

**ALKERMES PUBLIC LIMITED COMPANY**  
**DIRECTORS' REPORT AND CONSOLIDATED FINANCIAL STATEMENTS**  
**For the Financial Year Ended December 31, 2017**  
**Registered Company Number: 498284**

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## DIRECTORS' REPORT

### For the Financial Year Ended December 31, 2017

The directors present their report and the audited consolidated financial statements and related notes of Alkermes Public Limited Company (“Alkermes plc”) for the year ended December 31, 2017. 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 Annual 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 Annual 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” in this Annual Report are intended to include reference to the “biotechnology industry” and/or the “pharmaceutical industry” and (c) references to “licensees” are used interchangeably with references to “partners”.

### NOTE REGARDING TRADEMARKS

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

The following are trademarks of the respective companies listed: ABILIFY® and ABILIFY MAINTENA®—Otsuka Pharmaceutical Co., Ltd. (“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. (together with its affiliates, “Biogen”); BETASERON®—Bayer Pharma AG; BUNAVAIL™—BioDelivery Sciences; BYDUREON® and BYETTA®—Amylin Pharmaceuticals, LLC (“Amylin”); BYDUREON BCise™—AstraZeneca Pharmaceuticals LP;—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.; OCREVUS®—Genentech, Inc. (“Genentech”); SUBOXONE®, SUBUTEX® and SUBLOCADE®—Indivior plc; TRICOR®—Fournier Industrie et Sante Corporation; VICTOZA®—Novo Nordisk A/S LLC; ZOHYDRO™—Zogenix, Inc.; ZUBSOLV®—Orexo US, Inc.; and TRULICITY®, ZYPREXA® and ZYPREXA® RELPREVV®—Eli Lilly and Company. Other trademarks, trade names and service marks appearing in this Annual Report are the property of their respective owners. Solely for convenience, the trademarks and trade names in this Annual Report are referred to without the ® and ™ symbols, but such references should not be

construed as any indicator that their respective owners will not assert, to the fullest extent under applicable law, their rights thereto.

## 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”) center 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. Refer to the “Patents and Proprietary Rights” section of this Annual Report for information with respect to the intellectual property protection for these marketed products.

Summary information regarding our proprietary products:

<u>Product</u>	<u>Indication(s)</u>	<u>Licensee</u>	<u>Territory</u>
<i>ARISTADA</i>	Schizophrenia	None	Commercialized by Alkermes in the U.S.
<i>VIVITROL</i>	Alcohol dependence and Opioid dependence	None	Commercialized by Alkermes in the U.S.
		Cilag GmbH International (“Cilag”)	Russia and Commonwealth of Independent States (“CIS”)
Summary information regarding products that use our proprietary technologies:			
<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	U.S.
<i>FAMPYRA</i>		Biogen, under sublicense from Acorda	ROW
<i>BYDUREON and BYDUREON BCise</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, once-every-six-weeks and once-every-two-months dosing options to deliver and maintain therapeutic levels of medication in the body. ARISTADA has four dosing options (441 mg, 662 mg, 882 mg and 1064 mg) and is packaged in a ready-to-use, pre-filled product format. ARISTADA 1064 mg, our two-month dosing option, was approved by the U.S. Food and Drug Administration (“FDA”) in June 2017. We developed ARISTADA and manufacture and commercialize it 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 a once-monthly, non-narcotic, 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 2016 U.S. National Survey on Drug Use and Health, nearly 2 million people aged 18 or older in the U.S. had an opioid use disorder.

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 2016 U.S. National Survey on Drug Use and Health, an estimated 8 million people aged 12 or older had alcohol dependence. 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 (paliperidone palmitate)/TREVICTA (paliperidone palmitate 3-monthly injection) 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.

In January 2018, Janssen Pharmaceuticals NV and Janssen Pharmaceuticals, Inc. initiated a patent infringement lawsuit in the United States District Court for the District of New Jersey against Teva Pharmaceuticals USA, Inc. (“Teva”), who filed an ANDA seeking approval to market a generic version of INVEGA SUSTENNA before the expiration of United States Patent No. 9,439,906. The Company is not a party to these proceedings. For further discussion of the legal proceedings related to the patents covering INVEGA SUSTENNA, see Note 17, *Commitments and Contingencies* in the “Notes to Condensed Consolidated Statements” and “Item 3—Legal Proceedings” in this Annual Report and for information about risks relating to the INVEGA SUSTENNA Paragraph IV litigation, see “Principal Risks” in this Directors’ Report, and specifically the section entitled “—We or our licensees may face claims against intellectual property rights covering our products and competition from generic drug manufacturers.”

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 is the first schizophrenia treatment to be taken once every three months. TREVICTA is approved in the EU for the maintenance treatment of schizophrenia in adult patients who are clinically stable on XEPLION. INVEGA TRINZA/TREVICTA uses our proprietary technology and is manufactured by Janssen.

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

Revenues from Janssen accounted for approximately 33% and 36% of our consolidated revenues for the years ended December 31, 2017 and 2016, respectively. See “Collaborative Arrangements” in Part I of this Annual Report 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, and in May 2017, the EMA granted FAMPYRA a standard marketing authorization in the EU for the improvement of walking in adults with MS. AMPYRA and FAMPYRA incorporate our oral controlled-release technology. AMPYRA and FAMPYRA are manufactured by us.

We and/or Acorda 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. In response, we and/or Acorda filed lawsuits against certain of the ANDA filers in the U.S. District Court for the District of Delaware (the "Delaware Court") asserting infringement of U.S. Patent No. 5,540,938 (the "'938 Patent") , which we own, and U.S. Patent Nos. 8,007,826; 8,354,437; 8,440,703; and 8,663,685, which are owned by Acorda. On March 31, 2017, the Delaware Court upheld the '938 Patent, which pertains to the formulation of AMPYRA and is set to expire in July 2018, and invalidated U.S. Patent Nos. 8,007,826; 8,354,437; 8,440,703; and 8,663,685, which pertain to AMPYRA (the "Delaware Court Decision"). In May 2017, Acorda filed its appeal of the Delaware Court Decision with the U.S. Court of Appeals for the Federal Circuit (the "Federal Circuit") with respect to the findings on U.S. Patent Nos. 8,007,826; 8,354,437; 8,440,703; and 8,663,685. In June 2017, certain of the ANDA filers filed a cross-appeal of the Delaware Court Decision with the Federal Circuit with respect to the validity of the '938 Patent. We and Acorda filed an opening brief in August 2017 and the ANDA filers responded in October 2017. Each side subsequently filed a response and reply brief in November 2017. A date for oral argument before the Federal Circuit has not yet been set. For further discussion of the legal proceedings related to the patents covering AMPYRA, see Note 17, *Commitments and Contingencies* in the "Notes to Condensed Consolidated Statements" in this Annual Report and for information about risks relating to the AMPYRA Paragraph IV litigation, see "Principal Risks" in this Directors' Report , and specifically the section entitled "—We or our licensees may face claims against intellectual property rights covering our products and competition from generic drug manufacturers."

The legal proceedings in the Delaware Court related to the patents covering AMPYRA do not involve the patents covering FAMPYRA, and the latest of the patents covering FAMPYRA expires in April 2025 in the EU.

### *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 and BYDUREON BCise***

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.

In October 2017, AstraZeneca announced FDA approval of BYDUREON BCise, a new formulation of BYDUREON in a once-weekly, single-dose autoinjector device for adults with type 2 diabetes. AstraZeneca announced the U.S. launch of BYDUREON BCise in January 2018. A regulatory application for the new autoinjector device has also been accepted by the EMA.

### *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 current key 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 in "Part I, Item 1A—Risk Factors" of this Annual Report. Refer to the "Patents and Proprietary Rights" section in "Part I, Item 1—Business" of this Annual Report for information with respect to the intellectual property protection for our development candidates.

The following graphic summarizes the status of our key development programs:

<u>Product Candidate</u>	<u>Target Indication(s)</u>	<u>Status</u>
<i>Aripiprazole Lauroxil NanoCrystal® Dispersion</i> .	Schizophrenia	NDA Review
<i>ALKS 5461</i> . . . . .	Major Depressive Disorder (“MDD”)	NDA Review
<i>ALKS 3831</i> . . . . .	Schizophrenia	Phase 3
<i>BIIB098 (formerly ALKS 8700)</i> . . . . .	MS	Phase 3
<i>ALKS 4230</i> . . . . .	Cancer Immunotherapy	Phase 1

***Aripiprazole Lauroxil NanoCrystal Dispersion***

Aripiprazole Lauroxil NanoCrystal Dispersion (“AL<sub>NCD</sub>”) is a novel, investigational product designed to enable initiation onto any dose or duration of ARISTADA (aripiprazole lauroxil) extended-release injectable suspension for the treatment of schizophrenia. AL<sub>NCD</sub> uses our proprietary NanoCrystal technology and provides an extended-release aripiprazole lauroxil formulation having a smaller particle size than ARISTADA, thereby enabling faster dissolution and leading to more rapid achievement of therapeutic levels of aripiprazole. We have submitted a new drug application (“NDA”) to the FDA for AL<sub>NCD</sub> to be used as an initiation dose for ARISTADA for the treatment of schizophrenia. The FDA has issued a target action date for the AL<sub>NCD</sub> NDA of June 30, 2018 under the Prescription Drug User Fee Act.

***ALKS 5461***

ALKS 5461 is a proprietary, investigational, once-daily, oral medicine that acts as an opioid system modulator and represents a novel mechanism of action for the adjunctive treatment of major depressive disorder (“MDD”). ALKS 5461 is a fixed-dose combination of buprenorphine, a partial mu-opioid receptor agonist and kappa-opioid receptor antagonist, and samidorphan, a mu-opioid receptor antagonist.. 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.

The FORWARD (Focused On Results With A Rethinking of Depression) program for ALKS 5461 includes three core phase 3 efficacy studies (FORWARD-3, FORWARD-4 and FORWARD-5), as well as additional supportive studies to evaluate the long-term safety, dosing, pharmacokinetic profile and human abuse potential of ALKS 5461.

In January 2016, we announced the topline results of FORWARD-3 and FORWARD-4. Neither study met the primary efficacy endpoint, which compared ALKS 5461 to placebo on the change from baseline on the 10-item Montgomery—Asberg Depression Rating Scale (“MADRS-10”) total scores. FORWARD-4, which tested two dose levels of ALKS 5461 (2 mg/2 mg and 0.5 mg/0.5 mg) compared to placebo, showed a clear trend toward efficacy with the 2 mg/2 mg dose of ALKS 5461 on the primary endpoint, and post hoc analyses achieved statistical significance for the 2 mg/2 mg 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 (2 mg/2 mg) 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 for the adjunctive treatment of MDD in patients with an inadequate response to standard antidepressant therapies. ALKS 5461 2 mg/2 mg demonstrated statistically significant reductions in MADRS-10 scores compared to placebo and also met the primary endpoint of significantly reducing depression scores compared to placebo, as measured by the 6-item



Montgomery—Åsberg Depression Rating Scale (“MADRS-6”). The 1 mg/1 mg 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.

In February 2017 and July 2017, based on the results of FORWARD-5, the supportive evidence from FORWARD-4 and the successful phase 2 study of ALKS 5461 we met with the FDA’s Division of Psychiatric Products at a Type C meeting and a pre-NDA meeting, respectively, to discuss ALKS 5461. In January 2018, we completed submission of our NDA for ALKS 5461. The NDA is based on a comprehensive clinical efficacy and safety package with data from more than 30 clinical trials and more than 1,500 patients with MDD.

In March 2018, we received a Refusal to File letter from the FDA regarding its NDA for ALKS 5461. Upon its preliminary review, the FDA has taken the position that it is unable to complete a substantive review of the regulatory package, based on insufficient evidence of overall effectiveness for the proposed indication, and that additional well-controlled clinical trials are needed prior to the resubmission of the NDA for ALKS 5461. In addition, FDA has requested the conduct of a bioavailability study to generate additional bridging data between ALKS 5461 and the reference listed drug, buprenorphine. The company intends to appeal the FDA’s decision and seek immediate guidance, including requesting a Type A meeting with the FDA, to determine appropriate next steps and what additional information may be required to resubmit the NDA.

### *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 antipsychotic efficacy of olanzapine and a differentiated safety profile with favorable weight and metabolic properties.

The ENLIGHTEN clinical development program for ALKS 3831 includes two key studies: ENLIGHTEN-1, a study evaluating the antipsychotic efficacy of ALKS 3831 compared to placebo over four weeks and ENLIGHTEN-2, a study assessing weight gain with ALKS 3831 compared to olanzapine in patients with schizophrenia over six months. The program also includes supportive studies to evaluate the pharmacokinetic, metabolic and safety profile of ALKS 3831.

In June 2017, we announced positive preliminary topline results from ENLIGHTEN-1, a multinational, double-blind, randomized, phase 3 study that evaluated the antipsychotic efficacy, safety and tolerability of ALKS 3831 compared to placebo in patients experiencing an acute exacerbation of schizophrenia. ALKS 3831 met the prespecified primary endpoint demonstrating statistically significant reductions from baseline in Positive and Negative Syndrome Scale (“PANSS”) scores compared to placebo. The study also included an olanzapine arm, but was not designed to provide comparative efficacy or safety data between ALKS 3831 and olanzapine. Data from the study showed that olanzapine achieved similar improvements from baseline PANSS scores as compared to placebo. Results from ENLIGHTEN-2 are expected in the fall of 2018.

We recently completed the exploratory phase 1 metabolic study of ALKS 3831, assessing the effects of ALKS 3831 on important metabolic parameters compared to olanzapine, and expect to present initial results in the first half of 2018.

We expect to use safety and efficacy data from the ENLIGHTEN clinical development program, if successful, to serve as the basis for an NDA, which we plan to submit to the FDA in the first half of 2019.

#### ***BIIB098 (formerly ALKS 8700)***

BIIB098, formerly referred to as ALKS 8700, is a novel, proprietary, oral investigational monomethyl fumarate (“MMF”) prodrug in development for the treatment of relapsing forms of MS. BIIB098 is designed to rapidly and efficiently convert to MMF in the body and to offer differentiated features as compared to the currently marketed dimethyl fumarate, TECFIDERA. In March 2017, we initiated an elective, randomized, head-to-head phase 3 study designed to compare the gastrointestinal tolerability of BIIB098 to TECFIDERA in patients with relapsing-remitting MS.

The pivotal clinical program for BIIB098 consists of pharmacokinetic bridging studies comparing BIIB098 and TECFIDERA and a two-year, multicenter, open-label study designed to assess the safety of BIIB098, which we initiated in December 2015. During the third quarter of 2017, we completed the clinical registration requirements for BIIB098. We expect to complete the required non-clinical studies in 2018 and file a 505(b)(2) NDA in the second half of 2018.

In November 2017, we entered into an exclusive license and collaboration agreement with Biogen relating to BIIB098. For more information about the license and collaboration agreement with Biogen, see the “Collaborative Arrangements” section of this Annual Report. We expect to have initial results to share with Biogen in the first half of 2018 from the head-to-head phase 3 study.

#### ***ALKS 4230***

ALKS 4230 is an engineered fusion protein designed to preferentially bind and signal through the intermediate affinity interleukin-2 (“IL-2”) receptor complex, thereby selectively activating and increasing the number of immunostimulatory tumor-killing immune cells while avoiding the expansion of immunosuppressive cells that interfere with anti-tumor response. The selectivity of ALKS 4230 is designed to leverage the proven anti-tumor effects while overcoming limitations of existing IL-2 therapy, which activates both immunosuppressive and tumor-killing immune cells. Our phase 1 study for ALKS 4230 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 data from the first stage of the phase 1 study are expected in 2018.

#### **Other Programs**

##### ***Induction Protocols for Initiation onto VIVITROL (formerly ALKS 6428)***

In 2017, we completed two phase 3 clinical trials evaluating the efficacy and safety of an investigational induction protocol designed to help healthcare providers transition patients from physical dependence on opioids to initiation with VIVITROL. The investigational regimen, previously referred to as ALKS 6428, consisted of ascending doses of oral naltrexone administered in conjunction with ancillary medications, including buprenorphine, during a seven-day treatment period, prior to first VIVITROL injection. In February 2017, we announced results from the first phase 3 study in patients dependent on heroin or prescription opioids, in which data demonstrated that rates of transition to VIVITROL were comparable across all treatment groups. The primary endpoint of the study was not met, as patients in all treatment arms (ascending doses of naltrexone plus tapering doses of buprenorphine, ascending doses of naltrexone plus placebo, and placebo, in each case in conjunction with ancillary medications) performed equally well, with a similar percentage of patients in each

treatment arm successfully transitioning to initiation with VIVITROL. We recently completed the second phase 3 study of the investigational induction protocol in patients who wanted to transition from buprenorphine maintenance therapy to initiation with VIVITROL for the treatment of opioid dependence. The Company plans to publish the data from both phase 3 studies in peer-reviewed publications in 2018.

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

Please see “Results of Operations” for our R&D expenditures for the years ended December 31, 2017 and 2016.

### **Collaborative Arrangements**

We have entered into several collaborative arrangements to develop and commercialize products and, in connection with such arrangements, 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 this 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 end-market 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 in each country 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 end-market 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 each such country, with the exception of Canada, France, Germany, Italy, Japan, Spain and the United Kingdom, in each case, where the fifteen-year minimum 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 applicable calendar year. This percentage is determined based on Janssen's unit demand for such 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 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 net 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 products 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 the 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.

### ***Biogen***

Under a license and collaboration agreement, we granted Biogen a worldwide, exclusive, sublicensable license to develop, manufacture and commercialize BIIB098 and other products covered by patents licensed to Biogen under the agreement.

Upon entering into this agreement in November 2017, we received an up-front cash payment of \$28.0 million. We are also eligible to receive additional payments upon achievement of milestones, as follows: (i) a \$50.0 million option payment upon Biogen's decision to continue the collaboration after having reviewed certain data from our long-term safety clinical trial and part A of the head-to-head phase 3 gastrointestinal tolerability clinical trial comparing BIIB098 to TECFIDERA and (ii) a \$150.0 million payment upon an approval by the FDA on or before December 31, 2021 of a 505(b)(2) NDA (or, in certain circumstances, a 505(b)(1) NDA) for BIIB098. We are also eligible to receive additional payments upon achievement of milestones with respect to the first two products, other than BIIB098, covered by patents licensed to Biogen under the agreement.

In addition, we will receive a mid-teens percentage royalty on worldwide net sales of BIIB098, subject to, under certain circumstances, minimum annual payments for the first five years following FDA approval of BIIB098. We will also receive royalties on net sales of products, other than BIIB098, covered by patents licensed to Biogen under the agreement, at tiered royalty rates calculated as percentages of net sales ranging from high-single digits to sub-teen double-digits. All royalties are payable on a product-by-product and country-by-country basis until the later of (i) the last-to-expire patent right covering the applicable product in the applicable country and (ii) a specified period of time from the first commercial sale of the applicable product in the applicable country. Royalties for all products and the minimum annual payments for BIIB098 are subject to customary reductions.

Except in certain limited circumstances, until FDA approval of an NDA for BIIB098, we are responsible for the development of BIIB098 for the treatment of MS. Biogen paid a portion of the BIIB098 development costs we incurred in 2017 and, beginning on January 1, 2018, Biogen will be responsible for all BIIB098 development costs we incur, subject to annual budget limitations. After the date of FDA approval of an NDA for BIIB098 for the treatment of MS, Biogen will be responsible for all development and commercialization activities, as well as the costs of all such activities, for BIIB098 and all other products covered by patents licensed to Biogen under the agreement. We have retained the right to manufacture clinical supplies and commercial supplies of BIIB098 and all other products covered by patents licensed to Biogen under the agreement, subject to Biogen's right to manufacture or have manufactured commercial supplies as a back-up manufacturer and subject to good faith agreement by the parties on the terms of such manufacturing arrangements.

If BIIB098 discontinuations due to gastrointestinal adverse events in BIIB098's long-term safety clinical trial exceed a certain pre-defined threshold or BIIB098 demonstrates a greater rate of discontinuations as compared to TECFIDERA in part A of the head-to-head phase 3 gastrointestinal tolerability clinical trial, then "GI Inferiority" shall exist, and (i) Biogen shall have the right to recapture from us its \$50.0 million option payment through certain temporary reductions in royalty rates, (ii) the minimum annual payments Biogen owes to us shall terminate and (iii) there shall be no reversion of BIIB098 to us in the event that Biogen terminates the agreement and does not commercialize BIIB098.

Unless earlier terminated, the agreement will remain in effect until the expiry of all royalty obligations. Biogen has the right to terminate the agreement at will, on a product-by-product basis or in its entirety. Either party has the right to terminate the agreement following any governmental prohibition of the transactions effected by the agreement, or in connection with an insolvency event involving the other party. Upon termination of the agreement by either party, if, prior to such termination (i) BIIB098 did not meet GI Inferiority or (ii) BIIB098 met GI Inferiority but Biogen commercialized BIIB098, then, at our request, the BIIB098 program will revert to us.

### **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 an 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 Practices (“cGMP”) regulations and other 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 and services 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 supply chain is growing with an expanding external network of third-party service providers involved in the manufacture of our products who 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”), raw materials, or components, or in the 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 “Item 1A—Risk Factors” and specifically those sections entitled “—We rely on third parties to provide services in connection with the manufacture and distribution of our products” and “—We are subject to risks related to the manufacture of our products.”

#### ***Proprietary Products and Products using our Proprietary Technologies***

We manufacture microspheres for RISPERDAL CONSTA and VIVITROL, polymer for BYDUREON and BYDUREON BCise, and ARISTADA in our Wilmington, Ohio facility. We are currently operating one RISPERDAL CONSTA line, two VIVITROL lines and two ARISTADA lines at commercial scale. In 2018, we expect to qualify a dedicated fill line for the commercial production of VIVITROL diluent. 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. The FDA recently completed a pre-approval inspection and recommended the Athlone, Ireland facility for approval to manufacture commercial supplies of bulk intermediate NanoCrystal Dispersion of Meloxicam.

