436	\$ 40,386

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

(In thousands)	Balance at Beginning of Period	Additions <sup>(1)</sup>	Deductions	Balance at End of Period
Deferred tax asset valuation for the year ended December 31, 2015 . . . . .	\$ (71,796)	\$(34,950)	\$—	\$(106,746)
Deferred tax asset valuation for the year ended December 31, 2016 . . . . .	\$(106,746)	\$(35,113)	\$—	\$(141,859)

(1) The additions in each of the periods presented relate primarily to Irish NOL's.

At December 31, 2016 and 2015, the Company maintained a valuation allowance of \$4.8 million and \$2.6 million, respectively, against certain U.S. state deferred tax assets and \$137.1 million and \$104.2 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.

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

**14. INCOME TAXES (Continued)**

Subsequent to the adoption of Accounting Standards Codification (“ASC”) 718 on April 1, 2006, an additional \$64.0 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. As a result of the expected adoption of ASU 2016-9 in the first quarter of 2017, the Company anticipates that it will record a cumulative-effect adjustment to retained earnings of \$61.5 million to record a net deferred tax asset relative to these tax attribute carryforwards.

As of December 31, 2016, the Company had \$1.1 billion of Irish NOL carryforwards, \$8.0 million of U.S. federal NOL carryforwards, \$7.4 million of state NOL carryforwards, \$53.1 million of federal R&D credits, \$9.0 million of alternative minimum tax (“AMT”) credits and \$9.4 million of state tax credits which will either expire on various dates through 2036 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.

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:

<b>(In thousands)</b>	<b>December 31, 2016</b>	<b>December 31, 2015</b>
Prepaid expenses and other current assets . . . . .	\$ 188	\$ 188
Other assets—long-term . . . . .	862	1,050
Total deferred charges . . . . .	<u>\$1,050</u>	<u>\$1,238</u>

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

**14. INCOME TAXES (Continued)**

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

<b>(in thousands, except percentage amounts)</b>	<b>Year Ended December 31, 2016</b>	<b>Year Ended December 31, 2015</b>
Statutory tax rate . . . . .	12.5%	12.5%
Income tax provision, at statutory rate . . . . .	\$(26,798)	\$(28,001)
Change in valuation allowance . . . . .	35,290	37,312
Foreign rate differential <sup>(1)</sup> . . . . .	2,723	13,951
Share-based compensation . . . . .	2,072	738
Uncertain tax positions . . . . .	910	1,213
U.S. state income taxes, net of U.S. federal benefit . . . . .	(2)	557
Intercompany amounts <sup>(2)</sup> . . . . .	(5,209)	(3,649)
Irish rate differential <sup>(3)</sup> . . . . .	(5,231)	(7,318)
R&D tax credit . . . . .	(10,572)	(12,193)
Other permanent items <sup>(4)</sup> . . . . .	874	548
Income tax provision . . . . .	<u>\$ (5,943)</u>	<u>\$ 3,158</u>
Effective tax rate . . . . .	2.8%	(1.4)%

- (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) Intercompany amounts include cross-territory eliminations, the pre-tax effect of which has been eliminated in arriving at the Company's consolidated loss before taxes.
- (3) Represents income or losses of Irish companies subject to tax at a rate other than the Irish statutory rate.
- (4) 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:

<b>(In thousands)</b>	<b>Unrecognized Tax Benefits</b>
Balance, January 1, 2015 . . . . .	\$2,565
Additions based on tax positions related to the current period . . . . .	1,213
Balance, December 31, 2015 . . . . .	\$3,778
Reductions based on tax positions related to prior periods . . . . .	(7)
Additions based on tax positions related to the current period . . . . .	917
Balance, December 31, 2016 . . . . .	<u>\$4,688</u>

The unrecognized tax benefits at December 31, 2016, if recognized, would affect the Company's effective tax rate. The Company does not anticipate that the amount of existing unrecognized tax

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

**14. INCOME TAXES (Continued)**

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, 2016 and 2015, 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 2016 fiscal years remain subject to examination by the respective tax authorities. In Ireland, the years 2012 to 2016 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.

The year ended December 31, 2014 for Alkermes U.S. Holdings, Inc. is currently under examination by the Internal Revenue Service. The years ended December 31, 2015 and 2014 and the nine months ended December 31, 2013 for Alkermes U.S. Holdings, Inc. are currently under examination by the State of New York.

**15. 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, 2016, the total future annual minimum lease payments under the Company's non-cancelable operating leases are as follows:

<b>(In thousands)</b>	<b>Payment Amount</b>
Year Ended:	
2017 .....	\$ 6,055
2018 .....	6,157
2019 .....	6,210
2020 .....	4,010
2021 .....	1,719
Thereafter .....	<u>666</u>
Total future minimum lease payments .....	<u>\$24,817</u>

Rent expense related to operating leases charged to operations was \$8.1 million and \$7.2 million for the years ended December 31, 2016 and 2015, respectively. The amounts in 2015 were net of sublease income of \$0.7 million. In addition to its lease commitments, the Company had open purchase orders totaling \$432.0 million at December 31, 2016.

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.

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

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

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 in the accompanying consolidated statements of operations and comprehensive loss.

**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 assesses 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, 2016, 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 U.S. District Court for the District of Columbia (the "DC 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 the DC Court (a) expedite the legal proceedings; (b) 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) vacate FDA's approval of the ARISTADA NDA and vacate any FDA decisions or actions underlying or supporting or predicated upon that approval; (d) 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) 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 successfully intervened in, and received the DC Court's approval to become a party to, this action.