### ***Clinical Products***

We have established, and are operating, facilities with the capability to produce clinical supplies of injectable extended-release products as well as solid dosage and biologics 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 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 have developed 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 believe that we use customary pharmaceutical company practices to market our product and to educate physicians. Our practices include, the education of individual physicians, nurses, social workers,

counselors and other stakeholders involved in the treatment of opioid dependence, 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 100 individuals. VIVITROL is sold to pharmaceutical wholesalers, pharmacies, specialty distributors and treatment providers. Product sales of VIVITROL during the year ended December 31, 2017 to Cardinal Health, McKesson Corporation, AmerisourceBergen Corporation (“AmerisourceBergen”) and CVS Caremark Corporation represented approximately 19%, 18%, 18% and 11%, respectively, of total VIVITROL sales.

Our sales force for ARISTADA in the U.S. consists of approximately 220 individuals. ARISTADA is primarily sold to pharmaceutical wholesalers. Product sales of ARISTADA during the year ended December 31, 2017 to Cardinal Health, McKesson Corporation and AmerisourceBergen represented approximately 45%, 24% and 20%, 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, they are each responsible for the commercialization of any products developed under their respective agreement 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 biopharmaceutical 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 biopharmaceutical industry is 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 and Indivior plc, which is developing a once-monthly injectable risperidone for the treatment of schizophrenia. 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, ABILIFY MAINTENA, 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 SUBOXONE (buprenorphine HCl/naloxone HCl dehydrate sublingual tablets), SUBOXONE (buprenorphine/naloxone) Sublingual Film, SUBUTEX (buprenorphine HCl sublingual tablets) and, once launched, will compete with SUBLOCADE (once-monthly buprenorphine extended-release injection), each of which is, or will be, marketed and sold by Indivior plc, and BUNAVAIL buccal film (buprenorphine and naloxone) marketed by BioDelivery Sciences, PROBUPHINE (buprenorphine) from Titan Pharmaceuticals, Inc., and ZUBSOLV (buprenorphine and naloxone) marketed by Orexo US, Inc. VIVITROL also competes with methadone, oral naltrexone and 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 and BYDUREON BCise compete 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 and BYDUREON BCise also compete 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 and BYDUREON BCise.

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; OCREVUS from Genentech; 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, 2017, 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 the U.S., in addition to patent protection, ARISTADA is entitled to regulatory exclusivity until 2020, a benefit afforded to new chemical entities. U.S. Patent Nos. 8,431,576 and 8,796,276 described above also cover AL<sub>NCD</sub>. There are also pending patent applications that, if granted, would cover AL<sub>NCD</sub>.

***VIVITROL, RISPERDAL CONSTA, BYDUREON and BYDUREON BCise***

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, BYDUREON and BYDUREON BCise. The latest of our patents covering VIVITROL, RISPERDAL CONSTA, BYDUREON and BYDUREON BCise expire in 2029, 2023, 2025 and 2025 in the U.S., respectively, and 2021, 2021, 2024 and 2024 in the EU, respectively, and we own 16, 4, 11 and 10 unexpired Orange-Book listed U.S. patents covering VIVITROL, RISPERDAL CONSTA, BYDUREON and BYDUREON BCise, 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, in 2030. The latest of the patents covering INVEGA TRINZA/TREVICTA expired in 2017 in the U.S. (with regulatory exclusivity in the U.S. until May 2018) and will expire in 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. For a discussion of legal proceedings related to the patents covering INVEGA SUSTENNA, see Note 17, *Commitments and Contingencies* in the “Notes to Condensed Consolidated Statements.”

***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 2027 in the U.S. and 2025 in the EU (with regulatory exclusivity in the EU until 2021). For a discussion of legal proceedings related to the patents covering AMPYRA, see Note 17, *Commitments and Contingencies* in the “Notes to Condensed Consolidated 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	2030
	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

***BIIB098***

We have U.S. patents and patent applications, and a number of corresponding foreign counterparts, that cover BIIB098. Our U.S. patents and expiration dates for BIIB098 are:

- U.S. Patent No. 8,669,281, having claims to a composition of matter that covers BIIB098, 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.

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

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

Our trademarks, including VIVITROL and ARISTADA, are important to us and are generally covered by trademark applications or registrations in the U.S. Patent and Trademark Office and the patent or trademark offices of other countries. Products using our proprietary technologies also use trademarks that are owned by our licensees, such as the trademarks INVEGA SUSTENNA/XEPLION, INVEGA TRINZA/TREVICTA and RISPERDAL CONSTA, which are registered trademarks of Johnson & Johnson; BYDUREON, which is a registered trademark of Amylin; BYDUREON BCise, which is a registered trademark of AstraZeneca Pharmaceuticals LP; 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 trademark is used and in other countries as long as the trademark is registered. Trademark registrations generally are for fixed but renewable terms.

## **Employees**

As of February 2, 2018, we had approximately 2,000 full-time employees. A significant number of our management and professional employees have prior experience with pharmaceutical, biopharmaceutical 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 VIVITROL; ARISTADA; INVEGA SUSTENNA/XEPLION, INVEGA TRINZA/TREVICTA and RISPERDAL CONSTA; AMPYRA/FAMPYRA; and BYDUREON. Revenues from these key products accounted for 91% of our total revenues during 2017, as compared to 92% during 2016.

Under a license and collaboration agreement, we granted Biogen a worldwide, exclusive, sublicensable license to develop, manufacture and commercialize BIIB098 and other products covered by patents licensed to Biogen under the agreement. Upon entering into this agreement in November 2017, we received an up-front cash payment of \$28.0 million. We are also eligible to receive additional payments upon achievement of certain milestones and a mid-teens percentage royalty on worldwide net sales of BIIB098. Except in certain limited circumstances, until FDA approval of an NDA for BIIB098, we are responsible for the development of BIIB098 for the treatment of MS. Biogen paid a portion of the BIIB098 development costs we incurred in 2017 and, beginning on January 1, 2018, Biogen will be responsible for all BIIB098 development costs we incur, subject to annual budget limitations. This license and collaboration agreement is discussed in further detail within the *Notes to the Consolidated Financial Statements* section below.

In 2017, we incurred an operating loss of \$147.9 million, down from an operating loss of \$208.7 million in 2016. Revenues increased by \$157.7 million, which was primarily due to a \$106.7 million increase in net sales of VIVITROL and ARISTADA. This was partially offset by a \$96.9 million increase in operating expenses, which was primarily in support of the increase in net sales, and continued significant investment in our R&D pipeline and commercial organization. These items are discussed in further detail within the *Results of Operations* section below.

## **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, 2017 and 2016:

(In millions)	Year Ended December 31,		Change Favorable/ (Unfavorable)
	2017	2016	
Manufacturing and royalty revenues:			
INVEGA SUSTENNA/XEPLION & INVEGA			
TRINZA/TREVICTA . . . . .	\$214.9	\$184.2	\$ 30.7
AMPYRA/FAMPYRA . . . . .	117.0	114.2	2.8
RISPERDAL CONSTA . . . . .	84.9	87.2	(2.3)
BYDUREON . . . . .	45.7	45.6	0.1
Other . . . . .	42.8	56.0	(13.2)
Manufacturing and royalty revenues . . . . .	<u>\$505.3</u>	<u>\$487.2</u>	<u>\$ 18.1</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 net sales.

The increase in INVEGA SUSTENNA/XEPLION and INVEGA TRINZA/TREVICTA royalty revenues was due to an increase in Janssen's end-market net sales of INVEGA SUSTENNA/XEPLION and INVEGA TRINZA/TREVICTA. Janssen's end-market net sales of INVEGA SUSTENNA/XEPLION and INVEGA TRINZA/TREVICTA were \$2.6 billion and \$2.2 billion during the years ended December 31, 2017 and 2016, respectively.

The decrease in RISPERDAL CONSTA revenue 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 \$805.0 million and \$893.0 million, during the years ended December 31, 2017 and 2016, respectively. The decline in Janssen's end-market net sales led to a decrease in our royalty revenues of 10% in 2017 as compared to 2016. The manufacturing revenue we earned on shipments of RISPERDAL CONSTA to Janssen in 2017 was consistent with the amount earned we in 2016. While the number of units shipped to Janssen increased by 6% in 2017, this was offset by a lower average net selling price on the units shipped to Janssen as Janssen receives a lower sales price for units sold outside the U.S. The number of units shipped for resale in the U.S. decreased by 17% and the number of units shipped for resale in the rest of the world increased by 11%.

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, in 2030. The latest of the patents covering INVEGA TRINZA/TREVICTA expired in November 2017 in the U.S. (with regulatory exclusivity in the U.S. until May 2018) and will

expire in 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.

In January 2018, Janssen Pharmaceuticals NV and Janssen Pharmaceuticals, Inc. initiated a patent infringement lawsuit in the United States District Court for the District of New Jersey against Teva, who filed an ANDA seeking approval to market a generic version of INVEGA SUSTENNA before the expiration of United States Patent No. 9,439,906. For further discussion of the legal proceedings related to the patents covering INVEGA SUSTENNA, see Note 17, *Commitments and Contingencies* in the “Notes to Condensed Consolidated Statements” and for information about risks relating to the INVEGA SUSTENNA Paragraph IV litigation, see “Principal Risks” in this Directors’ Report , and specifically the section entitled “—We or our licensees may face claims against intellectual property rights covering our products and competition from generic drug manufacturers.”

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, 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 2017, as compared to 2016, was primarily due to a 4% increase in manufacturing revenue, which was due to an 11% increase in the amount of FAMPYRA shipped to Biogen, partially offset by an 8% decrease in the amount of AMPYRA shipped to Acorda.

On March 31, 2017, the Delaware Court upheld the ‘938 Patent, which pertains to the formulation of AMPYRA and is set to expire in July 2018, and invalidated U.S. Patent Nos. 8,007,826; 8,354,437; 8,440,703; and 8,663,685, which pertain to AMPYRA. If the Federal Circuit upholds the Delaware Court’s findings with respect to U.S. Patent Nos. 8,007,826; 8,354,437; 8,440,703; and 8,663,685 and the validity of the ‘938 Patent, we can expect competition from generic forms of AMPYRA as early as July 2018 when the ‘938 Patent expires. If the Federal Circuit upholds the Delaware Court’s findings with respect to U.S. Patent Nos. 8,007,826; 8,354,437; 8,440,703; and 8,663,685 and overturns the Delaware Court’s upholding of the validity of the ‘938 Patent, competition from generic forms of AMPYRA may occur before the July 2018 expiry of the ‘938 Patent. We can expect that competition from generic forms of AMPYRA would impact our manufacturing and royalty revenues. We expect our manufacturing and royalty revenues to decline in advance of generic entry in anticipation of reduced demand for AMPYRA. For further discussion of the legal proceedings related to the patents covering AMPYRA, see Note 17, *Commitments and Contingencies* in the “Notes to Condensed Consolidated Statements and for information about risks relating to the AMPYRA Paragraph IV litigation, see “Principal Risks” in this Directors’ Report , and specifically the section entitled “—We or our licensees may face claims against intellectual property rights covering our products and competition from generic drug manufacturers.”

### ***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 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, 2017 and 2016:

(In millions)	Year Ended December 31, 2017		Year Ended December 31, 2016	
	Amount	% of Sales	Amount	% of Sales
Product sales, gross . . . . .	\$ 657.7	100.0%	\$ 444.6	100.0%
Adjustments to product sales, gross:				
Medicaid rebates . . . . .	(147.8)	(22.5)%	(94.2)	(21.2)%
Product discounts . . . . .	(51.0)	(7.8)%	(35.1)	(7.9)%
Chargebacks . . . . .	(47.9)	(7.3)%	(31.5)	(7.1)%
Co-pay assistance . . . . .	(9.5)	(1.4)%	(8.5)	(1.9)%
Other . . . . .	(38.7)	(5.8)%	(19.2)	(4.3)%
Total adjustments . . . . .	(294.9)	(44.8)%	(188.5)	(42.4)%
Product sales, net . . . . .	<u>\$ 362.8</u>	<u>55.2%</u>	<u>\$ 256.1</u>	<u>57.6%</u>

The increase in product sales, gross in 2017, as compared to 2016, was due to a 33% increase in VIVITROL gross sales and a 129% increase in ARISTADA gross sales. The increase in VIVITROL gross sales was due to a 33% increase in the number of units sold as there was no change to the selling price of VIVITROL in 2017. The increase in sales of ARISTADA was primarily due to a 113% increase in the number of units sold and a 5% price increase, which was effective in April 2017. ARISTADA 441 mg, 662 mg and 882 mg launched in the U.S. in October 2015 and ARISTADA 1064 mg, our two-month dosing option, was approved by the FDA and launched in June 2017.

The increase in Medicaid rebates as a percentage of sales in 2017, as compared to 2016, was primarily due to an increase in the amount of VIVITROL sold under the Medicaid Drug Rebate Program.

Our product sales, net for VIVITROL were \$269.3 million and \$209.0 million in 2017 and 2016, respectively. Our product sales, net for ARISTADA were \$93.5 million and \$47.1 million in 2017 and 2016, 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 continue to increase.

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.

**License Revenue**

(In millions)	Year Ended December 31,		Change Favorable/ (Unfavorable)
	2017	2016	
License revenue . . . . .	<u>\$28.0</u>	<u>\$—</u>	<u>\$28.0</u>

The increase in license revenue in 2017, as compared to 2016, was due to revenue earned under our license and collaboration agreement with Biogen for BIIB098, as discussed in further detail within the *Notes to Consolidated Financial Statements* below.

**Research and Development Revenue**

(In millions)	Year Ended December 31,		Change Favorable/ (Unfavorable)
	2017	2016	
Research and development revenue . . . . .	<u>\$7.2</u>	<u>\$2.3</u>	<u>\$4.9</u>

The increase in R&D revenue in 2017, as compared to 2016, was primarily due to revenue earned under our license and collaboration agreement with Biogen for BIIB098, as discussed in further detail within the *Notes to Consolidated Financial Statements* below.

**Costs and Expenses**

**Cost of Goods Manufactured and Sold**

(In millions)	Year Ended December 31,		Change Favorable/ (Unfavorable)
	2017	2016	
Cost of goods manufactured and sold . . . . .	<u>\$154.7</u>	<u>\$132.1</u>	<u>\$(22.6)</u>

The increase in cost of goods manufactured and sold in 2017, as compared to 2016, was primarily due to the increase in cost of goods sold related to VIVITROL and ARISTADA and the increase in cost of goods manufactured related to RISPERDAL CONSTA. Cost of goods sold for VIVITROL and ARISTADA increased by \$9.5 million and \$5.2 million, respectively, driven by the increase in sales, and cost of goods manufactured for RISPERDAL CONSTA increased by \$3.7 million, driven by the increase in the number of units shipped to Janssen, as previously discussed.

**Research and Development Expenses**

For each of our R&D programs, we incur both external and internal expenses. External R&D expenses include 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)
	2017	2016	
External R&D Expenses:			
Key development programs:			
ALKS 3831 . . . . .	\$ 91.9	\$ 71.0	\$(20.9)
BIIB098 . . . . .	47.4	26.9	(20.5)
ALKS 5461 . . . . .	42.2	46.2	4.0
ARISTADA and ARISTADA line extensions . . .	13.7	36.3	22.6
ALKS 6428 . . . . .	10.6	16.3	5.7
ALKS 4230 . . . . .	7.0	4.8	(2.2)
Other external R&D expenses . . . . .	27.8	42.4	14.6
Total external R&D expenses . . . . .	<u>240.6</u>	<u>243.9</u>	<u>3.3</u>
Internal R&D expenses:			
Employee-related . . . . .	132.2	110.1	(22.1)
Occupancy . . . . .	9.6	9.0	(0.6)
Depreciation . . . . .	10.5	7.9	(2.6)
Other . . . . .	20.0	16.2	(3.8)
Total internal R&D expenses . . . . .	<u>172.3</u>	<u>143.2</u>	<u>(29.1)</u>
Research and development expenses . . . . .	<u>\$412.9</u>	<u>\$387.1</u>	<u>\$(25.8)</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 expenses related to ALKS 3831 in 2017, as compared to 2016, was primarily due to the timing of activity within the ENLIGHTEN-1 and ENLIGHTEN-2 pivotal trials, which were initiated in December 2015 and February 2016, respectively and activity for a supportive study in the ENLIGHTEN clinical development program for ALKS 3831, which was initiated in June 2017. The increase in expenses related to BIIB098 in 2017, as compared to 2016, was primarily due to further progression of the two-year, multicenter, open-label phase 3 study designed to assess the safety of BIIB098, which was initiated in December 2015 and is actively enrolling. We also initiated a phase 3 gastrointestinal tolerability study for BIIB098 in March 2017. The decrease in expenses related to ALKS 5461 in 2017, as compared to 2016, was primarily due to the completion of the three core phase 3 studies related to the program. We announced topline results of the FORWARD-3 and FORWARD-4 studies in January 2016 and topline results from FORWARD-5 were announced in October 2016. In January 2018, we completed our submission of an NDA to the FDA seeking marketing approval of ALKS 5461 for the adjunctive treatment of MDD. The decrease in expenses related to ARISTADA and ARISTADA line extensions in 2017, as compared to 2016, was primarily due to the timing of the phase 1 clinical study of extended dosing intervals of aripiprazole lauroxil in patients with schizophrenia. ARISTADA 1064 mg, our two-month dosing option, was approved by the FDA in June 2017 and we submitted an NDA to the FDA for ALNCD in October 2017, which was accepted by the FDA in November 2017. The decrease in expenses related to ALKS 6428 in 2017, as compared to 2016, was primarily due to the completion of a phase 3 clinical study initiated in September 2015 evaluating the safety, tolerability and efficacy of ALKS 6428 in patients with opioid

dependence. Topline results were announced in February 2017. The increase in expenses related to ALKS 4230 in 2017, as compared to 2016, was primarily related to the timing of the phase 1 study which was initiated in May 2016. Initial data from the first stage of the phase 1 study is expected in 2018.

The decrease in other external R&D expenses was primarily due to a \$10.0 million non-refundable, upfront payment in 2016 as partial consideration of a grant to us of rights and licenses pursuant to a collaboration and license option agreement with Reset Therapeutics, Inc. The remainder of the changes are due to activity 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 9% in 2017, as compared to 2016.

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

(In millions)	Year Ended December 31,		Change Favorable/ (Unfavorable)
	2017	2016	
Selling, general and administrative . . . . .	<u>\$421.6</u>	<u>\$374.1</u>	<u>\$(47.5)</u>

The increase in selling, general and administrative (“SG&A”) expense in 2017, as compared to 2016, was primarily due to a \$31.1 million increase in marketing and professional service fees and a \$13.4 million increase in employee-related expenses. The increase in marketing and professional services expenses was primarily due to additional brand investments in both VIVITROL and ARISTADA, as well as an increase in patient access support services, such as reimbursement and transition assistance, for both of these products. The increase in employee-related expenses was primarily due to a 17% increase in our SG&A-related headcount during 2017.

***Amortization of Acquired Intangible Assets***

(In millions)	Year Ended December 31,		Change Favorable/ (Unfavorable)
	2017	2016	
Amortization of acquired intangible assets . . . . .	<u>\$62.1</u>	<u>\$61.0</u>	<u>\$(1.1)</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.

Based on our most recent analysis, amortization of intangible assets included within our consolidated balance sheet at December 31, 2017 is expected to be approximately \$65.0 million, \$55.0 million, \$50.0 million, \$40.0 million and \$35.0 million in the years ending December 31, 2018 through 2022, respectively.

*Other Income (Expense), Net*

(In millions)	Year Ended December 31,		Change Favorable/ (Unfavorable)
	2017	2016	
Interest income . . . . .	\$ 4.6	\$ 3.8	\$ 0.8
Interest expense . . . . .	(12.0)	(14.9)	2.9
Change in the fair value of contingent consideration . . . . .	21.6	7.9	13.7
Other (expense), net . . . . .	(9.6)	(2.5)	(7.1)
Total other income (expense), net . . . . .	<u>\$ 4.6</u>	<u>\$ (5.7)</u>	<u>\$10.3</u>

The decrease in interest expense in 2017, as compared to 2016 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.

During the years ended December 31, 2017 and 2016, we determined that the fair value of the contingent consideration increased by \$21.6 million and \$7.9 million, respectively. The increases in 2017, as compared to 2016, were primarily due to the change in the structure of the development milestones, a shorter time to payment and improved probability of success on the milestones and royalties included in the contingent consideration. The increase in other (expense) income, net, in 2017, as compared to 2016, was primarily due to an impairment charge related to our investment in Reset, which was accounted for under the equity method. In September 2017, we recorded an other-than-temporary impairment charge of \$10.5 million, which represented our remaining investment in Reset, as we believe that Reset is unable to generate future earnings that justify the carrying amount of the investment.

*(Provision) Benefit for Income Taxes*

(In millions)	Year Ended December 31,		Change Favorable/ (Unfavorable)
	2017	2016	
Income tax (provision) benefit . . . . .	<u>\$(14.7)</u>	<u>\$5.9</u>	<u>\$(20.6)</u>

The income tax provision in 2017 and the income tax benefit in 2016 were primarily due to U.S. federal and state taxes. The unfavorable change in income taxes in 2017, as compared to 2016, was primarily due to the enactment of the Tax Cuts and Jobs Act (the “Act” or “Tax Reform”) and an increase in income earned in the U.S., partially offset by the recognition of excess tax benefits related to share-based compensation.

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 \$160.3 million at December 31, 2017.

In March 2016, the Financial Accounting Standards Board (“FASB”) issued guidance as part of its simplification initiative that involves several aspects of the accounting for share-based payment transactions including the requirement that all future excess tax benefits and tax deficiencies be recognized as income tax expense or benefit in the income statement. On January 1, 2017, we adopted this standard on a modified retrospective basis, which resulted in a favorable cumulative-effect

adjustment of \$61.5 million to accumulated deficit due to the change in the accounting treatment of excess tax benefits and tax deficiencies.

Tax Reform was enacted in December 2017. We are primarily subject to the business-related provisions outlined in Subtitle C to the Act, as well as the international tax provisions for inbound transactions outlined in Subtitle D, Part II, to the Act. We recorded a \$21.5 million discrete tax expense in the quarter ended December 31, 2017 to account for the reduction in the U.S. federal tax rate from 35% to 21%. The Act also removes the exception for performance-based compensation in §162(m) of the Internal Revenue Code (the “Code”) on a prospective basis. Performance-based compensation provided pursuant to a written binding agreement entered into prior to November 2, 2017 will continue to be deductible provided no significant modification is made to the agreement on or after that date. Following our preliminary assessment, we believe that performance-based compensation, provided prior to November 2, 2017, was provided pursuant to written binding agreements and will be deductible. As of December 31, 2017, we have a deferred tax asset of \$13.3 million for this item, which is recorded as a provisional amount. If our position is not sustained, then we would record a deferred tax expense for part or all of this amount. The accounting for this item is incomplete and may change as our interpretation of the provisions of the Act evolve, additional information becomes available or interpretive guidance is issued by the U.S. Treasury. The final determination will be completed no later than one year from the enactment of the Act.

The benefits from a reduced U.S. federal tax rate are expected to be offset, in part, by unfavorable adjustments to certain permanent differences such as non-deductible executive compensation under §162(m) of the Code and non-deductible meals and entertainment. The impact of the international provisions for inbound transactions are not expected to be material to our effective tax rate as we do not expect additional tax expense resulting from the Base Erosion and Anti-Abuse Tax (“BEAT”) which is based on payments made to non-U.S. affiliates. In addition, the new limitations on interest deductibility are unlikely to materially impact us on the basis of our current financing arrangements. We expect a modest positive improvement to our effective tax rate as a result of the Act. We continue to expect our effective tax rate to fluctuate in the near-term due to the distribution of our profit and losses between the jurisdictions in which we operate. Under the Act, the repeal of the alternative minimum tax and the immediate expensing of certain capital investments will provide near-term cash flow benefits, however, the required capitalization of \$174 R&D expenses beginning in 2022 will have an unfavorable cash flow impact. Our position with respect to the valuation allowance held against our deferred tax assets and undistributed foreign earnings does not change as a result of the Act. We will continue to evaluate the future impact of the Act and will update our disclosures as additional information and interpretive guidance becomes available and management’s analysis evolves.

At December 31, 2017, we maintained a valuation allowance of \$9.4 million against certain U.S. state deferred tax assets and \$163.4 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, 2017, we had \$1.2 billion of Irish NOL carryforwards, \$5.9 million of U.S. state NOL carryforwards, \$57.5 million of federal R&D credits, \$10.0 million of alternative minimum tax credits and \$11.9 million of U.S. state tax credits which either expire on various dates through 2037 or can be carried forward indefinitely. These loss and credit carryforwards are available to reduce certain future Irish and U.S. taxable income and tax and in the case of the alternative minimum tax credits, may be refundable. These loss and credit carryforwards are subject to review and possible adjustment by the appropriate taxing authorities. These loss and credit carryforwards, which may be utilized in a future period, may be subject to limitations based upon changes in the ownership of our ordinary shares.

## Liquidity and Capital Resources

Our financial condition is summarized as follows:

(In millions)	December 31, 2017	December 31, 2016
Cash and cash equivalents . . . . .	\$191.3	\$186.4
Investments—short-term . . . . .	242.2	310.9
Investments—long-term . . . . .	157.2	121.9
Total cash and investments . . . . .	<u>\$590.7</u>	<u>\$619.2</u>
Outstanding borrowings—short and long-term . . . . .	<u>\$281.4</u>	<u>\$283.7</u>

At December 31, 2017, our investments consisted of the following:

(In millions)	Amortized Cost	Gross Unrealized		Estimated Fair Value
		Gains	Losses	
Investments—short-term . . . . .	\$242.7	\$ —	\$(0.5)	\$242.2
Investments—long-term available-for-sale . . . . .	154.3	—	(0.8)	153.5
Investments—long-term held-to-maturity . . . . .	3.5	0.2	—	3.7
Total . . . . .	<u>\$400.5</u>	<u>\$0.2</u>	<u>\$(1.3)</u>	<u>\$399.4</u>

### Sources and Uses of Cash

We generated \$19.2 million and used \$63.8 million of cash from operating activities during the years ended December 31, 2017 and 2016, 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. In addition, Term Loan B-1 has an incremental facility capacity in an amount of \$140.0 million, plus additional amounts as long as we meet certain conditions, including a specified leverage ratio.

Our investment objectives are, first, to preserve liquidity and conserve capital and, second, to generate investment income. We mitigate credit risk in our cash reserves by maintaining a well-diversified portfolio that limits the amount of investment exposure as to institution, maturity and investment type. Our available-for-sale investments consist primarily of short- and long-term U.S. government and agency debt securities and corporate debt securities. We classify available-for-sale investments in an unrealized loss position, which do not mature within 12 months, as long-term investments. We have the intent and ability to hold these investments until recovery, which may be at maturity, and it is more-likely-than-not that we would not be required to sell these securities before recovery of their amortized cost. At December 31, 2017, 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, 2017 and 2016:

(In millions)	<u>Year Ended December 31, 2017</u>	<u>Year Ended December 31, 2016</u>
Cash and cash equivalents, beginning of period . .	\$186.4	\$181.1
Cash provided by (used in) operating activities .	19.2	(63.8)
Cash (used in) provided by investing activities .	(18.4)	127.2
Cash provided by (used in) by financing activities . . . . .	<u>4.1</u>	<u>(58.1)</u>
Cash and cash equivalents, end of period . . . . .	<u>\$191.3</u>	<u>\$186.4</u>

*Operating Activities*

The increase in cash provided by operating activities in 2017, as compared to 2016, was primarily due to a 21% increase in the amount of cash collected from our customers and a 46% decrease in the amount of taxes paid during the year, partially offset by a 17% increase in the amount of cash paid to our employees and a 6% increase in the amount of cash paid to our suppliers. The increase in the amount of cash we collected from our customers is primarily due to the increase in revenues in 2017, as compared to 2016. 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*

The increase in cash used in investing activities in 2017, as compared to 2016, was primarily due to an 15% increase in property, plant and equipment additions and a 2% decrease in net sales of investments. This was partially offset by a \$15.0 million investment in Reset Therapeutics, Inc., that we made in 2016. The increase in capital spending was primarily due to the timing of our capital projects, primarily 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, 2017 primarily include capital expenditures at our manufacturing facility in Wilmington, Ohio. We expect to spend approximately \$85.0 million during the year ended December 31, 2018 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 provided by financing activities in 2017, as compared to 2016, 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 2017, our financing activities consisted of \$7.1 million in cash received from our employees related to stock option exercises and \$3.0 million in principal payments we made under Term Loan B-1.



## **Borrowings**

At December 31, 2017, our borrowings consisted of \$284.3 million outstanding under Term Loan B-1. Please refer to Note 5, *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, 2017:

<u>Contractual Obligations</u>	<u>Total</u>	<u>Less Than One Year (2018)</u>	<u>One to Three Years (2019 - 2020)</u>	<u>Three to Five Years (2021 - 2022)</u>	<u>More than Five Years (After 2022)</u>
			(In thousands)		
Term Loan B-1—Principal . . . . .	\$284,250	\$ 3,000	\$ 6,000	\$275,250	\$ —
Term Loan B-1—Interest . . . . .	46,454	12,571	24,742	9,141	—
Operating lease obligations . . . . .	31,928	9,174	15,496	3,643	3,615
Purchase obligations . . . . .	473,868	473,868	—	—	—
Total contractual cash obligations . . . . .	<u>\$836,500</u>	<u>\$498,613</u>	<u>\$46,238</u>	<u>\$288,034</u>	<u>\$3,615</u>

As interest on Term Loan B-1 is based on a one, three or six month LIBOR rate of our choosing, we are using the three-month LIBOR rate, which was 1.69% at December 31, 2017 as this exceeds the LIBOR rate floor under the terms of Term Loan B-1 and is the frequency in which we make interest payments. 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, 2017, we had \$5.5 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, 2017, 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 (at December 31, 2016: none).

## **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 50% of our investments at December 31, 2017 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, 2017, our borrowings consisted of \$284.3 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%. We are using the three-month LIBOR rate, which was 1.69% at December 31, 2017. A 10% increase in the three-month LIBOR rate would have increased the amount of interest we owe under this agreement during the year ended December 31, 2017 by approximately \$0.4 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 licensees 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, 2017, 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 \$26.8 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 partially offset by the opposite impact of changes in the exchange ratio of the USD and the Euro on operating expenses and payables incurred at our Irish operations that are settled in Euro. For the year ended December 31, 2017, 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 \$6.9 million.

## **Principal Risks**

*You should consider carefully the risks described below in addition to the financial and other information contained in this Annual Report, including the matters addressed under the caption “Cautionary Note Concerning Forward-Looking Statements.” If any events described by the following risks actually occur, they could materially adversely affect our business, financial condition, cash flows or results of operations. This could cause the market price of our ordinary shares to decline.*

***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 using our proprietary technologies and from which we receive manufacturing and/or royalty revenue to the market and successfully commercializing them. We rely on these licensees in various respects, including commercializing such products; providing funding for development programs and conducting pre-clinical testing and clinical trials with respect to new formulations or other development activities for such products; and managing the regulatory approval process.

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 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 and FAMPYRA, respectively. AstraZeneca is responsible for commercializing BYDUREON and BYDUREON BCise. We have no involvement in the commercialization efforts for such products. Our revenues may fall below our expectations, the expectations of our licensees or those of investors, which could have a material adverse effect on our results of operations and the market 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 manufacturing and/or royalty 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 our key products.***

We depend substantially upon continued sales of INVEGA SUSTENNA/XEPLION, INVEGA TRINZA/TREVICTA and RISPERDAL CONSTA by Janssen, upon continued sales of AMPYRA/FAMPYRA by Acorda and its sublicensee, Biogen, and upon our continued sales of VIVITROL and ARISTADA. 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:

- the perception of physicians and other members of the healthcare community as to our products' safety and efficacy relative to that of competing products and the willingness or ability of physicians and other members of the healthcare community to prescribe or dispense, and patients to use, our products, including those that may be scheduled by the DEA (if and when approved);
- unfavorable publicity concerning us or our products, similar classes of drugs or the industry generally;
- 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;
- 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, including Paragraph IV litigation relating to INVEGA SUSTENNA and AMPYRA;
- 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 and oral antidepressants than our competitors.***

In October 2015, we launched ARISTADA into a highly competitive market in which it competes head-to-head with products marketed and sold by companies larger than us and with more experience than us in the commercialization of long-acting injectable atypical antipsychotic products for the treatment of schizophrenia.

We lack experience commercializing products in markets with multiple branded and generic competitors, including schizophrenia and depression and will face competition from companies with more experience and resources than we have.

If we are not able to attract and retain qualified personnel to serve in our sales and marketing organization, to maintain effective distribution networks and reimbursement for our products, or to otherwise effectively and efficiently support our commercialization activities, we may not be able to successfully commercialize our products 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 the FDA's or regulatory agencies' 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 licensees interpret it;
- the FDA or other regulatory agencies may not agree with our or our licensees' regulatory approval strategies, components of our or our licensees' filings, such as clinical trial designs, conduct and methodologies, or the sufficiency of our or our licensees' submitted data;
- the FDA or other regulatory agencies might not approve our or our licensees' manufacturing processes or facilities;
- the FDA or other regulatory agencies may not approve accelerated development timelines for our products;
- 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; and
- 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.

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 and could materially adversely affect our business, financial condition, cash flows and results of operations.

***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 licensees 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 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 or concerns, including those of 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 Europe and Israel. 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.

***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 BYDUREON BCise 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 and 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 using our technologies are granted to, or retained by, our third-party licensee (for example, in the cases of INVEGA SUSTENNA/XEPLION, INVEGA TRINZA/TREVICTA, BYDUREON and BYDUREON BCise) or approved sub-licensee, we have no control over the manufacturing, supply or distribution of the product. Supply or manufacturing issues encountered by such licensees or sublicenses could materially and adversely affect sales of products from which we receive revenue, 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 third-party providers 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 by us or our third-party providers 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, the existence of barriers to coverage of our products (such as prior authorization, criteria for use or other requirements), increases in our financial obligation to government payers (including due to changes in our AMP calculation), 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 2017, the State of California enacted as law SB-17, a drug pricing transparency bill that requires, among other things, that manufacturers notify the state and health insurers, and justify, any time such manufacturers plan to increase the price of a medication by sixteen percent (16%) or more over a two-year period. We expect similar state drug pricing initiatives to be proposed in 2018. 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 2018, we may face uncertainties as a result of likely continued federal and administrative efforts to repeal, substantially modify or invalidate some or all of the provisions of 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 our licenses;
- 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 and products. Our pending patent applications, together with those we may file in the future, or those we may license to or 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 third 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. There may be patents issued to third parties that relate to our products. There may also be patent applications filed by third parties that relate to some of our products. If patents exist or 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 business, financial condition, cash flows and results of operations could be materially adversely affected.

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, and those of our licensees, 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., and 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 biopharmaceutical industry has been the source of litigation, which is inherently costly and unpredictable.***

There is considerable uncertainty within the biopharmaceutical 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 or our licensees may



face claims against our intellectual property rights covering our products 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.

***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 our 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).

***The FDA or other regulatory agencies may impose limitations or post-approval requirements on any product approval.***

Even if regulatory approval to market a product is granted by the FDA or other regulatory agencies, the approval may impose limitations on the indicated use for which the product may be marketed or additional post-approval requirements with which we would need to comply in order to maintain the approval of such product. Our business could be seriously harmed if we do not complete these post-approval requirements and the FDA or other regulatory agencies, as a result, require us to change the label for our products.



Further, if a product for which we obtain regulatory approval is a controlled substance it 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 may change after its initial designation. We currently expect ALKS 5461 and ALKS 3831 to require such DEA final schedule designation prior to commercialization. A restrictive designation could adversely affect our ability to commercialize such products and could materially adversely affect our business, financial condition, cash flows and results of operations.

In addition, legislative and regulatory proposals have also been made to expand post-approval requirements and restrict sales and promotional activities for pharmaceutical products. We cannot be sure whether additional legislative changes will be enacted, or whether the FDA regulations, guidance or interpretations will be changed, or what the impact of such changes on the commercialization of our products, if any, may be.

***Litigation or arbitration against Alkermes, including securities litigation, or citizen petitions filed with the FDA, may result in financial losses, harm our reputation, divert management resources, negatively impact the approval of our products, or otherwise negatively impact our business.***

We may be the subject of certain claims, including those asserting violations of securities and fraud and abuse laws and derivative actions. Following periods of volatility in the market price of a company's securities, securities class action litigation has often been instituted against companies. In November 2017, a purported stockholder of ours filed a putative class action against us and certain of our officers on behalf of a putative class of purchasers of our securities during the period of February 24, 2015 to November 3, 2017. Such action alleges violations of Sections 10(b) and 20(a) of the Exchange Act based on allegedly false or misleading statements and omissions regarding our marketing practices related to VIVITROL, and seeks to recover unspecified damages for alleged inflation in the price of securities, and reasonable costs and expenses, including attorneys' fees. For further discussion of this putative class action, see Note 17, *Commitments and Contingencies* in the "Notes to Condensed Consolidated Statements" and "Item 3—Legal Proceedings" in this Annual Report. This punitive class action and any similar future litigation could result in substantial costs and a diversion of management's attention and resources, which could harm our business.

In June 2017, we received a subpoena from an Office of the U.S. Attorney for documents related to VIVITROL. We are cooperating with the government. If, as a result of the government's request, proceedings are initiated and we are found to have violated one or more applicable laws, we may be subject to significant liability, including without limitation, civil fines, criminal fines and penalties, civil damages and exclusion from federal funded healthcare programs such as Medicare and Medicaid, as well as potential liability under the federal anti-kickback statute and False Claims Act and state False Claims Acts, and be required to enter into a corporate integrity or other settlement with the government, any of which could materially affect our reputation, business, financial condition, cash flows and results of operations. Conduct giving rise to such liability could also form the basis for private civil litigation by third-party payors or other persons allegedly harmed by such conduct. In addition, if some of our existing business practices are challenged as unlawful, we may have to change those practices, including changes and impacts on the practices of our sales force, which could also have a material adverse effect on our business, financial condition, cash flows and results of operations.

We may not be successful in defending ourselves in litigation or arbitration which may result in large judgments or settlements against us, any of which could have a negative effect on our business, financial condition, cash flows and results of operations. Additionally, lawsuits can be expensive to defend, whether or not they have merit, and the defense of these actions may divert the attention of our management and other resources that would otherwise be engaged in managing our business. Our liability insurance coverage may not be sufficient to satisfy, or may not cover, any expenses or liabilities that may arise.

We may also be the subject of citizen petitions that request that the FDA refuse to approve, delay approval of, or impose additional approval requirements for our NDAs. If successful, such petitions can significantly delay, or even prevent, the approval of the NDA in question. Even if the FDA ultimately denies such a petition, the FDA may substantially delay approval while it considers and responds to the petition or impose additional approval requirements as a result of such petition. These outcomes and others could adversely affect our ability to generate revenues from the commercialization and sale of our products and products using our proprietary technologies, and our share price.

***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 approvals 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 the manufacture and sale of products, and other civil or criminal sanctions, including fines and penalties. Biopharmaceutical 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 applicable U.S. federal and state regulations and/or laws or all 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 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, 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, could also adversely affect our revenues and our potential to be profitable. The enactment in the U.S. of healthcare reform and 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. The costs of prescription pharmaceuticals in the United States has also been the subject of considerable discussion in the U.S. and the current administration has stated that it will address such

costs through new legislative and administrative measures. These measures, if adopted, could impact our ability to generate revenues from our products.

*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 and biopharmaceutical companies, including other companies with similar technologies, and manufacturers of generic drugs (see “—We or our licensees may face claims against our intellectual property rights covering our products 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/or 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 biopharmaceutical industry is 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 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 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 and Indivior plc, which is developing a once-monthly injectable risperidone for the treatment of schizophrenia. 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, ABILIFY MAINTENA, 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 SUBOXONE (buprenorphine HCl/naloxone HCl dehydrate sublingual tablets), SUBOXONE (buprenorphine/naloxone) Sublingual Film, SUBUTEX (buprenorphine HCl sublingual tablets) and, once launched, will compete with SUBLOCADE (once-monthly buprenorphine extended-release injection), each of which is, or will be, marketed and sold by Indivior plc, and BUNAVAIL buccal film (buprenorphine and naloxone) marketed by BioDelivery Sciences, PROBUPHINE (buprenorphine) from Titan Pharmaceuticals, Inc. and ZUBSOLV (buprenorphine and naloxone) marketed by Orexo US, Inc. It also competes with methadone, oral naltrexone and 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 and BYDUREON BCise compete 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 and BYDUREON BCise also compete 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 and BYDUREON BCise.

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; OCREVUS from Genentech; 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, including potential generic versions of AMPYRA.

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

If we are unable to compete successfully in the biopharmaceutical industry, our business, financial condition, cash flows and results of operations could be materially adversely affected.

***We or our licensees may face claims against intellectual property rights covering our products and competition from generic drug manufacturers.***

In the U.S., generic manufacturers of innovator drug products may file ANDAs and, in connection with such filings, 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 in the U.S. as “Paragraph IV” litigation.

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 Note 17, *Commitments and Contingencies* in the “Notes to Condensed Consolidated Statements.”

Similarly, Janssen Pharmaceuticals NV and Janssen Pharmaceuticals, Inc. initiated a patent infringement lawsuit against Teva, who filed an ANDA seeking approval to market a generic version of INVEGA SUSTENNA. For a discussion of the legal proceedings related to the patents covering INVEGA SUSTENNA, see Note 17, *Commitments and Contingencies* in the “Notes to Condensed Consolidated Statements.”

Although we intend to vigorously enforce our intellectual property rights, and we expect our licensees will do the same, there can be no assurance that we or our licensees will prevail in our defense of our patent rights. Our and our licensees’ existing patents could be invalidated, found unenforceable or found not to cover generic forms of our or our licensees’ 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 business, financial condition, cash flows and results of operations could be materially 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). Our product liability insurance coverage may not be sufficient to satisfy any liabilities that may arise. As our development activities progress and we continue to have commercial sales, this product liability insurance coverage may be inadequate, we may be unable to obtain adequate coverage at an acceptable cost or at all, or our insurer may disclaim coverage as to a future claim. This could prevent or limit our commercialization of our products. 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. These types of events could have a material adverse effect on our business, financial condition, cash flows and results of operations.

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

Our business involves the 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 these 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, 2017, our accumulated deficit was \$1,044.4 million, which was primarily the result of net losses incurred from 1987, the year Alkermes, Inc., was founded, through December 31, 2017, partially offset by net income over certain fiscal periods. There can be no assurance we will achieve sustained profitability.

A major component of our revenue is dependent on our licensees' and our ability to commercialize, and our and our licensees' ability to manufacture economically, our 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. and any other products that may be approved in the U.S. or in other countries;
- 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 other 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.

***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 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 licensees 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 “Item 7A—Quantitative and Qualitative Disclosures about Market Risk” 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, 2017, we have \$256.2 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 and results of operations.

***Our deferred tax assets may not be realized.***

As of December 31, 2017, we had approximately \$98.5 million in net deferred tax assets in the U.S. Included in this amount is approximately \$52.0 million of research and development tax credit carryforwards that can be used to offset federal tax in future periods. These carryforwards will expire within the next twenty years, with the earliest expiration occurring in 2020. It is possible that some or all of the deferred tax assets will not be realized, especially if we incur losses in the U.S. in the future. Losses may arise from unforeseen operating events (see “—We may not become profitable on a sustained basis” for additional information relating to operating losses) or the occurrence of significant excess tax benefits arising from the exercise of stock options and/or the vesting of restricted stock units. Unless we are able to generate sufficient taxable income in the future, a substantial valuation allowance to reduce the carrying value of our U.S. deferred tax assets may be required, which would materially increase our expenses in the period the allowance is recognized and materially adversely affect our business, financial condition and results of operations.