On July 28, 2016, the DC Court issued an opinion in favor of the Company and the FDA, affirming in all respects FDA's decision to approve ARISTADA for the treatment of schizophrenia, and denying the action filed by Otsuka for declaratory and injunctive relief. Otsuka has filed an appeal of the DC Court's decision with the U.S. Court of Appeals for the District of Columbia Circuit ("DC

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

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

Circuit”) asking the DC Circuit to reverse the DC Court’s decision, vacate FDA’s approval of the ARISTADA NDA and remand the case to the DC Court for consideration of any appropriate equitable remedy for Otsuka’s lost exclusivity. The DC Circuit’s appellate hearing for this matter occurred on December 12, 2016. The Company believes Otsuka’s action is without merit and will continue to vigorously defend ARISTADA against such action. For information about risks relating to this action, see “Principal Risks” of this Directors’ 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 the Company and/or its partner Acorda from Accord Healthcare, Inc. (“Accord”); Actavis Laboratories FL, Inc. (“Actavis”); Alkem Laboratories Ltd. (“Alkem”); Apotex Corporation and Apotex, Inc. (collectively, “Apotex”); 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, 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 held a bench trial that concluded on September 23, 2016. 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.

Mylan challenged the jurisdiction of the Delaware Court with respect to the Delaware action. In January 2015, the Delaware Court denied Mylan’s motion to dismiss. Subsequently, in January 2015, the Delaware Court granted Mylan’s request for an interlocutory appeal of its jurisdictional decision to the U.S. Court of Appeals for the Federal Circuit (the “Federal Circuit”). In March 2016, the Federal Circuit denied Mylan’s appeal, and the case remains in the Delaware Court. Mylan requested the Federal Circuit to reconsider its decision. However, on June 20, 2016, the Federal Circuit denied Mylan’s request. Mylan filed an appeal with the U.S. Supreme Court, which was denied. Due to Mylan’s motion to dismiss, the Company, along 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. In December 2014, the Company, along with Acorda, filed a motion in the Northern District of West Virginia to stay that



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

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

action in deference to the Delaware proceeding. In February 2014, the District Court for the Northern District of West Virginia granted the Company's motion to stay the proceeding. The patent infringement case against Mylan, however, is still proceeding in Delaware along with the cases against the other ANDA filers.

The Company and/or Acorda have entered into a settlement agreement with each of Accord, Actavis, Alkem, Apotex, 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 2025, 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 "Principal Risks" of this Directors' 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 ("IPR") petitions with the U.S. Patent and Trademark Office (the "USPTO"), challenging U.S. Patent Nos. 8,663,685; 8,440,703; 8,354,437 and 8,007,826 (which are owned by Acorda). In March 2016, the USPTO's Patent Trials and Appeal Board instituted the IPR. Oral argument for the IPR was held on January 19, 2017, and a ruling on the IPR petitions is expected in March 2017. 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 the Company and Acorda against ANDA filers is not impacted by these filings, and remains in effect.

**BYDUREON, RISPERDAL CONSTA AND VIVITROL IPR Proceedings**

On June 3, 2016, Luye Pharma Group Ltd., Luye Pharma (USA) Ltd., Shandong Luye Pharmaceutical Co., Ltd., and Nanjing Luye Pharmaceutical Co., Ltd. (collectively, "Luye") filed two separate IPR petitions challenging U.S. Patent Number 6,667,061 (the "061 Patent"), which is an Orange Book-listed patent for each of BYDUREON, RISPERDAL CONSTA and VIVITROL. The Company opposed the institution of these IPR petitions. On November 30, 2016, the USPTO's Patent Trials and Appeal Board instituted one of Luye's IPR petitions and denied instituting Luye's other IPR petition. Oral argument for the instituted IPR is currently scheduled for August 28, 2017. A decision on the instituted IPR would be expected, pursuant to the statutory time frame, by November 30, 2018.

The Company will vigorously defend the 061 Patent in the IPR proceedings. For information about risks relating to the 061 Patent IPR proceedings see "Principal Risks" of this Directors' Report and specifically the sections entitled "Patent protection for our products is important and uncertain" and

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

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

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

**16. DEBTORS**

	<b>December 31, 2016</b>	<b>December 31, 2015</b>
<b>(In thousands)</b>		
<i>Amounts falling due within one year</i>		
Trade receivables . . . . .	\$191,102	\$155,487
Prepaid expenses and other current assets . . . . .	39,345	26,286
	<u>230,447</u>	<u>181,773</u>
<i>Amounts falling due after more than one year</i>		
Contingent consideration . . . . .	63,200	55,300
Deferred income taxes . . . . .	47,768	40,856
Other debtors . . . . .	11,129	12,046
Total . . . . .	<u>\$352,544</u>	<u>\$289,975</u>

Included in accounts receivable at December 31, 2016 and 2015, are unbilled receivables of \$20.0 million and \$19.3 million, respectively. The Company’s allowance for doubtful accounts was \$0.1 million at December 31, 2016 and 2015.

**17. CREDITORS**

	<b>December 31, 2016</b>	<b>December 31, 2015</b>
<b>(In thousands)</b>		
<i>Amounts falling due within one year</i>		
Accrued expenses . . . . .	\$157,105	\$127,610
Trade creditors . . . . .	46,275	37,401
Deferred revenue . . . . .	1,938	1,735
Payroll taxes . . . . .	2,048	1,591
Accrued interest on long-term debt . . . . .	730	938
Value added tax . . . . .	396	599
Corporate tax . . . . .	194	358
Other taxes . . . . .	307	238
	<u>208,993</u>	<u>170,470</u>
<i>Amounts falling due after more than one year</i>		
Deferred income taxes . . . . .	328	470
Deferred revenue . . . . .	7,122	7,975
Other long-term liabilities . . . . .	16,833	12,610
Total . . . . .	<u>\$233,276</u>	<u>\$191,525</u>

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

**17. CREDITORS (Continued)**

Trade and other creditors are payable at various dates in the next three months in accordance with the suppliers' usual and customary credit terms. Tax amounts are repayable at various dates over the coming months in accordance with the applicable statutory provisions.

**18. CAPITAL EXPENDITURE COMMITMENTS**

The directors have authorized the Company to spend \$75.0 million for capital expenditures in the year ended December 31, 2017.

**19. RELATED PARTY DISCLOSURES**

The principal related party relationships requiring disclosure in the consolidated financial statements pertain to the existence of subsidiaries and associates and transactions with these entities entered into by the Group and the identification of key management personnel as addressed in greater detail below.

*Subsidiaries and Associates*

The consolidated financial statements include the results of operations, financial positions and cash flows of the Company and its subsidiaries and associates over which the Company has control. A listing of principal subsidiaries and associates is provided in Note 23, *Subsidiaries*, to the consolidated financial statements.

*Trading Transactions*

There were no transactions requiring disclosure under Section 67(1) of the Companies Act 2014.

*Compensation of Key Management Personnel of the Group*

Key management personnel are the Company's executive and non-executive directors and their compensation is disclosed in Note 21, *Directors' Remuneration*.

**20. EMPLOYEES**

The average number of persons employed by the Company during the years ended December 31, 2016 and 2015, respectively, was as follows:

	December 31, 2016	December 31, 2015
	(In thousands)	
Manufacturing . . . . .	597	608
Research and development . . . . .	383	319
Selling, general and administrative . . . . .	634	461
Total . . . . .	1,614	1,388

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

**20. EMPLOYEES (Continued)**

Employee costs included in profit and loss during the years ended December 31, 2016 and 2015 consisted of the following:

	December 31, 2016	December 31, 2015
	(In thousands)	
Wages and salaries . . . . .	\$237,289	\$199,233
Share-based compensation . . . . .	94,396	97,341
Social insurance costs <sup>(1)</sup> . . . . .	37,320	32,658
Defined contribution plan contributions . . . . .	12,162	10,261
Total . . . . .	\$381,167	\$339,493

(1) Social insurance costs include social security costs, employer paid payroll taxes and other employee benefits paid by the Company.

During the years ended December 31, 2016 and 2015, the Company capitalized \$0.1 million and \$1.5 million, respectively, as part of its tangible fixed assets and \$26.4 million and \$30.5 million, respectively as part of its stock.

**21. DIRECTORS' REMUNERATION**

Directors' remuneration is set forth in the table below. Mr. Pops, the Company's Chairman and Chief Executive Officer ("CEO"), is not compensated for his services as a director. Accordingly, the amounts below include compensation for Mr. Pops' service as Chief Executive Officer (referred to as "Managerial Services") as well as compensation for all non-employee directors in their capacities as such (referred to as "Director Services").

	December 31, 2016	December 31, 2015
	(In thousands)	
Managerial Services:		
Salary . . . . .	\$ 911	\$ 881
Non-equity incentive plan compensation . . . . .	1,644	1,765
Grant date fair value of stock awards . . . . .	2,259	2,849
Grant date fair value of option awards . . . . .	4,820	6,899
Company contribution to 401(k) plan . . . . .	13	13
Total . . . . .	\$9,647	\$12,407
Director Services:		
Fees paid in cash . . . . .	\$ 616	\$ 574
Grant date fair value of option awards . . . . .	3,500	2,223
Total . . . . .	\$4,116	\$ 2,797

The aggregate intrinsic value resulting from the exercise of stock options by the directors, including the Company's Chairman and CEO, during the year ended December 31, 2016 was \$7.2 million. The Company considers its directors to be key management personnel.

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

**22. AUDITORS' REMUNERATION**

Total auditors' remuneration, including expenses, accrued and paid to PwC and its affiliated firms for the years ended December 31, 2016 and 2015, respectively, are as follows:

	<b>December 31, 2016</b>	<b>December 31, 2015</b>
	<b>(In thousands)</b>	
Audit and review of group financial statements <sup>(1)</sup> . . . . .	\$1,659	\$1,696
Audit-related fees <sup>(2)</sup> . . . . .	23	683
Tax fees <sup>(3)</sup> . . . . .	400	573
All other fees <sup>(4)</sup> . . . . .	2	2
<b>Total</b> . . . . .	<b>\$2,084</b>	<b>\$2,954</b>

- (1) In the years ended December 31, 2016 and 2015, consists of fees for services related to the audit of the Company's annual consolidated financial statements, statutory audits and the review of the Company's quarterly consolidated financial statements, including the review of the Company's internal controls over financial reporting, and other engagements related to the fiscal year. Included in the years ended December 31, 2016 and 2015 are expenses of \$49 thousand and \$69 thousand, respectively.
- (2) For 2016, consists of fees for a royalty audit of one of our collaboration agreements. For the year ended December 31, 2015, consists of fees for the stand-alone audit of our manufacturing facility in Gainesville, Georgia, a royalty audit of one of our collaboration agreements and general advisory fees.
- (3) In the years ended December 31, 2016 and 2015, consists of fees for tax advisory services, other than those related to the audit of our annual consolidated financial statements and review of our quarterly consolidated financial statements.
- (4) In the years ended December 31, 2016 and 2015, consists of fees for access to the PwC on-line accounting research database.