***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 businesses 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 \$274.0 million of U.S. federal net operating loss (“NOL”) carryforwards and

\$38.0 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 biopharmaceutical industry over the last few years. If faced with a proxy contest, we may not be able to respond successfully to the contest, which would be disruptive to our business. Even if we are successful, our business could be adversely affected by a proxy contest involving us because:

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

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

***If any of our 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.

***We may be subject to numerous and varying privacy and security laws, and our failure to comply could result in penalties and reputational damage.***

We are subject to laws and regulations covering data privacy and the protection of personal information, including health information. The legislative and regulatory landscape for privacy and data protection continues to evolve, and there has been an increasing focus on privacy and data protection issues which may affect our business. In the U.S., numerous federal and state laws and regulations, including state security breach notification laws, state health information privacy laws, and federal and state consumer protection laws, govern the collection, use, disclosure, and protection of personal information. Each of these laws is subject to varying interpretations by courts and government agencies, creating complex compliance issues for us. If we fail to comply with applicable laws and regulations we could be subject to penalties or sanctions, including criminal penalties if we knowingly obtain or disclose individually identifiable health information from a covered entity in a manner that is not authorized or permitted by the Health Insurance Portability and Accountability Act of 1996, as amended by the Health Information Technology for Economic and Clinical Health Act, or HIPAA.

Numerous other countries have, or are developing, laws governing the collection, use and transmission of personal information as well. The EC and other jurisdictions have adopted data protection laws and regulations, which impose significant compliance obligations. For example, the EC adopted the EU Data Protection Directive, as implemented into national laws by the EU member states, which imposes strict obligations and restrictions on the ability to collect, analyze, and transfer personal data, including health data from clinical trials and adverse event reporting. Data protection authorities from different EU member states have interpreted the privacy laws differently, which adds to the complexity of processing personal data in the EU, and guidance on implementation and compliance practices are often updated or otherwise revised. In 2016, the EU formally adopted the General Data Protection Regulation, or GDPR, which will apply in all EU member states effective May 25, 2018 and will replace the current EU Data Protection Directive effective on that date. The GDPR introduces new data protection requirements in the EU and substantial fines for breaches of the data protection rules. The GDPR will increase our responsibility and liability in relation to personal data that we process and we may be required to put in place additional mechanisms to ensure compliance with the new EU data protection rules. Any failure to comply with the rules arising from the EU Data Protection Directive, the GDPR, and related national laws of EU member states, could lead to government enforcement actions and significant penalties against us, and could adversely affect our business, financial condition, cash flows and results of operations.

***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 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 2018, 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 include 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**

See Note 25, *Subsequent Events*, for information regarding events since the end of the financial year.

## Directors and Secretary

The names of the persons who were directors or secretary at any time during the year ended December 31, 2017 or since December 31, 2017 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)
Shane Cooke . . . . .	(Appointed March 30, 2018)
Wendy L. Dixon . . . . .	(Reappointed May 25, 2016)
Paul J. Mitchell . . . . .	(Reappointed May 24, 2017)
Richard F. Pops . . . . .	(Reappointed May 24, 2017)
Nancy L. Snyderman . . . . .	(Appointed May 25, 2016)
Nancy J. Wysenski . . . . .	(Reappointed May 27, 2015)
 <u>Secretary</u>	
Kathryn L. Biberstein . . . . .	(Appointed September 16, 2011, Resigned December 12, 2017)
David J. Gaffin . . . . .	(Appointed December 12, 2017)

## Acquisition or Disposal of Own Shares

<u>Own shares held by the Company (par value, \$0.01 per share) (Value in thousands)</u>	<u>Number</u>	<u>Value</u>
January 1, 2017 . . . . .	1,760,767	\$72,639
Acquired during the year . . . . .	287,409	16,708
December 31, 2017 . . . . .	<u>2,048,176</u>	<u>\$89,347</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 (at December 31, 2016: none). 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 22, *Directors' Remuneration*, of the consolidated financial statements. The interests of the directors and secretary in office at

December 31, 2017 and 2016 in the ordinary share capital of Alkermes plc are shown in the table below.

	Ordinary Shares <sup>(1)</sup> At December 31, 2017			Ordinary Shares <sup>(1)</sup> At January 1, 2017		
	Shares	Options	Restricted Share Units	Shares	Options	Restricted Share Units
<b>Directors</b>						
David W. Anstice . . . . .	55,000	191,800	—	15,000	217,600	—
Floyd E. Bloom . . . . .	147,923	191,800	—	128,881	197,600	—
Robert A. Breyer . . . . .	7,156	147,200	—	15,156	133,000	—
Wendy L. Dixon . . . . .	1,600	186,800	—	1,600	172,600	—
Paul J. Mitchell . . . . .	8,000	194,800	—	8,000	197,600	—
Richard F. Pops . . . . .	637,686	3,295,000	203,000	608,962	3,245,000	139,750
Nancy L. Snyderman . . . . .	—	57,800	—	—	43,600	—
Nancy J. Wysenski . . . . .	—	143,050	—	—	128,850	—
<b>Company Secretary</b>						
Kathryn L. Biberstein . . . . .	154,097	789,862	65,750	132,687	767,370	45,000
David J. Gaffin . . . . .	31,407	202,275	36,700	24,957	167,275	16,050

(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 2017.

#### Subsidiary Companies and Branches

Information regarding our subsidiaries is provided in Note 24, *Subsidiaries*, to the consolidated financial statements.

#### Going Concern

The board of directors has formed a judgment at the time of approving the financial statements that there is a reasonable expectation that the Company has adequate resources to continue in operational existence for the foreseeable future. In arriving at this conclusion, the board of directors 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's financial statements.

#### Annual General Meeting

The Annual General Meeting of the Company will take place at Connaught House, 1 Burlington Road, Dublin 4, Republic of Ireland on May 23, 2018. 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 and Risk Committee

The Company has established an Audit and Risk Committee.

## **Statutory Auditors**

The independent statutory auditors, PricewaterhouseCoopers 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 2017, 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 9, 2018

**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 of the UK, including Financial Reporting Standard 102 the Financial Reporting Standard applicable in the UK and Republic of Ireland 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 audit of the financial statements**

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#### **Opinion**

In our opinion:

- Alkermes plc's consolidated financial statements and company financial statements (the "financial statements") give a true and fair view of the group's and the company's assets, liabilities and financial position as at December 31, 2017 and of the group's loss and cash flows for the year then ended;
- the consolidated 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 group financial statements does not contravene any provision of Part 6 of the Companies Act 2014;
- the company financial statements have been properly prepared in accordance with Generally Accepted Accounting Practice in Ireland (accounting standards issued by the Financial Reporting Council of the UK, including Financial Reporting Standard 102 "The Financial Reporting Standard applicable in the UK and Republic of Ireland" and promulgated by the Institute of Chartered Accountants in Ireland and Irish law); and
- the financial statements have been properly prepared in accordance with the requirements of the Companies Act 2014.

We have audited the financial statements, included within the Directors' Report and Consolidated Financial Statements (the "Annual Report"), which comprise:

- the Consolidated Balance Sheet as at December 31, 2017;
- the Consolidated Profit and Loss Account for the year then ended;
- the Consolidated Statement of Comprehensive Loss for the year then ended;
- the Consolidated Statement of Cash Flows for the year then ended;
- the Consolidated Reconciliation of Movement in Shareholders' Funds for the year then ended;
- the Notes to the Consolidated Financial Statements, which include a summary of significant accounting policies;
- the Company Balance Sheet as at December 31, 2017;
- the Company Reconciliation of Movement in Shareholders' Funds for the year then ended; and
- the Notes to the Company Financial Statements, which include a summary of significant accounting policies.

Certain required disclosures have been presented elsewhere in the Annual Report, rather than in the notes to the financial statements. These are cross-referenced from the financial statements and are identified as audited.

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#### **Basis for opinion**

We conducted our audit in accordance with International Standards on Auditing (Ireland) ("ISAs (Ireland)") and applicable law. Our responsibilities under ISAs (Ireland) are further described in the Auditors' responsibilities for the audit of the financial statements section of our report. We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our opinion.

#### *Independence*

We remained independent of the group in accordance with the ethical requirements that are relevant to our audit of the financial statements in Ireland, which includes IAASA's Ethical Standard as applicable to listed entities, and we have fulfilled our other ethical responsibilities in accordance with these requirements.



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## Our audit approach

### Overview

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#### The scope of our audit



#### Materiality

- Overall group materiality: \$9 million (2016: \$10 million) which represents circa. 5% of income from continuing operations before income taxes, adjusted for discrete items, primarily initial Biogen license and collaboration agreement income.
- Company materiality: \$26 million (2016: \$26 million) which represents circa. 1% of net assets. For group and audit purposes, the lower group materiality of \$9 million was applied to all balances and transactions that did not eliminate on consolidation in the consolidated financial statements.

#### Audit Scope

- The group has one reportable segment and consisting of two primary geographic reporting components – United States (“U.S.”) and Ireland.
- We conducted full scope audits on both reporting components. We paid particular attention to these components due to their size or characteristics and to ensure appropriate audit coverage.
- Taken together, the territories and functions where we performed our audit accounted for 100% of group revenues, 100% of income before income taxes and 100% of group total assets.

#### Key Audit Matters

- Fair value of contingent consideration
- Rebates, discounts, chargebacks, allowances and returns in the U.S. biopharmaceutical industry, specifically the Medicaid Drug Rebate Program
- Realisability of deferred tax assets

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As part of designing our audit, we determined materiality and assessed the risks of material misstatement in the financial statements. In particular, we looked at where the directors made subjective judgements, for example in respect of significant accounting estimates that involved making assumptions and considering future events that are inherently uncertain. As in all of our audits we also addressed the risk of management override of internal controls, including evaluating whether there was evidence of bias by the directors that represented a risk of material misstatement due to fraud.

#### Key audit matters

Key audit matters are those matters that, in the auditors’ professional judgement, were of most significance in the audit of the financial statements of the current period and include the most significant assessed risks of material misstatement (whether or not due to fraud) identified by the auditors, including those which had the greatest effect on: the overall audit strategy; the allocation of resources in the audit; and directing the efforts of the engagement team. These matters, and any comments we make on the results of our procedures thereon, were addressed in the context of our audit of the financial statements as a whole, and in forming our opinion thereon, and we do not provide a separate opinion on these matters. This is not a complete list of all risks identified by our audit.



Key audit matter	How our audit addressed the key audit matter
<p><b>Fair value of contingent consideration</b>  <i>Refer to note 2 "summary of significant accounting policies and statement of compliance", note 6 "fair value" and note 11 "debtors".</i></p> <p>As discussed in Note 2 and Note 6 to the consolidated financial statements, the group recognizes contingent consideration at fair value on the acquisition date and revalues the contingent consideration at each reporting period, with changes in the fair value of contingent consideration recognized within the Consolidated Profit and Loss Account.</p> <p>The fair value is estimated through fair value models that incorporate probability-adjusted assumptions related to regulatory approvals, discount factors, risk-adjusted expected growth rates, and estimated expected future sales. The group utilizes a third party valuation expert in preparation of its fair value models. The group's estimate of the fair value of the contingent consideration is considered a critical accounting estimate.</p> <p>We focused on this area primarily due to the quantitative significance of the contingent consideration balance, which is associated with the group's Gainesville Transaction (\$84.8 million as of December 31, 2017) and because the valuation models used by management in determining the fair value are complex, highly judgmental and incorporate probability-adjusted assumptions related to regulatory approvals, discount factors, risk-adjusted expected growth rates, and estimated expected future sales.</p>	<ul style="list-style-type: none"> <li>• We obtained an understanding of management's process for determining the fair value of contingent consideration, including the valuation models and key assumptions.</li> <li>• We tested key controls over management's preparation and review of key assumptions.</li> <li>• We read and considered management's valuation report that was prepared with the assistance of a third party valuation expert.</li> <li>• We tested the appropriateness of the fair values assigned to the regulatory milestone, future royalties on net sales earn-out, and commercial milestones, together known as the contingent consideration, by assessing key assumptions such as: <ul style="list-style-type: none"> <li>○ the likelihood and expected timing of achieving the regulatory milestone by considering events to date and industry studies;</li> <li>○ projected net sales by considering the group's forecasts and external industry studies; and</li> <li>○ the discount rates applied to each element of the contingent consideration by reference to external market data.</li> </ul> </li> <li>• We evaluated and considered management's sensitivity analyses to ascertain the impact of reasonably possible changes in key assumptions and we performed our own independent sensitivity calculations to quantify the changes to management's models which could result in material changes to the fair value. Furthermore, we utilized a valuation specialist to assist with these procedures.</li> <li>• We also tested the mathematical accuracy of the valuation models and considered the appropriateness of these valuation models.</li> <li>• We evaluated the adequacy of the group's presentation and disclosure of the contingent consideration within the consolidated financial statements.</li> </ul>



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**Rebates, discounts, chargebacks, allowances and returns in the U.S. biopharmaceutical industry, specifically Medicaid Drug Rebate Program**

*Refer to note 2 "summary of significant accounting policies and statement of compliance".*

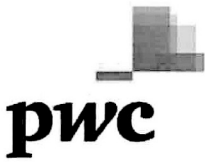
As outlined in Note 2 to the consolidated financial statements, the group makes sales to customers in the U.S. that fall under certain commercial and governmental reimbursement programs, of which the most significant is the Medicaid Drug Rebate Program.

Rebate provisions are recorded in the same period the related revenue is recognized, resulting in a reduction of product revenue and a rebate liability that is included in provisions for liabilities. Refer to Note 15 for details of the provision for liabilities movement.

We focused on this area due to the quantitative significance of the Medicaid Drug Rebate balance (\$89.8 million as of December 31, 2017) and because in the U.S. biopharmaceutical industry estimating the rebates is complex and require significant judgment.

In particular, we focused on the key assumptions utilized in the determination of the Medicaid Rebate provision. Those key assumptions primarily relate to, but are not limited to, the proportion of the inventory sold that will result in a Medicaid rebate claim.

- We obtained an understanding of management's process and methodology for determining the Medicaid rebates.
- We tested management's controls in the order-to-cash transaction cycle, including controls involving reconciliations between sales systems and the general ledger, claims and credits.
- We assessed the key assumptions by comparing the current forecasts of Medicaid units used by management to develop the estimate to historical trends.
- We performed an analysis of the rebate balance and deductions to sales year over year, assessed management's model, and considered the historical accuracy of the provision.
- We tested the mathematical accuracy of the calculation of the provision.
- We also evaluated the adequacy of the group's presentation and disclosure of its rebates policy, the judgements involved, and other related disclosures for the Medicaid Drug Rebate Program in the consolidated financial statements.



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**Realisability of Deferred Tax Assets**

*Refer to note 2 "summary of significant accounting policies and statement of compliance" and note 7 "income taxes".*

Note 2 and Note 7 to the consolidated financial statements, which detail the group's disclosure regarding income taxes, includes financial information related to deferred tax assets and the related valuation allowances. As set out in note 7, the deferred tax asset is \$129.3 million, net of a valuation allowance of \$172.8 million, primarily related to the Irish NOL carryforwards.

The recognized deferred tax assets relate primarily to the group's U.S. operations. We focused on this area primarily due to the quantitative significance of the deferred tax assets and related valuation allowance balances (deferred tax asset of \$107.8 million, net of a valuation allowance of \$9.4 million as of December 31, 2017) and because there is judgment in determining whether it is more-likely-than-not that the net deferred tax assets will be realised.

In particular, we focused on the evaluation and judgements made in assessing the likely future tax consequences of events that have been recognized in the group's consolidated financial statements or tax returns and estimating future profitability. A key assumption underlying this judgement is the estimate of tax benefits that could arise from the future exercise of stock options and/or the vesting of RSUs.

- We obtained management's analysis supporting its position regarding the positive and negative factors supporting the realisability of the deferred tax assets and utilized our tax specialists to assist in the evaluation of this analysis.
- We evaluated the rolling three years of actual and current year anticipated results to determine if the recoverability of deferred tax assets has changed and if a valuation allowance against the U.S. deferred tax assets may be required in part or in whole.
- We considered the U.S.'s forecast of future book income plus permanent items including the amount of built-in excess stock-based compensation deductions. As part of this process we agreed the forecast to the Board of Directors approved forecast. In addition, we compared the group's Board of Directors approved forecast to third-party analyst reports to assess the reasonableness of the group's revenue assumptions. Furthermore, we assessed the U.S.'s scheduling of utilizations of tax credits to assess the risk that any credits would expire unutilized.
- We evaluated and considered the correspondence with tax authorities and utilized our tax specialists to assist in analyzing the judgments used to determine provisions for tax matters based on their knowledge and experience of local regulations and practices.
- We evaluated the adequacy of the group's presentation and disclosure of the income tax policies and tax balances within the consolidated financial statements.



*How we tailored the audit scope*

The group is structured along two primary geographic reporting components – U.S. and Ireland. The consolidated financial statements are a consolidation of the two components and 16 legal entities.

We tailored the scope of our audit to ensure that we performed enough work to be able to give an opinion on the financial statements as a whole, taking into account the structure of the group, the accounting processes and controls, and the industry in which the group operates.

In determining our audit scope we first focused on individual reporting components and determined the type of work that needed to be performed at the reporting components by us, as the Irish group engagement team and PwC U.S. as the global engagement team.

Overall through the use of full scope audits and directed scope audits, we obtained coverage of 100% of group revenues, 100% of income before income taxes and 100% of group total assets. We allocated materiality levels and issued instructions to each component auditor. In addition to the audit report from each of the component auditors, we received detailed memoranda of examinations on work performed and relevant findings which supplemented our understanding of the component, its results and the audit findings and we participated in a number of local audit closing meetings. This together with additional procedures performed at a group level, gave us the evidence we needed for our opinion on the financial statements as a whole.

*Materiality*

The scope of our audit was influenced by our application of materiality. We set certain quantitative thresholds for materiality. These, together with qualitative considerations, helped us to determine the scope of our audit and the nature, timing and extent of our audit procedures on the individual financial statement line items and disclosures and in evaluating the effect of misstatements, both individually and in aggregate on the financial statements as a whole.

Based on our professional judgement, we determined materiality for the financial statements as a whole as follows:

	Group financial statements	Company financial statements
<i>Overall materiality</i>	\$9 million (2016: \$10 million.)	\$26 million (2016: \$26 million.)
<i>How we determined it</i>	5% of loss from continuing operations before income taxes, adjusted for discrete items, primarily initial Biogen license and collaboration agreement income.	1% of net assets. For group audit purposes, the lower group materiality of \$9 million was applied to all balances and transactions that did not eliminate on consolidation in the consolidated financial statements.
<i>Rationale for benchmark applied</i>	We deem loss before taxes for the year to be an appropriate benchmark as this benchmark is utilised by management, analysts and the general market when assessing the results of the group.	As the company is a holding company it is deemed that net assets are the most appropriate benchmark to calculate materiality.

We agreed with the Audit and Risk Committee that we would report to them misstatements identified during our audit above \$0.6 million (group audit) (2016: \$0.7 million) as well as misstatements below that amount which, in our view, warranted reporting for qualitative reasons. For the company audit our misstatement threshold was \$1.3 million (2016: \$1.3 million) as well as misstatements below that amount that, in our view, warranted reporting for qualitative reasons.

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### Conclusions relating to going concern

We have nothing to report in respect of the following matters in relation to which ISAs (Ireland) require us to report to you where:

- the directors' use of the going concern basis of accounting in the preparation of the financial statements is not appropriate; or
- the directors have not disclosed in the financial statements any identified material uncertainties that may cast significant doubt about the group's or the company's ability to continue to adopt the going concern basis of accounting for a period of at least twelve months from the date when the financial statements are authorised for issue.

However, because not all future events or conditions can be predicted, this statement is not a guarantee as to the group's or the company's ability to continue as a going concern.

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### Reporting on other information

The other information comprises all of the information in the Annual Report other than the financial statements and our auditors' report thereon. The directors are responsible for the other information. Our opinion on the financial statements does not cover the other information and, accordingly, we do not express an audit opinion or, except to the extent otherwise explicitly stated in this report, any form of assurance thereon.

In connection with our audit of the financial statements, our responsibility is to read the other information and, in doing so, consider whether the other information is materially inconsistent with the financial statements or our knowledge obtained in the audit, or otherwise appears to be materially misstated. If we identify an apparent material inconsistency or material misstatement, we are required to perform procedures to conclude whether there is a material misstatement of the financial statements or a material misstatement of the other information. If, based on the work we have performed, we conclude that there is a material misstatement of this other information, we are required to report that fact. We have nothing to report based on these responsibilities.

With respect to the Directors' Report, we also considered whether the disclosures required by the Companies Act 2014 have been included.

Based on the responsibilities described above and our work undertaken in the course of the audit, ISAs (Ireland) and the Companies Act 2014 require us to also report certain opinions and matters as described below.

In our opinion, based on the work undertaken in the course of the audit, the information given in the Directors' Report for the year ended 31 December 2017 is consistent with the financial statements and has been prepared in accordance with the applicable legal requirements.

Based on our knowledge and understanding of the group and company and their environment obtained in the course of the audit, we have not identified any material misstatements in the Directors' Report.

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### Responsibilities for the financial statements and the audit

#### *Responsibilities of the directors for the financial statements*

As explained more fully in the Statement of Directors' Responsibilities set out on page 64, the directors are responsible for the preparation of the financial statements in accordance with the applicable framework and for being satisfied that they give a true and fair view.

The directors are also responsible for such internal control as they determine is necessary to enable the preparation of financial statements that are free from material misstatement, whether due to fraud or error.



In preparing the financial statements, the directors are responsible for assessing the group's and the company's ability to continue as a going concern, disclosing as applicable, matters related to going concern and using the going concern basis of accounting unless the directors either intend to liquidate the group or the company or to cease operations, or have no realistic alternative but to do so.

*Auditors' responsibilities for the audit of the financial statements*

Our objectives are to obtain reasonable assurance about whether the financial statements as a whole are free from material misstatement, whether due to fraud or error, and to issue an auditors' report that includes our opinion. Reasonable assurance is a high level of assurance, but is not a guarantee that an audit conducted in accordance with ISAs (Ireland) will always detect a material misstatement when it exists. Misstatements can arise from fraud or error and are considered material if, individually or in the aggregate, they could reasonably be expected to influence the economic decisions of users taken on the basis of these consolidated financial statements.

A further description of our responsibilities for the audit of the financial statements is located on the Irish Auditing and Accounting Supervisory Authority website at: [https://www.iaasa.ie/getmedia/b2389013-1cf6-458b-9b8f-a98202dc9c3a/Description\\_of\\_auditors\\_responsibilities\\_for\\_audit.pdf](https://www.iaasa.ie/getmedia/b2389013-1cf6-458b-9b8f-a98202dc9c3a/Description_of_auditors_responsibilities_for_audit.pdf). This description forms part of our auditors' report.