Total fees paid to PwC Ireland in respect of the audit of the group accounts were \$0.5 million during the years ended December 31, 2016 and 2015, respectively. In addition, PwC Ireland received \$0.1 million and less than \$0.1 million for tax advisory services during the years ended December 31, 2016 and 2015, respectively.

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

**23. SUBSIDIARIES**

The subsidiaries of Alkermes plc are wholly-owned by Alkermes plc or one of its subsidiaries.

<u>Name</u>	<u>Nature of Business</u>	<u>Registered Office and Country of Incorporation</u>	<u>Percent of Ownership</u>
Alkermes Ireland Holdings Limited . . . . .	Holding Company	Connaught House, 1 Burlington Road Dublin 4, Ireland	100%
Alkermes Pharma Ireland Limited . . . . .	Manufacturing and R&D	Connaught House, 1 Burlington Road Dublin 4, Ireland	100%
Alkermes Finance Ireland Limited . . . . .	Finance Company	Connaught House, 1 Burlington Road Dublin 4, Ireland	100%
Daravita Pharma Ireland Limited . . . . .	Holding Company	Connaught House, 1 Burlington Road Dublin 4, Ireland	100%
Alkermes Finance Ireland (No.2) Limited . . . . .	Finance Company	Connaught House, 1 Burlington Road Dublin 4, Ireland	100%
Alkermes Finance Ireland (No.3) Limited . . . . .	Finance Company	Connaught House, 1 Burlington Road Dublin 4, Ireland	100%
Daravita Limited . . . . .	Non-Operating	Connaught House, 1 Burlington Road Dublin 4, Ireland	100%
Alkermes Science Four Limited . . . . .	Non-Operating	Connaught House, 1 Burlington Road Dublin 4, Ireland	100%
Alkermes Science Five Limited . . . . .	Non-Operating	Connaught House, 1 Burlington Road Dublin 4, Ireland	100%
Alkermes Science Six Limited . . . . .	Non-Operating	c/o H.P. House, 21 Laffan Street, Hamilton HM 09, Bermuda	100%
Alkermes Finance S.à r.l. . . . .	Finance Company	5, rue Guillaume Kroll L-1882 Luxembourg, R.C.S. Luxembourg	100%
Alkermes U.S. Holdings, Inc. . . . .	Holding Company	852 Winter Street, Waltham, MA 02451 United States	100%
Alkermes, Inc. . . . .	Manufacturing and R&D	852 Winter Street, Waltham, MA 02451 United States	100%
Alkermes Controlled Therapeutics, Inc. . . . .	Non-Operating	852 Winter Street, Waltham, MA 02451 United States	100%
Alkermes Europe, Ltd. . . . .	Non-Operating	c/o Mitre house, 160 Aldersgate Street London EC1A 4DD, United Kingdom	100%



**ALKERMES PLC**  
**COMPANY BALANCE SHEET**

	<u>Note</u>	<u>December 31, 2016</u>	<u>December 31, 2015</u>
		(In thousands)	
<b>ASSETS</b>			
<i>Fixed Assets</i>			
Financial assets . . . . .	7	\$1,986,070	\$1,963,747
<i>Current Assets</i>			
Debtors . . . . .	8	639,330	645,740
Cash at bank and in-hand . . . . .		<u>52,958</u>	<u>40,816</u>
TOTAL ASSETS . . . . .		<u>\$2,678,358</u>	<u>\$2,650,303</u>
<b>LIABILITIES</b>			
<i>Equity Shareholders' Funds</i>			
Share capital, \$0.01 par value . . . . .	10	\$ 1,539	\$ 1,518
Share premium . . . . .	11	522,024	501,218
Profit and loss account . . . . .	11	1,877,075	1,925,650
Treasury shares . . . . .	11	(72,639)	(58,661)
Other reserves . . . . .	11	<u>333,219</u>	<u>238,761</u>
Total equity shareholders' funds . . . . .		<u>2,661,218</u>	<u>2,608,486</u>
<i>Creditors</i>			
Creditors . . . . .	9	<u>17,140</u>	<u>41,817</u>
Total for creditors . . . . .		<u>17,140</u>	<u>41,817</u>
TOTAL LIABILITIES . . . . .		<u>\$2,678,358</u>	<u>\$2,650,303</u>

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

The Consolidated Financial Statements were approved by the Board of Directors on April 7, 2017 and signed on its behalf by:

/s/ RICHARD F. POPS  
Richard F. Pops  
*Chairman*

/s/ PAUL J. MITCHELL  
Paul J. Mitchell  
*Director*

**ALKERMES PLC**  
**RECONCILIATION OF MOVEMENT IN SHAREHOLDERS' FUNDS**

	Share Capital	Share Premium	Profit and Loss Account	Treasury Shares	Other Reserves	Total
	(In thousands)					
BALANCE—January 1, 2015	\$1,482	\$455,571	\$1,921,696	\$(32,052)	\$141,172	\$2,487,869
Net income	—	—	5,620	—	—	5,620
Share-based payment reserve	—	—	—	—	97,589	97,589
Shares issued under employee stock plans	35	44,943	—	—	—	44,978
Receipt of Alkermes' shares for the purchase of share options or to satisfy minimum tax withholding obligations related to share based awards	1	704	—	(26,609)	—	(25,904)
Transfer of share premium to Alkermes Pharma Ireland Limited	—	—	(1,666)	—	—	(1,666)
BALANCE—December 31, 2015	\$1,518	\$501,218	\$1,925,650	\$(58,661)	\$238,761	\$2,608,486
Net loss	—	—	(48,575)	—	—	(48,575)
Share-based payment reserve	—	—	—	—	94,458	94,458
Shares issued under employee stock plans	20	20,296	—	—	—	20,316
Receipt of Alkermes' shares for the purchase of share options or to satisfy minimum tax withholding obligations related to share based awards	1	510	—	(13,978)	—	(13,467)
BALANCE—December 31, 2016	\$1,539	\$522,024	\$1,877,075	\$(72,639)	\$333,219	\$2,661,218

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

**ALKERMES PLC**  
**NOTES TO THE PARENT COMPANY FINANCIAL STATEMENTS**

**1. General Information**

Alkermes plc (the “Company”) is a public limited company incorporated in Ireland. The address of its registered office is Connaught House, 1 Burlington Road, Dublin 4, Republic of Ireland.

On May 9, 2011, Alkermes plc, Alkermes, Inc., Elan and certain of their respective subsidiaries entered into the Business Combination Agreement and Plan of Merger (the “Business Combination Agreement”) pursuant to which Alkermes, Inc., and EDT agreed to combine their businesses under the Company in a cash and share transaction (the “Business Combination”). EDT, which operated as a business unit of Elan with its principal assets predominantly located in Ireland, developed and manufactured pharmaceutical products using its proprietary drug technologies in collaboration with pharmaceutical companies worldwide. On May 4, 2011, the Company was incorporated by Elan as Antler Science Two plc in connection with the negotiation and execution of the Business Combination Agreement solely to effect the Business Combination. Following the execution of the Business Combination Agreement, Elan contributed the assets and legal entities that comprised the EDT business to the Company through a combination of asset transfers, share transfers and other intercompany transactions, following which the EDT business was contained in several subsidiaries under the Company. On September 14, 2011, the Company changed its name to Alkermes plc.

On September 16, 2011, the business of Alkermes, Inc., and EDT were combined under the Company. As part of the Business Combination, a wholly owned subsidiary of the Company merge with and into Alkermes, Inc., with Alkermes, Inc., surviving as a wholly owned subsidiary of the Company.

**2. Statement of Compliance**

The entity financial statements have been prepared on the going concern basis and in accordance with Irish GAAP (accounting standards issued by the Financial Reporting Council of the UK and promulgated by the Institute of Chartered Accountants in Ireland and the Companies Act 2014). The entity financial statements comply with Financial Reporting Standard 102, ‘The Financial Reporting Standard applicable in the UK and Republic of Ireland 1(“FRS 102”) and the Companies Act 2014.

**3. Summary of Significant Accounting Policies**

*Basis of Preparation*

The financial statements of the Company present the balance sheet and the reconciliation of movement in shareholders’ funds on a stand-alone basis, including related party transactions.

The financial statements have been prepared under the historical cost.

The preparation of financial statements in conformity with FRS 102 requires the use of certain key assumptions concerning the future, and other key sources of estimation uncertainty at the end of the financial year. It also requires the directors to exercise its judgment in the process of applying the Company’s accounting policies. The areas involving a higher degree of judgment or areas where assumptions and estimates have a significant risk of causing a material adjustment to the carrying amounts of assets and liabilities within the next financial year are disclosed in Note 5.

*Going Concern*

The Company meets its day-to-day working capital requirements through its bank facilities. The Company’s forecasts and projections, taking account of reasonably possible changes in trading

## ALKERMES PLC

### NOTES TO THE PARENT COMPANY FINANCIAL STATEMENTS (Continued)

#### 3. Summary of Significant Accounting Policies (Continued)

performance, show that the Company should be able to operate within the level of its current facilities. After making enquiries, the directors have a reasonable expectation that the Company has adequate resources to continue in operational existence for the foreseeable future. Therefore these entity financial statements have been prepared on a going concern basis.

#### *Disclosure Exemptions for Qualifying Entities Under FRS 102*

FRS 102 allows a qualifying entity certain disclosure exemptions. As a qualifying entity the Company has availed of a number of exemptions from the disclosure requirements of FRS 102 in the preparation of the entity financial statements. The Company has notified its shareholders in writing about, and they do not object to, the disclosure exemptions availed of by the Company in the entity financial statements.

In accordance with FRS 102 the Company has availed of an exemption from the following paragraphs of FRS 102:

- Exemption from the requirements of Section 7 of FRS 102 and FRS 102 paragraph 3.17(d) to present a statement of cash flows.
- Exemption from the financial instrument disclosure requirements of Section 11 paragraphs 11.39 to 11.48A and Section 12 paragraphs 12.26 to 12.29A of FRS 102 providing the equivalent disclosures are included in the consolidated financial statements of the group in which the entity is consolidated.
- Exemption from certain disclosure requirements of Section 26 of FRS 102 (paragraphs 26.18(b), 26.19 to 26.21 and 26.23), in respect of share-based payments. and
- Exemption from the requirement of FRS 102 paragraph 33.7 to disclose key management personnel compensation in total.