*Use of this report*

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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**Other required reporting**

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**Companies Act 2014 opinions on other matters**

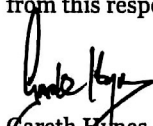
- We have obtained all the information and explanations which we consider necessary for the purposes of our audit.
- In our opinion the accounting records of the company were sufficient to permit the company financial statements to be readily and properly audited.
- The company balance sheet is agreement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

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**Companies Act 2014 exception reporting**

*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.

  
Gareth Hynes  
for and on behalf of PricewaterhouseCoopers  
Chartered Accountants and Statutory Audit Firm  
Dublin  
9 April 2018

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

	Note	Year Ended December 31,	
		2017	2016
(In thousands, except per share amounts)			
Manufacturing and royalty turnover . . . . .	3	\$ 505,308	\$ 487,247
Product sales, net . . . . .		362,834	256,146
License turnover . . . . .	3	28,000	—
Research and development turnover . . . . .	3	7,232	2,301
Total turnover . . . . .		<u>903,374</u>	<u>745,694</u>
Cost of sales . . . . .		<u>154,748</u>	<u>132,122</u>
Gross profit . . . . .		<u>748,626</u>	<u>613,572</u>
Research and development expense . . . . .		412,889	387,148
Selling, general and administrative expense . . . . .		421,578	374,130
Amortization of acquired intangible assets . . . . .	4	<u>62,059</u>	<u>60,959</u>
Operating loss . . . . .		<u>(147,900)</u>	<u>(208,665)</u>
Interest income . . . . .		4,649	3,752
Interest expense . . . . .	5	(12,008)	(14,889)
Change in the fair value of contingent consideration . . . . .	6	21,600	7,900
Other expense, net . . . . .		<u>(9,615)</u>	<u>(2,485)</u>
Total other income (expense), net . . . . .		<u>4,626</u>	<u>(5,722)</u>
Loss on ordinary activities, before income taxes . . . . .		<u>(143,274)</u>	<u>(214,387)</u>
Income tax (provision) benefit . . . . .	7	<u>(14,671)</u>	<u>5,943</u>
Loss on ordinary activities, after tax . . . . .		<u>\$(157,945)</u>	<u>\$(208,444)</u>
<b>LOSS PER ORDINARY SHARE:</b>			
Basic and diluted . . . . .	8	<u>\$ (1.03)</u>	<u>\$ (1.38)</u>
<b>WEIGHTED AVERAGE NUMBER OF ORDINARY SHARES</b>			
<b>OUTSTANDING:</b>			
Basic and diluted . . . . .	8	<u>153,415</u>	<u>151,484</u>

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

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

	<b>Year Ended December 31,</b>	
	<b>2017</b>	<b>2016</b>
	<b>(In thousands)</b>	
NET LOSS . . . . .	\$(157,945)	\$(208,444)
Unrealized (losses) gains on marketable securities:		
Holding (losses) gains, net of tax . . . . .	(518)	522
Unrealized (losses) gains on marketable securities . . . . .	(518)	522
COMPREHENSIVE LOSS . . . . .	\$(158,463)	\$(207,922)

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>2017</u>	<u>December 31,</u> <u>2016</u>
<b>ASSETS</b>			
<i>(In thousands)</i>			
<i>Fixed Assets</i>			
Intangible assets—Goodwill . . . . .	4	\$ 92,873	\$ 92,873
Intangible assets—Intellectual property . . . . .	4	256,168	318,227
Associated undertakings . . . . .	4	3,369	15,831
Tangible fixed assets . . . . .	9	<u>284,736</u>	<u>264,785</u>
Total fixed assets . . . . .		<u>637,146</u>	<u>691,716</u>
<i>Current Assets</i>			
Stock . . . . .	10	93,275	62,998
Debtors . . . . .	11	476,090	352,544
Investments . . . . .	12	399,420	432,787
Cash at bank and in-hand . . . . .		<u>191,296</u>	<u>186,378</u>
Total current assets . . . . .		<u>1,160,081</u>	<u>1,034,707</u>
<b>TOTAL ASSETS</b> . . . . .		<u><u>\$1,797,227</u></u>	<u><u>\$1,726,423</u></u>
<b>LIABILITIES</b>			
<i>Capital and Reserves</i>			
Called-up share capital presented as equity . . . . .	13	\$ 1,557	\$ 1,539
Share premium . . . . .		549,439	525,665
Profit and loss account . . . . .		312,972	409,395
Treasury shares . . . . .	13	(89,347)	(72,639)
Other reserves . . . . .		<u>428,187</u>	<u>345,521</u>
Total equity . . . . .		<u>1,202,808</u>	<u>1,209,481</u>
<i>Provisions for liabilities</i> . . . . .	15	117,078	59,761
<i>Creditors</i>			
Debt . . . . .	5	281,436	283,666
Creditors . . . . .	16	<u>195,905</u>	<u>173,515</u>
Total for creditors . . . . .		<u>477,341</u>	<u>457,181</u>
<b>TOTAL LIABILITIES</b> . . . . .		<u><u>\$1,797,227</u></u>	<u><u>\$1,726,423</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 9, 2018 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, 2017	December 31, 2016
	(In thousands)	
<b>CASH FLOWS FROM OPERATING ACTIVITIES:</b>		
Loss after tax . . . . .	\$(157,945)	\$(208,444)
Adjustments to reconcile net loss after tax to cash flows from operating activities:		
Depreciation and amortization . . . . .	98,523	94,256
Share-based compensation expense . . . . .	83,917	94,396
Impairment of investment in Reser Therapeutics, Inc. . . . .	10,471	—
Deferred income taxes . . . . .	7,234	(9,689)
Change in the fair value of contingent consideration . . . . .	(21,600)	(7,900)
Excess tax benefit from share-based compensation . . . . .	—	(4,229)
Loss on debt refinancing. . . . .	—	2,075
Other non-cash charges . . . . .	3,471	2,936
Changes in assets and liabilities:		
Receivables . . . . .	(42,489)	(35,616)
Inventory . . . . .	(30,191)	(26,381)
Prepaid expenses and other assets . . . . .	(9,506)	(15,014)
Accounts payable, accrued expenses and provision for liabilities . . . . .	72,658	45,870
Deferred revenue . . . . .	(1,447)	(649)
Other long-term liabilities . . . . .	6,094	4,587
Cash flows provided by (used in) operating activities . . . . .	19,190	(63,802)
<b>CASH FLOWS FROM INVESTING ACTIVITIES:</b>		
Additions to property, plant and equipment . . . . .	(51,300)	(43,657)
Proceeds from the sale of equipment . . . . .	162	194
Investment in Reser Therapeutics, Inc. . . . .	—	(15,000)
Purchases of investments . . . . .	(431,712)	(375,099)
Sales and maturities of investments . . . . .	464,494	560,805
Cash flows (used in) provided by investing activities . . . . .	(18,356)	127,243
<b>CASH FLOWS FROM FINANCING ACTIVITIES:</b>		
Proceeds from the issuance of ordinary shares for share-based compensation arrangements . . . . .	23,517	20,308
Excess tax benefit from share-based compensation . . . . .	—	4,229
Payment made in connection with debt refinancing . . . . .	—	(3,428)
Employee taxes paid related to net share settlement of equity awards . . . . .	(16,433)	(13,468)
Principal payments of long-term debt . . . . .	(3,000)	(65,813)
Cash flows provided by (used in) financing activities . . . . .	4,084	(58,172)
<b>NET INCREASE IN CASH AND CASH EQUIVALENTS . . . . .</b>	<b>4,918</b>	<b>5,269</b>
<b>CASH AND CASH EQUIVALENTS—Beginning of period . . . . .</b>	<b>186,378</b>	<b>181,109</b>
<b>CASH AND CASH EQUIVALENTS—End of period . . . . .</b>	<b>191,296</b>	<b>186,378</b>
<b>SUPPLEMENTAL CASH FLOW DISCLOSURE:</b>		
Cash paid for interest . . . . .	\$ 11,143	\$ 12,458
Cash paid for taxes . . . . .	\$ 2,992	\$ 5,531
Non-cash investing and financing activities:		
Purchased capital expenditures included in accounts payable and accrued expenses . . . . .	\$ 11,151	\$ 5,766

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	Treasury Shares	Other Reserves	Total
	(In thousands)					
BALANCE—January 1, 2016	\$1,518	\$504,867	\$ 616,009	\$(58,661)	\$250,542	\$1,314,275
Net loss	—	—	(208,444)	—	—	(208,444)
Other comprehensive income	—	—	—	—	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
Net loss	—	—	(157,945)	—	—	(157,945)
Cumulative effect adjustment related to change in accounting for excess tax benefits	—	—	61,522	—	—	61,522
Other comprehensive loss	—	—	—	—	(518)	(518)
Share-based payment reserve	—	—	—	—	83,184	83,184
Shares issued under employee stock plans	16	23,501	—	—	—	23,517
Receipt of Alkermes' shares for the purchase of share options or to satisfy minimum tax withholding obligations related to share based awards	2	273	—	(16,708)	—	(16,433)
BALANCE—December 31, 2017	\$1,557	\$549,439	\$ 312,972	\$(89,347)	\$428,187	\$1,202,808

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 financial statements 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.

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.

*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, 2017, substantially all these investments were classified as available for sale and were recorded at fair value.

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

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

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, 2017 and 2016 included U.S. treasury securities and a fixed term deposit account;
- *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, 2017 and 2016 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

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

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

products require a significant degree of judgment. At December 31, 2017 and 2016, assets utilizing Level 3 inputs included contingent consideration and warrants to purchase the common stock of Recro Pharma, Inc. (“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 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.

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

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

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 has 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.

*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.

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

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

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 a quantitative 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 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 impairment test. In the quantitative impairment test, 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 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 profit and loss account. Refer to Note 4, *Goodwill, Intangible Assets and Associated Undertakings*, 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 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.



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

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

*Turnover Recognition*

Collaborative Arrangements

The Company has entered into collaboration agreements with pharmaceutical companies including Janssen for INVEGA SUSTENNA<sup>®</sup>/XEPLION<sup>®</sup> and INVEGA TRINZA<sup>®</sup>/TREVICTA<sup>®</sup> as well as RISPERDAL CONSTA<sup>®</sup>, Acorda for AMPYRA<sup>®</sup>/FAMPYRA<sup>®</sup> and AstraZeneca for BYDUREON<sup>®</sup>. 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.

Multiple Element Arrangements

When entering into multiple element arrangements, the Company identifies its deliverables under the arrangement to determine if the deliverables are to be separate units of accounting or a single unit of accounting. Deliverables under the arrangement will be separate units of accounting provided that (i) a delivered item has value to the customer on a stand-alone basis and (ii) if the arrangement includes a general right of return relative to the delivered item, delivery or performance of the undelivered item is considered probable and substantially in the control of the vendor. Arrangement consideration is allocated to the separate units of accounting based on the fair value of each deliverable. The fair value of deliverables under the arrangement may be derived using a "best estimate of selling price" if vendor specific objective evidence and third-party evidence is not available.

Whenever the Company determines that an arrangement should be accounted for as a single unit of accounting, the Company determines the period over which the performance obligations will be performed and revenue will be recognized. Revenue will be recognized using either a proportional performance or straight-line method. The Company recognizes revenue using the proportional performance method when the level of effort required to complete its performance obligations under an arrangement can be reasonably estimated and such performance obligations are provided on a best-efforts basis.

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

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

The Company accounts for substantive milestones using the milestone method of revenue recognition for R&D arrangements. Under the milestone method, contingent consideration received

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

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

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

In November 2017, the Company granted Biogen, under a license and collaboration agreement, a worldwide, exclusive, sublicensable license to develop, manufacture and commercialize BIIB098 and other products covered by patents licensed to Biogen under the agreement. Upon entering into this agreement in November 2017, the Company received an up-front cash payment of \$28.0 million. The Company is also eligible to receive additional payments upon achievement of developmental milestones, as follows: (i) a \$50.0 million option payment upon Biogen's decision to continue the collaboration after having reviewed certain data from the Company's long-term safety clinical trial and part A of the head-to-head phase 3 gastrointestinal tolerability clinical trial comparing BIIB098 and TECFIDERA and (ii) a \$150.0 million payment upon an approval by the FDA on or before December 31, 2021 of a 505(b)(2) NDA (or, in certain circumstances, a 505(b)(1) NDA) for BIIB098. The Company is also eligible to receive additional payments upon achievement of milestones with respect to the first two products, other than BIIB098, covered by patents licensed to Biogen under the agreement. In addition, the Company will receive a royalty on worldwide net sales of BIIB098, subject to, under certain circumstances, minimum annual payments for the first five years following FDA approval of BIIB098, and worldwide net sales of products, other than BIIB098, covered by patents licensed to Biogen under the agreement. Biogen paid a portion of the BIIB098 development costs the Company incurred in 2017 and, beginning on January 1, 2018, Biogen will be responsible for all BIIB098 development costs the Company incurs, subject to annual budget limitations. The Company has retained the right to manufacture clinical supplies and commercial supplies of BIIB098 and all other products covered by patents licensed to Biogen under the agreement, subject to Biogen's right to manufacture or have manufactured commercial supplies as a back-up manufacturer and subject to good faith agreement by the parties on the terms of such manufacturing arrangements.

The Company evaluated the agreement under ASC Subtopic 605-25, Multiple Element Arrangements ("ASC 605-25"). The Company determined that it had four initial performance obligations: (i) the grant of the license to Biogen, (ii) future development services, (iii) assuming the Company enters into a supply agreement with Biogen, clinical supply and (iv) participation on a joint steering committee with Biogen. The participation on the joint service committee was considered to be perfunctory and thus not recognized as a separate unit of accounting. The deliverables, aside from the participation in the joint steering committee which was considered to be perfunctory, were determined to be separate units of accounting as they each have value to Biogen on a stand-alone basis.

The consideration allocable to the delivered unit or units of accounting is limited to the amount that is not contingent upon the delivery of additional items or meeting other specified performance

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

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

conditions. Therefore, the Company will exclude from the allocable consideration the milestone payments and royalties, regardless of the probability that such milestone and royalty payments will be made, until the events that give rise to such payments actually occur.

The Company allocated consideration to each unit of accounting using the relative selling price method based on its best estimate of selling price for the license and other deliverables. The Company used a discounted cash flow model to estimate the fair value of the license in order to determine the best estimate of selling price. To estimate the fair value of the license, the Company assessed the likelihood of the FDA's approval of BIIB098 and estimated the expected future cash flows assuming FDA approval and the intellectual property ("IP") protecting BIIB098. The Company then discounted these cash flows using a discount rate of 8.0%, which it believes captures a market participant's view of the risk associated with the expected cash flows. The best estimate of selling price of the development services and clinical supply were determined through third-party evidence. The Company believes that a change in the assumptions used to determine its best estimate of selling price for the license most likely would not have a significant effect on the allocation of consideration transferred.

At the date the license was delivered to Biogen, the revenue recognized for the license unit of accounting was limited to the lesser of the amount otherwise allocable using the relative selling price method or the non-contingent amount. During the three months ended December 31, 2017, the Company recognized license revenue of \$28.0 million based on the non-contingent amount, which was the upfront payment. Any consideration received subsequent to the delivery of the license will be allocated to the remaining units of accounting and recognized when the general revenue recognition criteria are met.

The Company determined that the future milestones it is entitled to receive are substantive milestones. The Company is entitled to receive an option payment of \$50.0 million upon Biogen's decision to continue the collaboration after having reviewed certain data from our long-term safety clinical trial and part A of the head-to-head phase 3 gastrointestinal tolerability clinical trial comparing BIIB098 and TECFIDERA and a \$150.0 million payment upon approval by the FDA on or before December 31, 2021 of a 505(b)(2) NDA (or, in certain circumstances, a 505(b)(1) NDA) for BIIB098. Given the challenges inherent in developing and obtaining approval for pharmaceutical and biologic products, there was substantial uncertainty as to whether these milestones would be achieved at the time the license and collaboration agreement was entered into.

*Manufacturing turnover*—The Company recognizes manufacturing turnover from the sale of products it manufactures for resale by its licensees. 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 partners. As the end-market sale occurs after the Company has shipped its product and the risk of loss has passed to its partner, the Company estimates the sales price for such products based on information supplied to it by the Company's 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 the Company's actual and estimated manufacturing turnover has not been material.

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

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

*Royalty turnover*—The Company recognizes royalty turnover related to the sale of products by its 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 partner and collectability is reasonably assured. Royalties on AMPYRA are earned in the period that 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 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 the Company’s actual and estimated royalty turnover has not been material.

*License turnover*—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.

*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.

Product Sales, Net

The Company’s product sales, net consist of sales of VIVITROL®, and since its approval by the U.S. Federal Food and Drug Administration (“FDA”) in October 2015, ARISTADA®, in the U.S. primarily to wholesalers, specialty distributors and 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*—the Company records accruals for rebates to states under the Medicaid Drug Rebate Program as a reduction of sales when the product is shipped into the distribution channel. The Company rebates individual states for all eligible units purchased under the Medicaid program based on a rebate per unit calculation, which is based on the Company’s average manufacturer prices. The Company estimates expected unit sales and rebates per unit under the Medicaid program and adjust its rebate based on actual unit sales and rebates per unit. To date, actual Medicaid rebates have not differed materially from the Company’s estimates;
- *Chargebacks*—chargebacks are discounts that occur when contracted indirect customers purchase directly from wholesalers and specialty distributors. Contracted customers generally purchase the product at its contracted price. The wholesaler or specialty distributor, in turn, then generally charges back to the Company the difference between the wholesale acquisition cost and the

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

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

contracted price paid to the wholesaler or specialty distributor by the customer. The allowance for chargebacks is based on actual and expected utilization of these programs. Chargebacks could exceed historical experience and the Company's estimates of future participation in these programs. To date, actual chargebacks have not differed materially from the Company's estimates;

- *Product Discounts*—cash consideration, including sales incentives, given by the Company under agreements with a number of wholesaler, distributor, pharmacy, and treatment provider customers that provide them with a discount on the purchase price of products. To date, actual product discounts have not differed materially from the Company's estimates;
- *Co-pay Assistance*—the Company has a program whereby a patient can receive monetary assistance each month toward their product co-payment, co-insurance or deductible, provided the patient meets certain eligibility criteria. Reserves for such co-pay assistance are recorded upon the product sale. To date, actual co-pay assistance has not differed materially from the Company's estimates; and
- *Product Returns*—the Company records an estimate for product returns at the time its customer takes title to the Company's product. The Company estimates this liability based on its historical return levels and 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, 2017, the product return reserve was estimated to be approximately 1.5% of each of the Company's VIVITROL and ARISTADA gross product sales.

***Foreign Currency***

The Company's functional and reporting currency is the U.S. dollar. Transactions in foreign currencies are recorded at the exchange rate prevailing on the date of the transaction. The resulting monetary assets and liabilities are translated into U.S. dollars at exchange rates prevailing on the subsequent balance sheet date. Gains and losses as a result of translation adjustments are recorded within "Other income (expense), net" in the accompanying consolidated profit and loss account. During the years ended December 31, 2017 and 2016, the Company recorded a gain on foreign currency translation of \$3.7 million and \$0.1 million, respectively.

***Concentrations***

Financial instruments that potentially subject the Company to concentrations of credit risk are receivables and marketable securities. Billings to large pharmaceutical companies account for the majority of the Company's receivables, and collateral is generally not required from these customers. To mitigate credit risk, the Company monitors the financial performance and credit worthiness of its customers. The following represents revenue and receivables from the Company's customers exceeding

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

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

10% of the total in each category as of December 31, 2017 and 2016 and for the years ended December 31, 2017 and 2016:

<u>Customer</u>	<u>Year Ended December 31, 2017</u>		<u>Year Ended December 31, 2016</u>	
	<u>Receivables</u>	<u>Revenue</u>	<u>Receivables</u>	<u>Revenue</u>
Janssen . . . . .	31%	33%	33%	36%
Acorda . . . . .	14%	13%	17%	15%

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, was as follows:

<u>(In thousands)</u>	<u>Year Ended December 31, 2017</u>	<u>Year Ended December 31, 2016</u>
Turnover by region:		
U.S. . . . .	\$700,090	\$557,312
Ireland . . . . .	9,706	4,407
Rest of world . . . . .	193,578	183,975
Assets by region:		
Current assets:		
U.S. . . . .	\$402,481	\$382,168
Ireland . . . . .	403,167	407,761
Rest of world . . . . .	3,196	749
Long-term assets:		
U.S.:		
Other . . . . .	\$360,641	\$236,175
Ireland:		
Intangible assets . . . . .	\$256,168	\$318,227
Goodwill . . . . .	92,873	92,873
Other . . . . .	278,701	288,470

***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, with the exception of those expenses related to BIIB098 are not tracked by individual program as they benefit multiple programs or its technologies in general.



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

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

*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, 2017 and 2016, advertising costs totaled \$34.4 million and \$24.0 million, respectively.

*Share-Based Compensation*

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

Stock Options

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

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

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

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

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, 2017</u>	<u>Year Ended December 31, 2016</u>
Expected option term . . . . .	5 - 8 years	5 - 7 years
Expected stock volatility . . . . .	43% - 47%	39% - 53%
Risk-free interest rate . . . . .	1.69% - 2.38%	0.95% - 2.14%
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 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 probable to the date the Company deems the event is likely to occur. Cumulative adjustments are recorded quarterly to reflect subsequent changes in the estimated outcome of performance-related conditions until the date results are determined.

*Income Taxes*

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

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

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

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 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, 2017 and 2016, the Company contributed \$9.8 million and \$8.1 million, respectively, to match employee deferrals under the 401(k) Plan.

**Defined Contribution Plan**

The Company maintains a defined contribution plan for its Ireland-based employees (the "Defined Contribution Plan"). The Defined Contribution Plan provides for eligible employees to contribute up to the maximum of 40%, depending upon their age, of their total taxable earnings subject to an earnings cap of €115,000. The Company provides a match of up to 18% of taxable earnings depending upon an

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

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

individual's contribution level. During the years ended December 31, 2017 and 2016, the Company contributed \$3.7 million and \$3.2 million, respectively, in contributions to the Defined Contribution Plan.

*Reclassifications*

Certain prior year balances have been reclassified to conform to current year presentation.