#### *Foreign Currency*

##### Functional and presentation currency

The Company's functional and presentation currency is the U.S. dollar, denominated by the symbol "\$" and unless otherwise stated, the financial statements have been presented in thousands

##### Transactions and balances

Transactions during the period denominated in foreign currencies have been translated at the rates of exchange ruling at the dates of the transactions. Assets and liabilities denominated in foreign currencies are translated to U.S. dollars at the rates of exchange at the balance sheet date. The resulting profits or losses are dealt with in the profit and loss account.

#### *Financial assets*

Investments in group undertakings in the financial statements of the Company is carried at historical cost less accumulated impairment losses. See Note 7, *Investment in Subsidiaries*, below for further information.

**ALKERMES PLC**  
**NOTES TO THE PARENT COMPANY FINANCIAL STATEMENTS (Continued)**

**3. Summary of Significant Accounting Policies (Continued)**

*Dividend income from shares in group undertakings*

Dividend income from group undertakings are recognized in the period in which they are received.

*Share premium*

The difference between the proceeds received on issue of shares and the nominal value of the shares is credited to the share premium account.

*Taxation*

Corporation tax is provided on taxable profits at current rates. Deferred taxation is accounted for in respect of all timing differences at tax rates enacted or substantially enacted at the balance sheet date. Timing differences arise from the inclusion of items of income and expenditure in tax computation in periods different from those in which they are included in the financial statements. A deferred tax asset is only recognized when it is more likely than not the asset will be recoverable in the foreseeable future out of suitable taxable profits from which the underlying timing differences can be recovered.

*Share capital presented as equity*

Equity shares issued are recognized at the proceeds received. Incremental costs directly attributable to the issue of new equity shares or options are shown in equity as a deduction, net of tax, from the proceeds.

*Treasury Shares*

These represent shares of Alkermes plc acquired from employees for the purchase of employee stock options or to satisfy minimum tax withholding obligations related to employee share based awards. Treasury shares are treated as a deduction from the profit and loss reserves until the shares are cancelled, reissued or disposed of. When such shares are subsequently sold or reissued, any consideration received, increases shareholders' funds.

At December 31, 2016, the Company has approximately \$101.0 million available to repurchase ordinary shares pursuant to a share 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. The Company has not repurchased any ordinary shares under this program since September 16, 2011.

*Share-based payments*

The Company and its subsidiaries operate equity-settled share-based compensation plans. The fair value of the employee services received in exchange for the grant of the options has been valued using the Black-Scholes option pricing model. In accordance with Section 26 of FRS 102 'Share-based Payments', the resulting cost for the Company's employees is charged to the profit and loss account over the vesting period. The value of the charge is adjusted to reflect expected and actual levels of awards vesting. The cost for awards granted to the Company's subsidiaries' employees represents additional capital contributions by the Company to its subsidiaries. An additional investment in subsidiaries has been recorded in respect of those awards granted to the Company's subsidiaries'

## ALKERMES PLC

### NOTES TO THE PARENT COMPANY FINANCIAL STATEMENTS (Continued)

#### 3. Summary of Significant Accounting Policies (Continued)

employees, with a corresponding increase in the Company's shareholder equity. The additional capital contribution is based on the fair value at the grant date of the awards issued, allocated over the life of the underlying grant's vesting period. Proceeds received from employees, if any, for the exercise of share-based instruments increase the share capital and share premium accounts of the Company.

The Company has an arrangement in place with its operating subsidiaries whereby a share-based payment reserve is recorded to "Other Reserves" with a corresponding decrease to the Company's "Investment in Subsidiaries" equal to the fair value of (1) restricted stock units on the date of vest and (2) the fair value of stock options on the date of exercise, less the share price on the date of grant, which is the cost of the stock option to the employee. To the extent cash received from the vesting of restricted stock units and stock option exercises exceeds the fair value of restricted stock units and stock options on the date of grant, this amount is recorded as a reduction of stock compensation expense in the Company's statement of operations.

Note 12, *Share-Based Compensation*, of the 2016 Alkermes PLC Consolidated Financial Statements provides additional details of the Group share-based compensation plans.

#### *Contingencies*

Contingent liabilities, arising as a result of past events, are not recognized as a liability because it is not probable that the Company will be required to transfer economic benefits in settlement of the obligation or the amount cannot be reliably measured at the end of the financial year. Possible but uncertain obligations are not recognized as liabilities but are contingent liabilities. Contingent liabilities are disclosed in the financial statements unless the probability of an outflow of resources is remote.

Contingent assets are not recognized. Contingent assets are disclosed in the financial statements when an inflow of economic benefits is probable.

#### *Financial Instruments*

The Company has chosen to adopt Sections 11 and 12 of FRS 102 in respect of financial instruments.

##### Financial assets

Basic financial assets, including trade and other receivables and cash and bank balances, are initially recognized at transaction price, unless the arrangement constitutes a financing transaction, where the transaction is measured at the present value of the future receipts discounted at a market rate of interest. Such assets are subsequently carried at amortized cost using the effective interest method. At the end of each reporting period financial assets measured at amortized cost are assessed for objective evidence of impairment. If an asset is impaired the impairment loss is the difference between the carrying amount and the present value of the estimated cash flows discounted at the asset's original effective interest rate. The impairment loss is recognized in profit or loss. If there is decrease in the impairment loss arising from an event occurring after the impairment was recognized the impairment is reversed. The reversal is such that the current carrying amount does not exceed what the carrying amount would have been had the impairment not previously been recognized. The impairment reversal is recognized in profit or loss.

## ALKERMES PLC

### NOTES TO THE PARENT COMPANY FINANCIAL STATEMENTS (Continued)

#### 3. Summary of Significant Accounting Policies (Continued)

Financial assets are derecognized when (a) the contractual rights to the cash flows from the asset expire or are settled, (b) substantially all the risks and rewards of the ownership of the asset are transferred to another party or (c) control of the asset has been transferred to another party who has the practical ability to unilaterally sell the asset to an unrelated third party without imposing additional restrictions.

##### Financial liabilities

Basic financial liabilities, including trade and other payables and loans from fellow group companies, are initially recognized at transaction price, unless the arrangement constitutes a financing transaction, where the debt instrument is measured at the present value of the future receipts discounted at a market rate of interest.

Trade creditors are obligations to pay for goods or services that have been acquired in the ordinary course of business from suppliers. Trade creditors are classified as current liabilities if payment is due within one year or less. If not, they are presented within creditors amounts falling due after more than one year.

Financial liabilities are derecognized when the liability is extinguished, that is when the contractual obligation is discharged, cancelled or expires.

##### *Cash and Cash Equivalents*

Cash and cash equivalents includes cash in hand, deposits held at call with banks, other short term highly liquid investments with original maturities of three months or less. Bank overdrafts are shown within borrowings in current liabilities. Cash and cash equivalents are initially measured at transaction price and subsequently measured at amortised cost. Bank deposits which have original maturities of more than three months are not cash and cash equivalents and are presented as current asset investments.

#### 4. Profit for the Financial Year

In accordance with section 304 (2) of the Companies Act 2014 and Section 341 of the Companies Act 2014, the Company is availing of the exemption from presenting its individual profit and loss account to the Annual General Meeting and from filing it with the Registrar of Companies. The Company's net loss for the financial year ended December 31, 2016 and net income for the financial year ended December 31, 2015, determined in accordance with Irish GAAP, was \$48.6 million and \$5.6 million, respectively.

#### 5. Critical Accounting Judgments and Estimation Uncertainty

The preparation of the Company's financial statements 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 its investments in subsidiaries and share-based compensation. The Company bases its estimates on historical experience and on various other assumptions that are believed to be reasonable, the results of which form the basis for making judgments about the carrying values of assets and liabilities. Actual results may differ from these estimates under different assumptions or conditions.



**ALKERMES PLC**

**NOTES TO THE PARENT COMPANY FINANCIAL STATEMENTS (Continued)**

**6. Employees and Directors**

The Company had no employees during the year. The Company's directors are not employees but are remunerated for their service by the parent company. See Note 21, *Directors' Remuneration* of the notes to the consolidated financial statements for a summary of their remuneration.

**7. Investments in Subsidiaries**

	<u>(In thousands)</u>
Balance—January 1, 2015, at cost . . . . .	\$1,959,842
Capital contribution in respect of share-based payment plans . . . . .	95,365
Reduction—equity recharge from subsidiaries . . . . .	<u>(91,460)</u>
Balance—December 31, 2015, at cost . . . . .	\$1,963,747
Capital contribution in respect of share-based payment plans . . . . .	91,580
Reduction—equity recharge from subsidiaries . . . . .	<u>(69,257)</u>
Balance—December 31, 2016, at cost . . . . .	<u><u>\$1,986,070</u></u>

The Company's only direct subsidiary is Alkermes Ireland Holdings Limited ("AIHL") of which it owns 100%. AIHL is a holding company, incorporated in the Republic of Ireland and a registered office located at Connaught House, 1 Burlington Road, Dublin 4, Republic of Ireland.

**8. Debtors**

	<u>December 31,</u> <u>2016</u>	<u>December 31,</u> <u>2015</u>
	<u>(In thousands)</u>	
<i>Amounts falling due within one year</i>		
Trade receivables . . . . .	\$ 11,773	\$ 1,814
Prepaid expenses and other current assets . . . . .	700	703
Intercompany notes and loans receivable . . . . .	494,655	291,778
	<u>507,128</u>	<u>294,295</u>
<i>Amounts falling due after one year</i>		
Intercompany loans receivable . . . . .	130,000	350,000
Other debtors . . . . .	2,202	1,445
	<u>132,202</u>	<u>351,445</u>
Total . . . . .	<u><u>\$639,330</u></u>	<u><u>\$645,740</u></u>

**ALKERMES PLC**

**NOTES TO THE PARENT COMPANY FINANCIAL STATEMENTS (Continued)**

**8. Debtors (Continued)**

The Company's intercompany notes and loans receivable due within one year consists of the following:

<u>Borrower</u>	<u>Maturity</u>	<u>Interest Rate</u>	<u>Balance at December 31,</u>	
			<u>2016</u>	<u>2015</u>
(in thousands)				
Alkermes Pharma Ireland Limited . . . . .	July 8, 2017	3.25%	\$160,000	\$ —
Alkermes Pharma Ireland Limited . . . . .	November 16, 2017	3.50%	132,000	—
Alkermes Finance Ireland No. 3 Limited	Repayable upon demand	None	188,455	288,078
Daravita Pharma Ireland Limited . . . . .	Repayable upon demand	None	3,600	3,600
Alkermes Science Six Limited . . . . .	Repayable upon demand	None	10,500	—
Alkermes Science Six Limited. . . . .	Repayable upon demand	None	100	100
Total . . . . .			<u>\$494,655</u>	<u>\$291,778</u>