*New Accounting Pronouncements*

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

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 and require additional disclosures.

This guidance becomes effective for the Company in its year ending December 31, 2018 and the Company will adopt it using the modified retrospective method. The Company has determined that the new guidance will necessitate a change in how it records manufacturing revenue for certain of its arrangements with its licensees. Under current GAAP, the Company records manufacturing revenue from the sale of products it manufactures for resale by its partners after the Company has shipped such products and risk of loss has passed to the Company's partner, assuming persuasive evidence of an arrangement exists, the sales price is fixed or determinable and collectability is reasonably assured. Under the new guidance, the terms within certain of the Company's manufacturing contracts will require that manufacturing revenue be recorded as products are manufactured rather than upon shipment. Revenue earned under the Company's other manufacturing contracts will continue to be recorded at a point in time, when control passes from the Company to the customer. The Company has determined that the adoption of this guidance will result in an immaterial change to its January 1, 2018 opening balance sheet and is evaluating the disclosure requirements under this new guidance.

In January 2016, the FASB issued guidance that enhances the reporting model for financial instruments by addressing certain aspects of recognition, measurement, presentation and disclosure of financial instruments. The amendments in this guidance 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

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

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

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 has determined that the adoption of this standard will not have a material impact 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 guidance will have on its consolidated financial statements.

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 became effective for the Company on January 1, 2017, and the adoption of this guidance did not have an impact on the Company's 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: (i) all excess tax benefits and tax deficiencies be recognized as income tax expense or benefit in the income statement; (ii) excess tax benefits be classified as an operating activity in the statement of cash flows; (iii) 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; (iv) the threshold to qualify for equity classification permits withholding up to the maximum statutory tax rates in the applicable jurisdictions; and (v) 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 became effective for the Company on January 1, 2017. The amendments related to (i), (iii) and (iv) were adopted by the Company on a modified retrospective basis, which resulted in a cumulative-effect adjustment to reduce accumulated deficit by \$61.5 million related to the timing of when excess tax benefits are recognized. The Company elected to continue to record expense only for those awards that are expected to vest. The amendments related to (ii) and (v) were adopted using the prospective transition method.

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

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

In June 2016, the FASB issued guidance to provide financial statement users with more decision-useful information about the expected credit losses on financial instruments and other commitments to extend credit held by a reporting entity at each reporting date. To achieve this objective, the amendments in this guidance replace the incurred loss impairment methodology in current GAAP with a methodology that reflects expected credit losses and requires consideration of a broader range of reasonable and supportable information to inform credit loss estimates. This guidance becomes effective for the Company in its year ending December 31, 2020, with early adoption permitted for the Company in its year ending December 31, 2019. The Company is currently assessing the impact that this guidance will have on its consolidated financial statements.

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, with early adoption permitted. The Company elected to early adopt this guidance as of January 1, 2017. The adoption of this guidance had no impact on the Company's statement of cash flows.

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 its year ending December 31, 2018, and upon adoption of the new standard, a cumulative-effect adjustment of approximately \$0.9 million will be recorded within retained earnings, related to the reversal of an unamortized deferred tax charge on a prior sale of intellectual property between Alkermes Inc. and Alkermes Pharma Ireland Limited.

In January 2017, 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, with early adoption permitted for transactions that occurred before the issuance date or effective date of the guidance if the transactions were not reported in financial statements that have been issued or made available for issuance. The Company elected to early adopt this guidance, as of January 1, 2017. The adoption of this guidance had no impact on the Company's consolidated financial statements.

In January 2017, the FASB issued guidance that simplifies the test for goodwill impairment. This guidance removes Step 2 of the goodwill impairment test, which requires a hypothetical purchase price allocation. Under the amended guidance, a goodwill impairment charge will now be recognized for the amount by which the carrying value of a reporting unit exceeds its fair value, not to exceed the carrying amount of goodwill. This guidance is effective for the Company in its year ending December 31, 2020, with early adoption permitted for any impairment tests performed after January 1, 2017. The Company elected to early adopt this guidance as of January 1, 2017. The adoption of this guidance had no impact on the Company's consolidated financial statements.

In May 2017, the FASB issued guidance that amends the scope of modification accounting for share-based payment arrangements to address both diversity in practice and the cost and complexity of accounting for the change to the terms or conditions of a share-based payment award. The amendment provides guidance about which changes to the terms or conditions of a share-based payment award require an entity to apply modification accounting. The guidance becomes effective for the Company in



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

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

its year ending December 31, 2018 and early adoption is permitted. The standard may impact the Company in future periods if modifications are made to certain of its share-based awards.

In July 2017, the FASB issued guidance that addresses narrow issues identified as a result of the complexity associated with applying GAAP for certain financial instruments with characteristics of liabilities and equity. The guidance becomes effective for the Company in its year ending December 31, 2019 and early adoption is permitted. The Company is currently assessing the impact that this guidance will have on its consolidated financial statements.

**3. COLLABORATIVE ARRANGEMENTS**

The Company has entered into several collaborative arrangements to develop and commercialize products and, in connection with such arrangements, to access technologies, financial, marketing, manufacturing and other resources. Refer to the “Patents and Proprietary Rights” section in this Annual Report for information with respect to intellectual property protection for these products. The collaboration turnover the Company has earned in the years ended December 31, 2017 and 2016 was as follows:

	<b>Year Ended December 31,</b>	
	<b>2017</b>	<b>2016</b>
	<b>(In thousands)</b>	
<b>MANUFACTURING AND ROYALTY TURNOVER:</b>		
Significant collaborative arrangements . . . . .	\$462,568	\$431,302
All other collaborative arrangements . . . . .	42,740	55,945
Total manufacturing and royalty turnover . . . . .	\$505,308	\$487,247
<b>LICENSE TURNOVER:</b>		
Significant collaborative arrangements . . . . .	\$ 28,000	\$ —
Total license turnover . . . . .	\$ 28,000	\$ —
<b>RESEARCH AND DEVELOPMENT TURNOVER:</b>		
Significant collaborative arrangements . . . . .	\$ 2,314	\$ 403
All other collaborative arrangements . . . . .	4,918	1,898
Total research and development turnover . . . . .	\$ 7,232	\$ 2,301

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.

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

**3. COLLABORATIVE ARRANGEMENTS (Continued)**

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

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

Under its agreements with Janssen, the Company recognized royalty revenues from the end-market net sales of INVEGA SUSTENNA/XEPLION and INVEGA TRINZA/TREVICTA of \$214.9 million and \$184.2 million during the years ended December 31, 2017 and 2016, 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 end-market 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 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 each such country, with the

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

**3. COLLABORATIVE ARRANGEMENTS (Continued)**

exception of Canada, France, Germany, Italy, Japan, Spain and the United Kingdom, in each case where the fifteen-year minimum 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 a percentage of Janssen's net unit sales price for RISPERDAL CONSTA for the applicable calendar year. This percentage is determined based on Janssen's unit demand for such 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 the Company. In the event that Janssen terminates the manufacturing and supply agreement without terminating the license agreements, the royalty rate payable to the Company on Janssen's net sales of RISPERDAL CONSTA would increase from 2.5% to 5.0%.

Under its agreements with Janssen, the Company recognized manufacturing revenues related to RISPERDAL CONSTA of \$64.8 million and \$64.9 million during the years ended December 31, 2017 and 2016, respectively. Under its agreements with Janssen, the Company recognized royalty revenues related to RISPERDAL CONSTA of \$20.1 million and \$22.3 million during the years ended December 31, 2017 and 2016, 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. 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 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 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

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

**3. COLLABORATIVE ARRANGEMENTS (Continued)**

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 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 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 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 manufacturing 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 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 amended and restated 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:

- 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

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

**3. COLLABORATIVE ARRANGEMENTS (Continued)**

royalties in accordance with its amended and restated license agreement for the product, and either manufacturing fees as a percentage of net selling price for product manufactured by the Company or compensating fees for product manufactured by third parties.

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

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

During the years ended December 31, 2017 and 2016, the Company recognized \$117.0 million and \$114.2 million, respectively, of revenues from its arrangements with Acorda.

***AstraZeneca***

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

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

**3. COLLABORATIVE ARRANGEMENTS (Continued)**

Under the Company's 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, the Company will receive royalties equal to 8% of net sales from the first 40 million units of BYDUREON products 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) 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 the Company's patents licensed under the 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 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, 2017 and 2016, the Company recognized \$45.7 million and \$45.6 million, respectively, of revenues from its arrangements with respect to BYDUREON.

***Biogen***

Under a license and collaboration agreement, the Company granted Biogen a worldwide, exclusive, sublicensable license to develop, manufacture and commercialize BIIB098 and other products covered by patents licensed to Biogen under the agreement.

Upon entering into this agreement in November 2017, the Company received an up-front cash payment of \$28.0 million. The Company is also eligible to receive additional payments upon achievement of milestones, as follows: (i) a \$50.0 million option payment upon Biogen's decision to continue the collaboration after having reviewed certain data from our long-term safety clinical trial and part A of the head-to-head phase 3 gastrointestinal tolerability clinical trial comparing BIIB098 to TECFIDERA and (ii) a \$150.0 million payment upon an approval by the FDA on or before December 31, 2021 of a 505(b)(2) NDA (or, in certain circumstances, a 505(b)(1) NDA) for BIIB098. The Company is also eligible to receive additional payments upon achievement of milestones with respect to the first two products, other than BIIB098, covered by patents licensed to Biogen under the agreement.

In addition, the Company will receive a mid-teens percentage royalty on worldwide net sales of BIIB098, subject to, under certain circumstances, minimum annual payments for the first five years following FDA approval of BIIB098. The Company will also receive royalties on net sales of products, other than BIIB098, covered by patents licensed to Biogen under the agreement, at tiered royalty rates calculated as percentages of net sales ranging from high-single digits to low sub-teen double-digits. All royalties are payable on a product-by-product and country-by-country basis until the later of (i) the last-to-expire patent right covering the applicable product in the applicable country and (ii) a specified period of time from the first commercial sale of the applicable product in the applicable country. Royalties for all products and the minimum annual payments for BIIB098 are subject to customary reductions.



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

**3. COLLABORATIVE ARRANGEMENTS (Continued)**

Except in certain limited circumstances, until FDA approval of an NDA for BIIB098, the Company is responsible for the development of BIIB098 for the treatment of MS. Biogen paid a portion of the BIIB098 development costs the Company incurred in 2017 and, beginning on January 1, 2018, Biogen will be responsible for all BIIB098 development costs the Company incurs, subject to annual budget limitations. After the date of FDA approval of an NDA for BIIB098 for the treatment of MS, Biogen will be responsible for all development and commercialization activities, as well as the costs of all such activities, for BIIB098 and all other products covered by patents licensed to Biogen under the agreement. The Company has retained the right to manufacture clinical supplies and commercial supplies of BIIB098 and all other products covered by patents licensed to Biogen under the agreement, subject to Biogen's right to manufacture or have manufactured commercial supplies as a back-up manufacturer and subject to good faith agreement by the parties on the terms of such manufacturing arrangements.

If BIIB098 discontinuations due to gastrointestinal adverse events in BIIB098's long-term safety clinical trial exceed a certain pre-defined threshold or BIIB098 demonstrates a greater rate of discontinuations as compared to TECFIDERA in part A of the head-to-head phase 3 gastrointestinal tolerability clinical trial, then "GI Inferiority" shall exist, and (i) Biogen shall have the right to recapture from the Company its \$50.0 million option payment through certain temporary reductions in royalty rates, (ii) the minimum annual payments Biogen owes to the Company shall terminate, and (iii) there shall be no reversion of BIIB098 to the Company in the event that Biogen terminates the agreement and does not commercialize BIIB098.

Unless earlier terminated, the agreement will remain in effect until the expiry of all royalty obligations. Biogen has the right to terminate the agreement at will, on a product-by-product basis or in its entirety. Either party has the right to terminate the agreement following any governmental prohibition of the transactions effected by the agreement, or in connection with an insolvency event involving the other party. Upon termination of the agreement by either party, if, prior to such termination (i) BIIB098 did not meet GI Inferiority or (ii) BIIB098 met GI Inferiority but Biogen commercialized BIIB098, then, at the Company's request, the BIIB098 program will revert to the Company.

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

**4. 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 December 31, 2016 . . . . .	\$92,873	\$ 465,590	\$ 74,600	\$ 42,560	\$ 582,750
At December 31, 2017 . . . . .	\$92,873	\$ 465,590	\$ 74,600	\$ 42,560	\$ 582,750
<b>Accumulated Depreciation:</b>					
At January 1, 2016 . . . . .	\$ —	\$(168,218)	\$(18,294)	\$(17,052)	\$(203,564)
Expensed during the year . . . . .	—	(50,100)	(6,090)	(4,769)	(60,959)
At December 31, 2016 . . . . .	—	(218,318)	(24,384)	(21,821)	(264,523)
Expensed during the year . . . . .	—	(51,074)	(6,899)	(4,086)	(62,059)
At December 31, 2017 . . . . .	\$ —	\$(269,392)	\$(31,283)	\$(25,907)	\$(326,582)
<b>Net Book Amount:</b>					
At December 31, 2017 . . . . .	\$92,873	\$ 196,198	\$ 43,317	\$ 16,653	\$ 256,168
At December 31, 2016 . . . . .	\$92,873	\$ 247,272	\$ 50,216	\$ 20,739	\$ 318,227

The Company's finite-lived intangible assets consist of collaborative agreements and the NanoCrystal and OCR technologies acquired as part of the EDT acquisition. The Company recorded \$62.1 million and \$61.0 million of amortization expense related to its finite-lived intangible assets during the years ended December 31, 2017 and 2016, respectively. Based on the Company's most recent analysis, amortization of intangible assets included within its consolidated balance sheets at December 31, 2017 is expected to be approximately \$65.0 million, \$55.0 million, \$50.0 million, \$40.0 million and \$35.0 million in the years ending December 31, 2018 through 2022, respectively. Although the Company believes such available information and assumptions are reasonable, given the inherent risks and uncertainties underlying its expectations regarding such future revenues, there is the potential for the Company's actual results to vary significantly from such expectations. If revenues are projected to change, the related amortization of the intangible assets will change in proportion to the change in revenues.

The Company performed its annual goodwill impairment test as of October 31, 2017. The Company elected to assess qualitative factors to determine whether it was necessary to perform the qualitative impairment test. Based on the weight of all available evidence, the Company determined that the fair value of each reporting unit more-likely-than-not exceeded its carrying value.

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

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

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

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. In September 2017, the Company recorded an other-than-temporary impairment charge of \$10.5 million, which represented the Company's remaining investment in Reset, as the Company believes that Reset is unable to generate future earnings that justify the carrying amount of the investment. During the years ended December 31, 2017 and 2016, the Company recorded a reduction in its investment in Reset of \$2.8 million and \$1.7 million, respectively, which represented 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 "Other assets" in the accompanying consolidated balance sheets.

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. As of December 31, 2017, the Company's total contribution in Fountain was equal to €3.7 million, and its commitment represents approximately 7% of the partnership's total funding. The Company is accounting for its investment in Fountain under the equity method. During the years ended December 31, 2017, 2016 and 2015, the Company recorded a reduction in its investment in Fountain of \$0.1 million, 0.4 million and \$0.2 million, respectively, which represented the Company's proportionate share of Fountain's net loss for this period. At December 31, 2017 and 2016, the Company's investment is equal to, \$3.7 million (€2.8 million), and \$2.5 million (€2.1 million), respectively, which is included within "Intangible assets—Associated undertaking" in the accompanying consolidated balance sheets.

**5. LONG-TERM DEBT**

Long-term debt consists of the following:

(In thousands)	December 31,	
	2017	2016
Term Loan B-1, due September 25, 2021 . . . . .	\$281,436	\$283,666
Less: current portion . . . . .	(3,000)	(3,000)
Long-term debt . . . . .	\$278,436	\$280,666

***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

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

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

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. 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 profit and loss account.

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>	
2018 .....	\$ 3,000
2019 .....	3,000
2020 .....	3,000
2021 .....	<u>275,250</u>
Total .....	<u>\$284,250</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, 2017.

At December 31, 2017, the Company’s balance of unamortized deferred financing costs and unamortized original issue discount costs were \$1.0 million and \$1.8 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, 2017 and 2016, the Company had amortization expense of \$0.8 million and \$0.9 million related to deferred financing costs and original issue discount.

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

**6. 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)	<u>December 31, 2017</u>	<u>Level 1</u>	<u>Level 2</u>	<u>Level 3</u>
<b>Assets:</b>				
Cash equivalents . . . . .	\$ 1,889	\$ 1,889	\$ —	\$ —
U.S. government and agency debt securities . . . . .	198,918	124,958	73,960	—
Corporate debt securities . . . . .	140,087	—	140,087	—
International government agency debt securities . . . . .	56,735	—	56,735	—
Contingent consideration . . . . .	84,800	—	—	84,800
Common stock warrants . . . . .	1,395	—	—	1,395
Total . . . . .	<u>\$483,824</u>	<u>\$126,847</u>	<u>\$270,782</u>	<u>\$86,195</u>

(In thousands)	<u>December 31, 2016</u>	<u>Level 1</u>	<u>Level 2</u>	<u>Level 3</u>
<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>

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, 2017. 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, 2017:

(In thousands)	<u>Fair Value</u>
Balance, January 1, 2017 . . . . .	\$64,592
Change in the fair value of contingent consideration . . . . .	21,600
Increase in the fair value of warrants . . . . .	3
Balance, December 31, 2017 . . . . .	<u>\$86,195</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 and other industry and economic events. The Company validated the prices developed using the

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

**6. FAIR VALUE (Continued)**

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.

At December 31, 2017, the Company determined the value of the Gainesville Transaction's contingent consideration using the following valuation approaches:

- The Company is entitled to receive \$45.0 million upon regulatory approval of an NDA for the first Meloxicam Product. The fair value of the regulatory milestone was estimated based on applying the likelihood of achieving the regulatory milestone and applying a discount rate from the expected time the milestone occurs to the balance sheet date. The Company expects the regulatory milestone event to occur in the second quarter of 2018 and used a discount rate of 3.0%;
- The Company is entitled to receive future royalties on net sales of Meloxicam Products. To estimate the fair value of the future royalties, we assessed the likelihood of a Meloxicam Product being approved for sale and estimated the expected future sales given approval and IP protection. We then discounted these expected payments using a discount rate of 15.0%, which we believe captures a market participant's view of the risk associated with the expected payments; and
- We are entitled to receive payments of up to \$80.0 million upon achieving certain sales milestones on future sales of the Meloxicam Product. The sales milestones were determined through the use of a real options approach, where net sales are simulated in a risk-neutral world. To employ this methodology, we used a risk-adjusted expected growth rate based on its assessments of expected growth in net sales of the approved Meloxicam Product, 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, which ranged from 3.5% to 5.4%.

At December 31, 2017 and 2016, the Company determined that the value of the Gainesville Transaction's contingent consideration was \$84.8 million and \$63.2 million, respectively. The Company recorded the increase of \$21.6 million and \$7.9 million in the value of the contingent consideration during the years ended December 31, 2017 and 2016, respectively, within "Change in the fair value of contingent consideration" in the accompanying consolidated profit and loss account.

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, 2017, 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



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

**6. FAIR VALUE (Continued)**

company used a Black-Scholes model with the following assumptions to determine the fair value of these warrants at December 31, 2017:

	<u>Year Ended</u> <u>December 31, 2017</u>
Closing stock price at December 31, 2017 . . . . .	\$ 9.25
Warrant strike price . . . . .	\$19.46
Expected term (years) . . . . .	4.27
Risk-free interest rate . . . . .	2.09%
Volatility . . . . .	77.0%

The increase in the fair value of the warrants of less than \$0.1 million and the decrease in the fair value of the warrants of \$0.4 million during the years ended December 31, 2017 and 2016, respectively, was recorded within “Other income (expense), net” in the accompanying consolidated profit and loss account.

The carrying amounts reflected in the consolidated balance sheets for cash and cash equivalents, receivables, 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, 2017 consisted of a \$300.0 million term loan, bearing interest at LIBOR plus 2.75% with a LIBOR floor of 0.75% and maturity of 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, 2017:

<u>(In thousands)</u>	<u>Carrying</u> <u>Value</u>	<u>Estimated</u> <u>Fair Value</u>
Term Loan B-1 . . . . .	\$281,436	\$285,671

**7. INCOME TAXES**

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

<u>(In thousands)</u>	<u>Year Ended</u>	
	<u>December 31,</u> <u>2017</u>	<u>December 31,</u> <u>2016</u>
Current income tax provision:		
U.S. federal . . . . .	\$ (6,964)	\$(3,163)
U.S. state . . . . .	(350)	(480)
Rest of world . . . . .	(123)	(103)
Deferred income tax (provision) benefit:		
U.S. federal . . . . .	(8,188)	9,278
Ireland . . . . .	933	269
U.S. state . . . . .	21	142
Total tax (provision) benefit . . . . .	<u>\$(14,671)</u>	<u>\$ 5,943</u>

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

**7. INCOME TAXES (Continued)**

The income tax provision in 2017 and the income tax benefit in 2016 was primarily due to U.S. federal and state taxes. The unfavorable change in income taxes in 2017, as compared to 2016, was primarily due to the enactment of the Tax Cuts and Jobs Act (the “Act” or “Tax Reform”) and an increase in income earned in the U.S., partially offset by the recognition of excess tax benefits related to share-based compensation. A \$4.2 million million benefit was recorded to additional paid-in capital in the year ended December 31, 2016, 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.

Tax Reform was enacted in December 2017. The Company is primarily subject to the business related provisions outlined in Subtitle C to the Act, as well as the international tax provisions for inbound transactions outlined in Subtitle D, Part II, to the Act. The Company recorded a \$21.5 million discrete tax expense in the quarter ended December 31, 2017 to account for the reduction in the U.S. federal tax rate from 35% to 21%. The Act also removes the exception for performance based compensation in §162(m) of the Internal Revenue Code (the “Code”) on a prospective basis. Performance based compensation provided pursuant to a written binding agreement entered into prior to November 2, 2017 will continue to be deductible provided no significant modification is made. The Company believes that performance based compensation, provided prior to November 2, 2017, was provided pursuant to written binding agreements and will be deductible. As of December 31, 2017, the Company has a deferred tax asset of \$13.3 million for this item, which is recorded as a provisional amount. If the Company’s position is not sustained, then it would record a deferred tax expense for part or all of this amount. The accounting for this item is incomplete and may change as the Company’s interpretation of the provisions of the Act evolve, additional information becomes available or interpretive guidance is issued by the U.S. Treasury. The final determination will be completed no later than one year from the enactment of the Act.

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 \$160.3 million at December 31, 2017.

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, 2017	December 31, 2016
Ireland . . . . .	\$(172,363)	\$(212,198)
U.S. . . . .	2,414	(18,935)
Rest of world . . . . .	26,675	16,746
Loss before provision for income taxes . . . . .	<u>\$(143,274)</u>	<u>\$(214,387)</u>

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

**7. INCOME TAXES (Continued)**

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

<b>(In thousands)</b>	<b>December 31, 2017</b>	<b>December 31, 2016</b>
Deferred tax assets:		
Irish NOL carryforwards . . . . .	\$ 177,435	\$ 156,147
Tax credits . . . . .	71,366	7,608
Share-based compensation . . . . .	40,048	52,479
Other . . . . .	13,239	12,233
Less: valuation allowance . . . . .	<u>(172,797)</u>	<u>(141,859)</u>
Total deferred tax assets . . . . .	<u>129,291</u>	<u>86,608</u>
Deferred tax liabilities:		
Intangible assets . . . . .	(18,184)	(20,805)
Property, plant and equipment . . . . .	(12,040)	(17,541)
Other . . . . .	<u>(818)</u>	<u>(826)</u>
Total deferred tax liabilities . . . . .	<u>(31,042)</u>	<u>(39,172)</u>
Net deferred tax assets . . . . .	<u>\$ 98,249</u>	<u>\$ 47,436</u>

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 including the requirement that all future excess tax benefits and tax deficiencies be recognized as income tax expense or benefit in the income statement. On January 1, 2017, the Company adopted this standard on a modified retrospective basis, which resulted in a \$57.8 million increase to its deferred tax assets, a \$3.7 million decrease in liabilities and a \$61.5 million favorable cumulative-effect adjustment to accumulated deficit due to the change in the accounting treatment of excess tax benefits.

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

<b>(In thousands)</b>	<b>Balance at Beginning of Year</b>	<b>Additions<sup>(1)</sup></b>	<b>Balance at End of Year</b>
Deferred tax asset valuation for the year ended			
December 31, 2016 . . . . .	\$(106,746)	\$(35,113)	\$(141,859)
Deferred tax asset valuation for the year ended			
December 31, 2017 . . . . .	\$(141,859)	\$(30,938)	\$(172,797)

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

At December 31, 2017, the Company maintained a valuation allowance of \$9.4 million against certain U.S. state deferred tax assets and \$163.4 million against certain Irish deferred tax assets as the Company has determined that it is more-likely-than-not that these net deferred tax assets will not be realized. If the Company demonstrates consistent profitability in the future, the evaluation of the recoverability of these deferred tax assets could change and the remaining valuation allowances could be released in part or in whole. If the Company incurs losses in the U.S. in the future, or experiences significant excess tax benefits arising from the future exercise of stock options and/or the vesting of RSUs, the evaluation of the recoverability of the U.S. deferred tax assets could change and a valuation allowance against the U.S. deferred tax assets may be required in part or in whole.

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

**7. INCOME TAXES (Continued)**

As of December 31, 2017, the Company had \$1.2 billion of Irish NOL carryforwards, \$5.9 million of state NOL carryforwards, \$57.5 million of federal R&D credits, \$10.0 million of alternative minimum tax (“AMT”) credits and \$11.9 million of state tax credits which will either expire on various dates through 2037 or can be carried forward indefinitely. These loss and credit carryforwards are available to reduce certain future Irish and foreign taxable income and tax and, in the case of the alternative minimum tax credits, may be refundable. These loss and credit carryforwards are subject to review and possible adjustment by the appropriate taxing authorities. These loss and credit carryforwards, which may be utilized in a future period, may be subject to limitations based upon changes in the ownership of the Company’s ordinary shares.

In addition to deferred tax assets and liabilities, the Company recorded deferred charges related to certain intercompany asset transfers. Deferred charges are included in the following accounts:

(In thousands)	<u>December 31, 2017</u>	<u>December 31, 2016</u>
Prepaid expenses and other current assets . . . . .	\$188	\$ 188
Other assets—long-term . . . . .	<u>686</u>	<u>862</u>
Total deferred charges . . . . .	<u>\$874</u>	<u>\$1,050</u>

The Company will adopt ASU 2016-16 effective January 1, 2018 requiring an unfavorable cumulative-effect adjustment of \$0.9 million recorded to accumulated deficit to write-off the unamortized deferred tax charge at December 31, 2017. In addition, the Company will record a \$17.8 million deferred tax asset to take account of certain basis differences on intangible assets, with a corresponding adjustment to valuation allowance.

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

**7. INCOME TAXES (Continued)**

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

<b>(In thousands, except percentage amounts)</b>	<b>Year Ended December 31, 2017</b>	<b>Year Ended December 31, 2016</b>
Statutory tax rate . . . . .	12.5%	12.5%
Income tax provision, at statutory rate . . . . .	\$ 17,909	\$ 26,798
Change in valuation allowance . . . . .	(26,771)	(35,290)
Federal tax law change <sup>(1)</sup> . . . . .	(21,453)	—
Impairment on equity method investment . . . . .	(1,662)	—
Uncertain tax positions . . . . .	(830)	(910)
Foreign rate differential <sup>(2)</sup> . . . . .	682	(2,723)
Share-based compensation . . . . .	1,205	(2,072)
U.S. state income taxes, net of U.S. federal benefit . . . . .	558	2
Intercompany amounts <sup>(3)</sup> . . . . .	5,041	5,209
Irish rate differential <sup>(4)</sup> . . . . .	2,675	5,231
R&D credit . . . . .	9,326	10,572
Other permanent items <sup>(5)</sup> . . . . .	<u>(1,351)</u>	<u>(874)</u>
Income tax (provision) benefit . . . . .	<u>(14,671)</u>	<u>\$ 5,943</u>
Effective tax rate . . . . .	(10.2)%	2.8%

- (1) Represents a \$21.5 million deferred tax expense recorded as a discrete item during the three months ended December 31, 2017 as a result of the reduction in the U.S. federal tax rate from 35% to 21%.
- (2) Represents income or losses of non-Irish subsidiaries, including U.S. subsidiaries, subject to tax at a rate other than the Irish statutory rate.
- (3) 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.
- (4) Represents income or losses of Irish companies subject to tax at a rate other than the Irish statutory rate.
- (5) Other permanent items include, but are not limited to, non-deductible meals and entertainment expenses, non-deductible lobbying expenses and non-deductible compensation of senior officers of the Company.

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

**7. INCOME TAXES (Continued)**

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

(In thousands)	<u>Unrecognized Tax Benefits</u>
Balance, January 1, 2016 . . . . .	\$3,778
Reductions based on tax positions related to prior periods . . . . .	(7)
Additions based on tax positions related to the current period . . . . .	<u>917</u>
Balance, December 31, 2016 . . . . .	\$4,688
Reductions based on tax positions related to prior periods . . . . .	(47)
Additions based on tax positions related to the current period . . . . .	<u>877</u>
Balance, December 31, 2017 . . . . .	<u>\$5,518</u>

The unrecognized tax benefits at December 31, 2017, if recognized, would affect the Company's effective tax rate. The Company does not anticipate that the amount of existing unrecognized tax benefits will significantly increase or decrease within the next 12 months. The Company has elected to include interest and penalties related to uncertain tax positions as a component of its provision for taxes. For the years ended December 31, 2017, 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 2014 through 2017 fiscal years remain subject to examination by the respective tax authorities. In Ireland, the years 2013 to 2017 remain subject to examination by the Irish tax authorities. Additionally, because of the Company's Irish and U.S. loss carryforwards and credit carryforwards, certain tax returns from fiscal years 1999 onward may also be examined. These years generally remain open for three to four years after the loss carryforwards and credit carryforwards have been utilized.

During 2017, the IRS completed its examination of the year ended December 31, 2014 for Alkermes U.S. Holdings, Inc. without any material adjustments. The State of New York concluded their examination of Alkermes U.S. Holdings, Inc. for the years ended December 31, 2015 and 2014 and the nine months ended December 31, 2013, without any material adjustment. The years ended December 31, 2015 and 2014 for Alkermes U.S. Holdings, Inc. are currently under examination by the State of Illinois.

**8. 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, 2017 and 2016, 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)**

**8. 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,	
	2017	2016
Stock options . . . . .	9,540	10,166
Restricted stock units . . . . .	2,119	1,320
Total . . . . .	<u>11,659</u>	<u>11,486</u>

**9. TANGIBLE FIXED ASSETS**

Tangible fixed assets consists of the following:

	Land and Buildings	Furniture, Fixtures and Equipment	Leasehold Improvements	Construction in Progress	Total
	(In thousands)				
<b>Cost:</b>					
At January 1, 2016 . . . . .	\$142,710	\$ 218,718	\$ 16,597	\$ 51,542	\$ 429,567
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>
Additions at cost . . . . .	2,707	30,087	337	23,553	56,684
Transfers . . . . .	—	10,537	—	(10,537)	—
Disposals . . . . .	—	(2,606)	—	—	(2,606)
At December 31, 2017 . . . . .	<u>\$161,491</u>	<u>\$ 289,455</u>	<u>\$ 19,578</u>	<u>\$ 54,270</u>	<u>\$ 524,794</u>
<b>Accumulated Depreciation:</b>					
At January 1, 2016 . . . . .	\$(48,659)	\$(118,895)	\$ (7,194)	\$ —	\$(174,748)
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>
Charged during the year . . . . .	(5,474)	(28,563)	(2,427)	—	(36,464)
Disposals . . . . .	—	2,337	—	—	2,337
At December 31, 2017 . . . . .	<u>\$(59,373)</u>	<u>\$(168,931)</u>	<u>\$(11,754)</u>	<u>\$ —</u>	<u>\$(240,058)</u>
<b>Net Book Amount:</b>					
At December 31, 2017 . . . . .	<u>\$102,118</u>	<u>\$ 120,524</u>	<u>\$ 7,824</u>	<u>\$ 54,270</u>	<u>\$ 284,736</u>
At December 31, 2016 . . . . .	<u>\$104,885</u>	<u>\$ 108,732</u>	<u>\$ 9,914</u>	<u>\$ 41,254</u>	<u>\$ 264,785</u>

Depreciation expense was \$36.5 million and \$33.3 million for the years ended December 31, 2017 and 2016, respectively. During the years ended December 31, 2017 and 2016, the Company wrote off furniture, fixtures and equipment that had a carrying value of \$0.1 million and \$0.9 million,

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

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

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

**10. STOCK**

Stock consists of the following:

<b>(In thousands)</b>	<b>December 31, 2017</b>	<b>December 31, 2016</b>
Raw materials . . . . .	\$29,883	\$19,413
Work in process . . . . .	38,964	21,811
Finished goods <sup>(1)</sup> . . . . .	<u>24,428</u>	<u>21,774</u>
Total stock . . . . .	<u>\$93,275</u>	<u>\$62,998</u>

(1) At December 31, 2017 and 2016, the Company had \$8.7 million and \$7.1 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, 2017 and 2016, the Company had a provision for stock obsolescence of \$2.8 million and \$2.6 million, respectively.

**11. DEBTORS**

	<b>December 31, 2017</b>	<b>December 31, 2016</b>
	<b>(In thousands)</b>	
<i>Amounts falling due within one year</i>		
Trade receivables . . . . .	\$233,590	\$191,102
Prepaid expenses and other current assets . . . . .	<u>48,475</u>	<u>39,345</u>
	<u>\$282,065</u>	<u>\$230,447</u>
<i>Amounts falling due after more than one year</i>		
Contingent consideration . . . . .	\$ 84,800	\$ 63,200
Deferred income taxes . . . . .	98,560	47,768
Other debtors . . . . .	<u>10,665</u>	<u>11,129</u>
Total . . . . .	<u>\$476,090</u>	<u>\$352,544</u>

Included in accounts receivable at December 31, 2017 and 2016, are unbilled receivables of \$22.7 million and \$20.0 million, respectively. The Company's allowance for doubtful accounts was \$0.2 million and \$0.1 million at December 31, 2017 and 2016, respectively.

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

**12. 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, 2017</b>				
Short-term investments:				
Available-for-sale securities:				
U.S. government and agency debt securities . . . . .	\$150,673	\$ 1	\$ (363)	\$150,311
Corporate debt securities . . . . .	56,552	3	(58)	56,497
International government agency debt securities . . . . .	35,478	1	(79)	35,400
Total short-term investments . . . . .	<u>242,703</u>	<u>5</u>	<u>(500)</u>	<u>242,208</u>
Long-term investments:				
Available-for-sale securities:				
Corporate debt securities . . . . .	83,924	—	(334)	83,590
U.S. government and agency debt securities . . . . .	48,948	—	(341)	48,607
International government agency debt securities . . . . .	21,453	—	(118)	21,335
	<u>154,325</u>	<u>—</u>	<u>(793)</u>	<u>153,532</u>
Held-to-maturity securities:				
Fixed term deposit account . . . . .	1,667	222	—	1,889
Certificates of deposit . . . . .	1,791	—	—	1,791
	<u>3,458</u>	<u>222</u>	<u>—</u>	<u>3,680</u>
Total long-term investments . . . . .	<u>157,783</u>	<u>222</u>	<u>(793)</u>	<u>157,212</u>
Total investments . . . . .	<u>\$400,486</u>	<u>\$227</u>	<u>\$(1,293)</u>	<u>\$399,420</u>
<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>

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

**12. INVESTMENTS (Continued)**

Realized gains and losses on the sales and maturities of marketable securities, which were identified using the specific identification method, were as follows:

(In thousands)	Year Ended December 31,	
	2017	2016
Proceeds from the sales and maturities of marketable securities . . . . .	\$464,494	\$560,805
Realized gains . . . . .	\$ 9	\$ 206
Realized losses . . . . .	\$ 3	\$ 28

The Company's available-for-sale and held-to-maturity securities at December 31, 2017 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 . . . . .	\$234,771	\$234,273	\$1,791	\$1,791
After 1 year through 5 years . . . . .	162,257	161,467	1,667	1,889
Total . . . . .	\$397,028	\$395,740	\$3,458	\$3,680

At December 31, 2017, the Company believed that the unrealized losses on its available-for-sale investments were temporary. The investments with unrealized losses consisted of U.S. government and agency debt securities, corporate debt securities and international government debt securities. The unrealized losses are a result of market conditions related to increasing interest rates. 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.

**13. SHARE CAPITAL PRESENTED AS EQUITY**

*Share Capital*

(In thousands, except per share amounts)	December 31,	
	2017	2016
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

The directors are authorised to issue all or any of the authorised but unissued preferred shares from time to time in one or more classes or series, and to fix for each such class or series such voting

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

**13. SHARE CAPITAL PRESENTED AS EQUITY (Continued)**

powers (full or limited or without voting powers), designations, preferences and relative, participating, optional or other special rights and qualifications, limitations or restrictions thereof as are stated and expressed, or in any resolution or resolutions providing for the issue of such class or series adopted by the board of directors as hereinafter provided, including, without limitation, and subject to the Company's Articles of Incorporation ("Articles") and applicable law, the authority to provide that any such class or series may be:

- redeemable at the option of the Company, with the manner of the redemption to be set by the board of directors, and redeemable at such time or times, including upon a fixed date, and at such price or prices;
- entitled to receive dividends (which may be cumulative or non-cumulative) at such rates, on such conditions at such times and in respect of such dividend periods (the "Dividend Periods"), and payable in preference to, or in such relation to, the dividends payable on any other class or classes of shares or any other series;
- entitled to such rights upon the dissolution of, or upon any distribution of the assets of, the Company; or
- convertible into, or exchangeable for, shares of any other class or classes of shares, or of any other series of the same or any other class or classes of shares, of the Company at such price or prices or at such rates of exchange and with such adjustments as the directors determine, which rights and restrictions may be as stated in such resolution or resolutions of the directors as determined by them in accordance with this Article 14. The board of directors may at any time before the allotment of any preferred share by further resolution in any way amend the designations, preferences, rights, qualifications, limitations or restrictions, or vary or revoke the designations of such preferred shares.

The holders of ordinary shares shall be:

- entitled to dividends on a *pro rata* basis in accordance with the relevant provisions of these Articles;
- entitled to participate *pro rata* in the total assets of the Company in the event of the Company's winding up; and
- entitled, subject to the right of the Company, to set record dates for the purpose of determining the identity of holders of ordinary shares entitled to notice of and/or vote at a general meeting, to attend general meetings of the Company and shall be entitled to one vote for each ordinary

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

**13. SHARE CAPITAL PRESENTED AS EQUITY (Continued)**

share registered in their name in the Register of Members, both in accordance with the relevant provisions of these Articles.

<b>Issued Ordinary Shares (par value, \$0.01 per share) (Value in thousands)</b>	<b>Number</b>	<b>Value</b>
Balance at January 1, 2016 . . . . .	152,128,941	\$1,518
Issuance of ordinary shares under employee stock plans . . . . .	<u>2,062,340</u>	<u>21</u>
Balance at December 31, 2016 . . . . .	154,191,281	\$1,539
Issuance of ordinary shares under employee stock plans . . . . .	<u>1,866,351</u>	<u>18</u>
Balance at December 31, 2017 . . . . .	<u>156,057,632</u>	<u>\$1,557</u>

***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, 2017, 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, 2017 and 2016, the Company did not acquire any ordinary shares under the repurchase program.

***Treasury Shares***

<b>Treasury Shares (par value, \$0.01 per share) (Value in thousands)</b>	<b>Number</b>	<b>Value</b>
Balance at January 1, 2016 . . . . .	1,427,952	\$58,661
Acquired during the year . . . . .	<u>332,815</u>	<u>13,978</u>
Balance at December 31, 2016 . . . . .	1,760,767	\$72,639
Acquired during the year . . . . .	<u>287,409</u>	<u>16,708</u>
Balance at December 31, 2017 . . . . .	<u>2,048,176</u>	<u>\$89,347</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.



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

**14. SHARE-BASED COMPENSATION**

*Share-based Compensation Expense*

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

(In thousands)	Year Ended	
	December 31, 2017	December 31, 2016
Cost of goods manufactured and sold . . . . .	\$ 7,596	\$ 8,633
Research and development . . . . .	22,635	24,023
Selling, general and administrative . . . . .	53,686	61,740
Total share-based compensation expense . . . . .	\$83,917	\$94,396

During the years ended December 31, 2017 and 2016, \$0.4 million and \$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.

At December 31, 2017, there were 9.5 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.

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

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

*Stock Options*

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

	<u>Number of Shares</u>	<u>Weighted Average Exercise Price</u>
Outstanding, January 1, 2017 . . . . .	14,202,167	\$33.17
Granted . . . . .	2,030,075	\$55.04
Exercised . . . . .	(1,135,670)	\$20.95
Forfeited . . . . .	(266,433)	\$51.81
Expired . . . . .	(56,727)	\$68.97
Outstanding, December 31, 2017 . . . . .	<u>14,773,412</u>	\$36.64
Exercisable, December 31, 2017 . . . . .	<u>9,692,044</u>	\$29.57

The weighted average grant date fair value of stock options granted during the years ended December 31, 2017 and 2016 was \$25.81 and \$17.11, respectively. The aggregate intrinsic value of stock options exercised during the years ended December 31, 2017 and 2016 was \$40.4 million and \$35.0 million, respectively.

At December 31, 2017, there were 5.0 million stock options expected to vest with a weighted average exercise price of \$50.09 per share, a weighted average contractual remaining life of 8.3 years and an aggregate intrinsic value of \$39.0 million. At December 31, 2017, the aggregate intrinsic value of stock options exercisable was \$259.1 million with a weighted average remaining contractual term of 4.7 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, 2017, there was \$50.6 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, 2017 and 2016 was \$23.5 million and \$20.3 million, respectively.

*Time-Vested Restricted Stock Units*

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

	<u>Number of Shares</u>	<u>Weighted Average Grant Date Fair Value</u>
Unvested, January 1, 2017 . . . . .	2,074,416	\$42.60
Granted . . . . .	703,630	\$54.85
Vested . . . . .	(730,085)	\$43.14
Forfeited . . . . .	(111,153)	\$44.73
Unvested, December 31, 2017 . . . . .	<u>1,936,808</u>	\$46.72

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

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

The weighted average grant date fair value of time-vested RSUs granted during the years ended December 31, 2017 and 2016 were \$54.85 and \$32.27, respectively. The total fair value of time-vested RSUs that vested during the years ended December 31, 2017 and 2016 were \$31.5 million and \$26.0 million, respectively.

At December 31, 2017, there was \$34.4 million of total unrecognized compensation cost related to unvested time-vested RSUs, which will be recognized over a weighted average remaining contractual term of 1.9 years.

***Performance-Based Restricted Stock Units***

In February 2017, the board of directors approved awards of performance-based restricted stock units (“PRSUs”) to all employees employed by the Company during 2017, in each case subject to vesting on the achievement of two future key milestones in the Company’s clinical-stage pipeline and the achievement of a revenue-related goal; provided that, if any such vesting event occurs during the first year after grant, the vesting of the PRSU award will not occur until the one-year anniversary of the grant date. The award will expire if the performance conditions have not been met on or before the three-year anniversary of the grant date.

A summary of PRSU activity is presented in the following table:

	<u>Number of Shares</u>	<u>Weighted Average Grant Date Fair Value</u>
Unvested, January 1, 2017 . . . . .	—	—
Granted . . . . .	1,169,949	\$54.73
Vested . . . . .	(60,700)	\$54.78
Forfeited . . . . .	(596)	\$54.57
Unvested, December 31, 2017 . . . . .	<u>1,108,653</u>	\$54.72

The grant date fair value of the PRSUs was equal to the market value of the Company’s stock on the date of grant. At December 31, 2017, the Company does not consider it probable that the performance criteria will be met and has not recognized any share-based compensation expense related to these PRSUs. At December 31, 2017, there was \$60.7 million of unrecognized compensation cost related to these PRSUs, which would be recognized in accordance with the terms of the award when the Company deems it probable that the performance criteria will be met.