The Company's intercompany loans receivable with a maturity greater than one year consists of the following loans:

<u>Borrower</u>	<u>Maturity</u>	<u>Interest Rate</u>	<u>Balance at December 31,</u>	
			<u>2016</u>	<u>2015</u>
(in thousands)				
Alkermes Pharma Ireland Limited . . . . .	July 8, 2017	3.25%	\$ —	\$160,000
Alkermes Pharma Ireland Limited . . . . .	November 16, 2017	3.50%	—	60,000
Alkermes Pharma Ireland Limited . . . . .	January 1, 2018	3.25%	130,000	130,000
Total . . . . .			<u>\$130,000</u>	<u>\$350,000</u>

**9. Creditors**

	<u>December 31,</u> <u>2016</u>	<u>December 31,</u> <u>2015</u>
(In thousands)		
<i>Amounts falling due within one year</i>		
Accrued expenses . . . . .	\$ 745	\$ 752
Trade creditors . . . . .	22	22
Intercompany payables . . . . .	16,373	41,043
Total . . . . .	<u>\$17,140</u>	<u>\$41,817</u>

Trade and other creditors are payable at various dates in the next three months in accordance with the suppliers' usual and customary credit terms. Intercompany payables are amounts due to subsidiaries related to transactions in the normal course of business and are expected to be repaid in the next three months.

**ALKERMES PLC**

**NOTES TO THE PARENT COMPANY FINANCIAL STATEMENTS (Continued)**

**10. Share Capital**

<u>(In thousands, except per share amounts)</u>	<b>December 31,</b>	
	<b>2016</b>	<b>2015</b>
Authorized:		
40,000 ordinary shares of €1 par value . . . . .	\$ 40,000	\$ 40,000
50,000,000 preferred shares of \$0.01 par value . . . . .	500,000	500,000
450,000,000 ordinary shares of \$0.01 par value . . . . .	4,500,000	4,500,000
Share Capital . . . . .	\$5,040,000	\$5,040,000
<b>Issued Ordinary Shares (par value, \$0.01 per share)</b> <b>(Value in thousands)</b>	<b>Number</b>	<b>Value</b>
Balance at January 1, 2015 . . . . .	148,545,150	\$1,482
Issuance of ordinary shares under employee stock plans . . . . .	3,583,791	36
Balance at December 31, 2015 . . . . .	152,128,941	\$1,518
Issuance of ordinary shares under employee stock plans . . . . .	2,062,340	21
Balance at December 31, 2016 . . . . .	154,191,281	\$1,539

See Note 12, *Share-Based Compensation*, to the Consolidated Financial Statements for additional information regarding equity shareholder’s funds.

**11. Reserves**

The Company’s reserves consist of the following:

- Share premium—includes amounts received by the Company for the excess of the fair value over par value for the issuance of its common stock; the excess of the fair value over the cost of employee share options; and the par value of shares received from employees for the purchase of share options.
- Profit and loss account—includes the Company’s accumulated net income or loss;
- Treasury shares—includes shares of Alkermes plc acquired from employees for the purchase of employee stock options or to satisfy minimum tax withholding obligations related to employee share based awards. Treasury shares are treated as a deduction from the profit and loss reserves until the shares are cancelled, reissued or disposed of. When such shares are subsequently sold or reissued, any consideration received, increases shareholders’ funds.
- Other reserves—includes a share-based payment reserve, which represents the share-based compensation expense for the cost of the awards granted to the Company’s subsidiaries’ employees plus an additional capital contribution made by the Company’s subsidiaries to the Company equal to the fair value of the Company’s ordinary shares on the date options are exercised or RSU’s vest, less the proceeds received.

**12. Related Party Transactions**

The Company has not disclosed any other related party transactions as it has availed of the exemption available under the provisions of FRS 102 Section 33.1A “Related Party Disclosures” which

**ALKERMES PLC**

**NOTES TO THE PARENT COMPANY FINANCIAL STATEMENTS (Continued)**

**12. Related Party Transactions (Continued)**

exempts disclosure of transactions entered into between two or more members of a group, provided that any subsidiary which is a party to the transaction is wholly owned by a member of that group.

**13. Contingencies**

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 assesses 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, 2016, there are no potential losses from claims, asserted or unasserted, or legal proceedings the Company feels are probable of occurring.

**14. Auditors' Remuneration**

Remuneration, including expenses, for the statutory audit and other services carried out for the Company by the Company's auditors is as follows:

(In thousands)	Year Ended	
	December 31, 2016	December 31, 2015
Audit of the Company's individual accounts . . . . .	\$10	\$10
Other assurance services . . . . .	—	—
Tax advisory services . . . . .	—	—
Other non-audit services . . . . .	—	—
Total . . . . .	\$10	\$10

See Note 22, *Auditors' Remuneration*, to the Consolidated Financial Statements for additional information regarding fees paid to PwC and its affiliated firms by the Company.

**15. Approval of the Financial Statements**

The financial statements were approved and authorized for issue by the board of directors on April 7, 2017 and were signed on its behalf on that day.

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