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

**15. PROVISIONS FOR LIABILITIES**

Provisions for liabilities consists of the following:

	<u>Medicaid Rebates</u>	<u>Product Returns</u>	<u>Other</u>	<u>Total</u>
	(In thousands)			
Balance at January 1, 2017 . . . . .	\$ 43,772	\$13,542	\$ 2,447	\$ 59,761
Additions . . . . .	147,755	6,676	32,540	186,971
Amounts utilized . . . . .	<u>(101,726)</u>	<u>(1,450)</u>	<u>(26,478)</u>	<u>(129,654)</u>
Balance at December 31, 2017 . . . . .	<u>\$ 89,801</u>	<u>\$18,768</u>	<u>\$ 8,509</u>	<u>\$ 117,078</u>

**16. CREDITORS**

	<u>December 31, 2017</u>	<u>December 31, 2016</u>
	(In thousands)	
<i>Amounts falling due within one year</i>		
Accrued expenses . . . . .	\$124,388	\$107,310
Trade creditors . . . . .	55,526	46,275
Deferred revenue . . . . .	1,956	1,938
Payroll taxes . . . . .	2,413	2,048
Accrued interest on long-term debt . . . . .	844	730
Value added tax . . . . .	999	396
Corporate tax . . . . .	21	194
Other taxes . . . . .	<u>147</u>	<u>307</u>
	<u>\$186,294</u>	<u>\$159,198</u>
<i>Amounts falling due after more than one year</i>		
Deferred income taxes . . . . .	\$ 308	\$ 328
Deferred revenue . . . . .	5,657	7,122
Other long-term liabilities . . . . .	<u>3,646</u>	<u>6,867</u>
Total . . . . .	<u>\$195,905</u>	<u>\$173,515</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. Tax amounts are repayable at various dates over the coming months in accordance with the applicable statutory provisions.

**17. COMMITMENTS AND CONTINGENCIES**

*Lease Commitments*

The Company leases certain of its offices, research laboratories and manufacturing facilities under operating leases that expire through the year 2029. 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

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

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

December 31, 2017, the total future annual minimum lease payments under the Company's non-cancelable operating leases are as follows:

(In thousands)	<u>Payment Amount</u>
Years Ending December 31,:	
2018 . . . . .	\$ 9,174
2019 . . . . .	9,092
2020 . . . . .	6,404
2021 . . . . .	2,448
2022 . . . . .	1,195
Thereafter . . . . .	<u>3,615</u>
Total future minimum lease payments . . . . .	<u>\$31,928</u>

Rent expense related to operating leases charged to operations was \$9.4 million and \$8.1 million for the years ended December 31, 2017 and 2016, respectively. In addition to its lease commitments, the Company had open purchase orders totaling \$473.9 million at December 31, 2017.

***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, 2017, there are no potential losses from claims, asserted or unasserted, or legal proceedings the Company feels are probable of occurring.

**INVEGA SUSTENNA ANDA Litigation**

In January 2018, Janssen Pharmaceuticals NV and Janssen Pharmaceuticals, Inc. initiated a patent infringement lawsuit in the United States District Court for the District of New Jersey against Teva, who filed an ANDA seeking approval to market a generic version of INVEGA SUSTENNA before the expiration of United States Patent No. 9,439,906. Requested judicial remedies included recovery of litigation costs and injunctive relief. The Company is not a party to these proceedings. For information about risks relating to the INVEGA SUSTENNA Paragraph IV litigation, see "Principal Risks" in this Directors' Report and specifically the section entitled "—We or our licensees may face claims against intellectual property rights covering our products and competition from generic drug manufacturers."

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

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

**AMPYRA ANDA Litigation**

Ten separate Paragraph IV Certification Notices have been received by 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. (“Roxane”); Sun Pharmaceutical Industries Limited and Sun Pharmaceuticals Industries Inc. (collectively, “Sun”); and Teva Pharmaceuticals USA, Inc. (“Teva,” and collectively with Accord, Actavis, Alkem, Apotex, Aurobindo, Mylan, Par, Roxane and Sun, the “ANDA Filers”) advising that each of the ANDA Filers had submitted an abbreviated NDA (“ANDA”) to the FDA seeking marketing approval for generic versions of AMPYRA (dalfampridine) Extended-Release Tablets, 10 mg. The ANDA Filers challenged the validity of the Orange

Book-listed patents for AMPYRA, and they 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 No. 5,540,938 (the “938 Patent”), which the Company owns, and U.S. Patent Nos. 8,007,826; 8,354,437; 8,440,703; and 8,663,685, which are owned by Acorda. Requested judicial remedies included recovery of litigation costs and injunctive relief. 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 Federal Circuit. In March 2016, the Federal Circuit denied Mylan’s appeal. 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.

All lawsuits were filed within 45 days from the date of receipt of each of the Paragraph IV Certification Notices from the ANDA Filers. As a result, a 30-month statutory stay of approval period applied to each of the ANDA Filers’ ANDAs under the U.S. Drug Price Competition and Patent Term Restoration Act of 1984 (the “Hatch-Waxman Act”). The 30-month stay started on January 22, 2015, and restricted the FDA from approving the ANDA Filers’ ANDAs until July 2017 at the earliest, unless a Federal district court issued a decision adverse to all of the asserted Orange Book-listed patents prior to that date. Lawsuits with eight of the ANDA Filers have been consolidated into a single case.

The Company and/or Acorda 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 a result of the settlement agreements, the Settling ANDA Filers will be permitted to market generic versions of AMPYRA in the U.S. at a specified date in the future. The parties submitted their respective settlement agreements to the U.S. Federal Trade Commission and the U.S. Department of Justice, as required by federal law. The settlements with the Settling ANDA Filers did not impact the patent litigation that the Company and Acorda brought against the remaining ANDA Filers (the “Non-Settling ANDA Filers”), as described in this Annual Report.

On March 31, 2017, after a bench trial, the Delaware Court issued an opinion (the “Delaware Court Decision”), upholding the validity of the ‘938 Patent, which pertains to the formulation of AMPYRA and is set to expire in July 2018, and finding that Apotex, Mylan, Roxane and Teva



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

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

stipulated that their proposed generic forms of AMPYRA infringed the '938 Patent. The Delaware Court also invalidated U.S. Patent Nos. 8,007,826; 8,354,437; 8,440,703; and 8,663,685. In May 2017, Acorda filed its appeal of the Delaware Court Decision with the U.S. Court of Appeals for the Federal Circuit (the "Federal Circuit") with respect to the findings on U.S. Patent Nos. 8,007,826; 8,354,437; 8,440,703; and 8,663,685. In June 2017, the Non-Settling ANDA Filers filed their cross-appeal of the Delaware Court Decision with the Federal Circuit with respect to the validity of the '938 Patent. The Company and Acorda filed their opening brief on August 7, 2017. The Non-Settling ANDA Filers responded on October 2, 2017. The Company and Acorda filed a response and reply brief on November 13, 2017, and the Non-Settling ANDA Filers filed their reply brief on November 27, 2017. A date for oral argument before the Federal Circuit has not yet been set.

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" in this Directors' Report and specifically see the section entitled "—We or our licensees may face claims against intellectual property rights covering our products and competition from generic drug manufacturers."

**Government Matters**

On June 22, 2017, the Company received a subpoena from an Office of the U.S. Attorney for documents related to VIVITROL. The Company is cooperating with the government.

**Securities Litigation**

On November 22, 2017, a purported stockholder of the Company filed a putative class action against the Company and certain of its officers in the United States District Court for the Southern District of New York captioned *Gagnon v. Alkermes plc, et al.*, No. 1:17-cv-09178. The complaint was filed on behalf of a putative class of purchasers of Alkermes securities during the period of February 24, 2015 to November 3, 2017, and alleges violations of Sections 10(b) and 20(a) of the Securities Exchange Act of 1934, as amended, based on allegedly false or misleading statements and omissions regarding the Company's marketing practices related to VIVITROL. The lawsuit seeks, among other things, unspecified damages for alleged inflation in the price of securities, and reasonable costs and expenses, including attorneys' fees. For information about risks relating to this action, see "Principal Risks" of this Directors' Report and specifically the section entitled "—Litigation or arbitration against Alkermes, including securities litigation, or citizen petitions filed with the FDA, may result in financial losses, harm our reputation, divert management resources, negatively impact the approval of our products, or otherwise negatively impact our business."

**18. CAPITAL EXPENDITURE COMMITMENTS**

The directors have authorized the Company to spend \$85.0 million for capital expenditures in the year ending December 31, 2018.

**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

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

**19. RELATED PARTY DISCLOSURES (Continued)**

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 is provided in Note 24, *Subsidiaries*, and information regarding associates is provided in Note 4, *Goodwill, Intangible Assets and Associated undertakings*, to the consolidated financial statements.

*Trading Transactions*

There were no transactions requiring disclosure under Sch. 3, Section 67(1) of the Irish 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 22, *Directors' Remuneration*.

**20. LOANS TO DIRECTORS**

Irish company law prohibits the Group from making a loan or a quasi loan to a director of the Group unless certain conditions are met. No loans or quasi-loans have been made to any director of the Group during the financial year.

**21. EMPLOYEES**

The average number of persons employed by the Company during the years ended December 31, 2017 and 2016, respectively, was as follows:

	December 31, 2017	December 31, 2016
	(In thousands)	
Manufacturing . . . . .	707	597
Research and development . . . . .	438	383
Selling, general and administrative . . . . .	719	634
Total . . . . .	1,864	1,614

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

**21. EMPLOYEES (Continued)**

Employee costs included in profit and loss during the years ended December 31, 2017 and 2016 consisted of the following:

	<b>December 31, 2017</b>	<b>December 31, 2016</b>
	<b>(In thousands)</b>	
Wages and salaries . . . . .	\$279,779	\$237,289
Share-based compensation . . . . .	83,916	94,396
Social insurance costs <sup>(1)</sup> . . . . .	44,080	37,320
Defined contribution plan contributions . . . . .	14,440	12,162
Total . . . . .	\$422,215	\$381,167

(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, 2017 and 2016, the Company capitalized \$0.5 million and \$0.1 million, respectively, as part of its tangible fixed assets and \$47.6 million and \$26.4 million, respectively, as part of its stock.

**22. 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 CEO (referred to as "Managerial Services") as well as compensation for all non-employee directors in their capacities as such (referred to as "Director Services").

	<b>December 31, 2017</b>	<b>December 31, 2016</b>
	<b>(In thousands)</b>	
<b>Managerial Services:</b>		
Emoluments . . . . .	\$2,078	\$2,555
Benefits under long term incentive schemes . . . . .	3,161	2,259
Company contribution to 401(k) plan . . . . .	14	13
Total . . . . .	\$5,253	\$4,827
<b>Director Services:</b>		
Fees paid in cash . . . . .	\$ 658	\$ 616
Total . . . . .	\$ 658	\$ 616

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, 2017 was \$8.3 million (December 31, 2016: \$7.2 million). The Company considers its directors to be key management personnel.

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

**23. AUDITORS' REMUNERATION**

Total auditors' remuneration, including expenses, accrued and paid to PricewaterhouseCoopers and its affiliated firms for the years ended December 31, 2017 and 2016, respectively, were as follows:

	<b>December 31, 2017</b>	<b>December 31, 2016</b>
	<b>(In thousands)</b>	
Audit and review of group financial statements <sup>(1)</sup> . . . .	\$1,860	\$1,659
Audit-related fees <sup>(2)</sup> . . . . .	263	23
Tax fees <sup>(3)</sup> . . . . .	517	400
All other fees <sup>(4)</sup> . . . . .	2	2
Total . . . . .	<u>2,642</u>	<u>\$2,084</u>

- (1) In the years ended December 31, 2017 and 2016, consisted 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, 2017 and 2016 are expenses of \$85 thousand and \$49 thousand, respectively.
- (2) In the year ended December 31, 2016, consisted of fees for a royalty audit of one of our collaboration agreements.
- (3) In the years ended December 31, 2017 and 2016, consisted 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, 2017 and 2016, consisted of fees for access to the PricewaterhouseCoopers on-line accounting research database.

Total fees paid to PricewaterhouseCoopers Ireland in respect of the audit of the group financial statements were \$0.5 million during the years ended December 31, 2017 and 2016, respectively. In addition, PricewaterhouseCoopers Ireland received \$0.1 million for tax advisory services during both of the years ended December 31, 2017 and 2016, respectively.

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

**24. 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, Republic of Ireland	100%
Alkermes Pharma Ireland Limited . . . . .	Manufacturing and R&D	Connaught House, 1 Burlington Road Dublin 4, Republic of Ireland	100%
Alkermes Finance Ireland Limited . . . . .	Finance Company	Connaught House, 1 Burlington Road Dublin 4, Republic of Ireland	100%
Daravita Pharma Ireland Limited . . . . .	Holding Company	Connaught House, 1 Burlington Road Dublin 4, Republic of Ireland	100%
Alkermes Finance Ireland (No.2) Limited . . . . .	Finance Company	Connaught House, 1 Burlington Road Dublin 4, Republic of Ireland	100%
Alkermes Finance Ireland (No.3) Limited . . . . .	Finance Company	Connaught House, 1 Burlington Road Dublin 4, Republic of Ireland	100%
Daravita Limited . . . . .	Non-Operating	Connaught House, 1 Burlington Road Dublin 4, Republic of Ireland	100%
Alkermes Science Four Limited . . . . .	Non-Operating	Connaught House, 1 Burlington Road Dublin 4, Republic of Ireland	100%
Alkermes Science Five Limited . . . . .	Non-Operating	Connaught House, 1 Burlington Road Dublin 4, Republic of 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%

**25. SUBSEQUENT EVENTS**

In March 2018, the Company amended the 2023 Term Loan, formerly referred to as Term Loan B-1, pursuant to which, among other things, the due date of the 2023 Term Loan was extended from September 25, 2021 to March 26, 2023 and the interest payable was reduced from LIBOR plus 2.75% with a LIBOR floor of 0.75% to LIBOR plus 2.25% with no LIBOR floor.

In March 2018, the Company entered into a lease agreement to lease approximately 220,000 square feet of office and laboratory space in Waltham, Massachusetts (“900 Winter Street”). The term of the lease shall commence on the earlier of (i) the Delivery Date (defined as (i) the later of January 20, 2020, or (ii) the date on which the landlord substantially completes its work in accordance with the terms of the lease), or (ii) the date the Company enters into possession of all or any substantial portion of 900 Winter Street for the conduct of its business (the “Commencement Date”). The initial lease term expires on last day of the calendar month in which the fifteenth anniversary of the Commencement Date, with an option to extend for an additional ten (10) years.

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

	<u>Note</u>	<u>December 31, 2017</u>	<u>December 31, 2016</u>
<b>ASSETS</b>			
<i>Fixed Assets</i>			
Financial assets . . . . .	7	\$1,987,201	\$1,986,070
<i>Current Assets</i>			
Debtors . . . . .	8	698,730	639,330
Cash at bank and in-hand . . . . .		<u>38,971</u>	<u>52,958</u>
<b>TOTAL ASSETS</b> . . . . .		<u><b>\$2,724,902</b></u>	<u><b>\$2,678,358</b></u>
<b>LIABILITIES</b>			
<i>Creditors</i>			
Creditors . . . . .	9	<u>\$ 2,535</u>	<u>\$ 17,140</u>
Total for creditors . . . . .		<u>2,535</u>	<u>17,140</u>
<i>Equity Shareholders' Funds</i>			
Share capital, \$0.01 par value . . . . .	10	1,557	1,539
Share premium . . . . .	11	545,803	522,024
Profit and loss account . . . . .	11	1,847,862	1,877,075
Treasury shares . . . . .	11	(89,347)	(72,639)
Other reserves . . . . .	11	<u>416,492</u>	<u>333,219</u>
Total equity shareholders' funds . . . . .		<u><b>\$2,722,367</b></u>	<u><b>\$2,661,218</b></u>
<b>TOTAL LIABILITIES</b> . . . . .		<u><b>\$2,724,902</b></u>	<u><b>\$2,678,358</b></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 9, 2018 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, 2016 . . . . .	\$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
Net loss . . . . .	—	—	(29,213)	—	—	(29,213)
Share-based payment reserve . . . . .	—	—	—	—	83,273	83,273
Shares issued under employee stock plans . . . . .	16	23,506	—	—	—	23,522
Receipt of Alkermes' shares for the purchase of share options or to satisfy minimum tax withholding obligations related to share based awards . . . . .	2	273	—	(16,708)	—	(16,433)
BALANCE—December 31, 2017 . . . . .	\$1,557	\$545,803	\$1,847,862	\$(89,347)	\$416,492	\$2,722,367

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

**ALKERMES PLC**  
**NOTES TO THE 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 (“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, *Critical Accounting Judgments and Estimation Uncertainty*.

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

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

***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 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.

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 are carried at historical cost less accumulated impairment losses. See Note 7, *Financial Assets*, below for further information.

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

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

*Dividend Income from Shares in Group Undertakings*

Dividend income from group undertakings is recognized in the period in which it is 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, 2017, 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 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 14, *Share-Based Compensation*, of the 2017 Alkermes plc consolidated financial statements provides additional details of the Group's share-based compensation plans.

#### *Contingencies*

Contingent liabilities, arising as a result of past events, are not recognized as a liability because (i) 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 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. Loss 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 years ended December 31, 2017 and 2016, determined in accordance with Irish GAAP, was \$29.2 million and \$48.6 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 the carrying value of investments in subsidiaries and measurement of 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 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 22, *Directors' Remuneration* of the notes to the consolidated financial statements for a summary of their remuneration.

**7. Financial Assets**

Financial assets relate to investments in subsidiaries.

	<u>(In thousands)</u>
Balance—January 1, 2016, 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 . . . . .	\$1,986,070
Capital contribution in respect of share-based payment plans . . . . .	80,659
Reduction—equity recharge from subsidiaries . . . . .	<u>(79,528)</u>
Balance—December 31, 2017, at cost . . . . .	<u><u>\$1,987,201</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. See Note 24, *Subsidiaries*, in the consolidated financial statements for the list of direct subsidiaries.

**8. Debtors**

	<u>December 31,</u> <u>2017</u>	<u>December 31,</u> <u>2016</u>
	<u>(In thousands)</u>	
<i>Amounts falling due within one year</i>		
Trade receivables . . . . .	\$ 1,180	\$ 11,773
Prepaid expenses and other current assets . . . . .	715	700
Intercompany notes and loans receivable . . . . .	<u>307,466</u>	<u>494,655</u>
	<u>\$309,361</u>	<u>\$507,128</u>
<i>Amounts falling due after one year</i>		
Intercompany loans receivable . . . . .	\$386,000	\$130,000
Other debtors . . . . .	<u>3,369</u>	<u>2,202</u>
	<u>389,369</u>	<u>132,202</u>
Total . . . . .	<u><u>\$698,730</u></u>	<u><u>\$639,330</u></u>



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

**8. Debtors (Continued)**

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

<u>Borrower</u>	<u>Maturity</u>	<u>Interest Rate</u>	<u>Balance at December 31,</u>	
			<u>2017</u>	<u>2016</u>
(in thousands)				
Alkermes Pharma Ireland Limited . . . . .	January 1, 2018	3.25%	\$130,000	\$ —
Alkermes Finance Ireland No.3 Limited . . . . .	Repayable upon demand	Variable	163,266	—
Alkermes Science Six Limited . . . . .	Repayable upon demand	None	10,500	10,500
Alkermes Finance Ireland No. 3 Limited . . . . .	Repayable upon demand	None	3,600	188,455
Alkermes Science Six Limited. . . . .	Repayable upon demand	None	100	100
Alkermes Pharma Ireland Limited . . . . .	July 8, 2017	3.25%	—	160,000
Alkermes Pharma Ireland Limited . . . . .	November 16, 2017	3.50%	—	132,000
Daravita Pharma Ireland Limited . . . . .	Repayable upon demand	None	—	3,600
<b>Total . . . . .</b>			<u>\$307,466</u>	<u>\$494,655</u>

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

<u>Borrower</u>	<u>Maturity</u>	<u>Interest Rate</u>	<u>Balance at December 31,</u>	
			<u>2017</u>	<u>2016</u>
(in thousands)				
Alkermes Pharma Ireland Limited . . . . .	January 1, 2018	3.25%	\$ —	\$130,000
Alkermes Pharma Ireland Limited . . . . .	July 8, 2022	7.00%	160,000	—
Alkermes Pharma Ireland Limited . . . . .	September 27, 2022	7.00%	226,000	—
<b>Total . . . . .</b>			<u>\$386,000</u>	<u>\$130,000</u>

**9. Creditors**

	<u>December 31,</u>	<u>December 31,</u>
	<u>2017</u>	<u>2016</u>
(In thousands)		
<i>Amounts falling due within one year</i>		
Accrued expenses . . . . .	\$ 745	\$ 745
Trade creditors . . . . .	9	22
Intercompany payables . . . . .	1,781	16,373
<b>Total . . . . .</b>	<u>\$2,535</u>	<u>\$17,140</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 COMPANY FINANCIAL STATEMENTS (Continued)**

**10. Share Capital**

<u>(In thousands, except per share amounts)</u>	<b>December 31,</b>	
	<b>2017</b>	<b>2016</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, 2016 . . . . .	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
Issuance of ordinary shares under employee stock plans . . . . .	1,866,351	18
Balance at December 31, 2017 . . . . .	156,057,632	\$1,557

See Note 14, *Share-Based Compensation*, to the Consolidated Financial Statements for additional information regarding equity shareholder’s funds.

**11. Reserves**

The Company’s reserves consisted 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 less 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 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, 2017, there were no potential losses from claims, asserted or unasserted, or legal proceedings the Company felt were probable of occurring (at December 31, 2016: none).

**14. Auditors' Remuneration**

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

(In thousands)	Year Ended	
	December 31, 2017	December 31, 2016
Audit of the Company's individual financial statements . . .	\$10	\$10
Other assurance services . . . . .	—	—
Tax advisory services . . . . .	—	—
Other non-audit services . . . . .	—	—
Total . . . . .	\$10	\$10

See Note 23, *Auditors' Remuneration*, to the Consolidated Financial Statements for additional information regarding fees paid to PricewaterhouseCoopers 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 9, 2018 and were signed on its behalf on that day.



