ALKERMES PUBLIC LIMITED COMPANY

DIRECTORS' REPORT AND CONSOLIDATED FINANCIAL STATEMENTS

For the Financial Year Ended December 31, 2018

Registered Company Number: 498284

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DIRECTORS' REPORT

For the Financial Year Ended December 31, 2018

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, 2018. 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 Irish law).

NOTE REGARDING COMPANY AND PRODUCT REFERENCES

Use of the terms such as "us," "we," "our," "Alkermes" or the "Company" in this Directors' Report is meant to refer to Alkermes plc and its consolidated subsidiaries. Except as otherwise suggested by the context, (a) references to "products" or "our products" in this Directors' Report include our marketed products, marketed products using our proprietary technologies, our product candidates, product candidates using our proprietary technologies, development products and development products using our proprietary technologies (b) references to the "biopharmaceutical industry" in this Directors' 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 ("™"), including ALKERMES®, ARISTADA®, ARISTADA INITIO®, CaRE®, CODAS®, IPDAS®, LinkeRx®, MXDAS®, NanoCrystal®, SODAS®, and VIVITROL®.

The following are trademarks of the respective companies listed: ABILIFY® and ABILIFY MAINTENA®—Otsuka Pharmaceutical Co., Ltd. ("Otsuka Pharm. Co."); AMPYRA®, and 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; BRIXADI®—Braeburn Inc.; BUNAVAIL™—BioDelivery Sciences; —CAMPRAL®—Merck Sante; COPAXONE®—Teva Pharmaceutical Industries Ltd.; EXTAVIA® and GILENYA®—Novartis AG; INVEGA SUSTENNA®, RISPERDAL CONSTA® INVEGA TRINZA®, TREVICTA® and XEPLION®—Johnson & Johnson (or its affiliates); LATUDA®—Dainippon Sumitomo Pharma Co., Ltd.; NOVANTRONE® and REBIF®—Ares Trading S.A.; OCREVUS®—Genentech, Inc. ("Genentech"); PROBUPHINE®— Titan Pharmaceuticals, Inc.; REXULTI®— H. Lundbeck A/S plc; PERSERIS®— SUBOXONE®, SUBUTEX® and SUBLOCADE®—Indivior plc (or its affiliates); VICTOZA®—Novo Nordisk A/S LLC; ZUBSOLV®—Orexo US, Inc.; ZYPREXA® RELPREVV®—Eli Lilly and Company; and VRAYLAR®— Forest Laboratories, LLC . Other trademarks, trade names and service marks appearing in this Directors' Report are the property of their respective owners. Solely for convenience, the trademarks and trade names in this Directors' Report are referred to without the ® and ™ symbols, but such references should not be construed as any indicator that their respective owners will not assert, to the fullest extent under applicable law, their rights thereto.

CAUTIONARY NOTE CONCERNING FORWARD-LOOKING STATEMENTS

This document contains and incorporates by reference "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995, as amended. In some cases, these statements can be identified by the use of forward-looking terminology such as "may," "will," "could," "should," "would," “expect,” “anticipate,” “continue,” “believe,” “plan,” “estimate,” “intend,” or other similar words. These statements discuss future expectations and contain projections of results of operations or of financial condition, or state trends and known uncertainties or other forward-looking information. Forward-looking statements in this Directors’ Report include, without limitation, statements regarding:

- our expectations regarding our financial performance, including revenues, expenses, gross margins, liquidity, capital expenditures and income taxes;
- our expectations regarding our products, including those expectations related to product development, regulatory filings, regulatory approvals and regulatory timelines, therapeutic and commercial scope and potential, and the costs and expenses related to such activities;
- our expectations regarding the initiation, timing and results of clinical trials of our products;
- our expectations regarding the competitive landscape, and changes therein, related to our products, including competition from generic forms of our products or competitive products and competitive development programs;
- our expectations regarding the financial impact of currency exchange rate fluctuations and valuations;
- our expectations regarding future amortization of intangible assets;
- our expectations regarding our collaborations, licensing arrangements and other significant agreements with third parties relating to our products, including our development programs;
- our expectations regarding the impact of new legislation and related regulations and the adoption of new accounting pronouncements;
- our expectations regarding near-term changes in the nature of our market risk exposures or in management’s objectives and strategies with respect to managing such exposures;
- our ability to comply with restrictive covenants of our indebtedness and our ability to fund our debt service obligations;
- our expectations regarding future capital requirements and capital expenditures and our ability to finance our operations and capital requirements;
- our expectations regarding the timing, outcome and impact of administrative, regulatory, legal and other proceedings related to our patents, other proprietary and intellectual property (“IP”) rights, and our products; and
- other factors discussed elsewhere in this Directors’ Report.

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

This Directors’ Report includes data that we obtained from industry publications and third-party research, surveys and studies. Industry publications and third-party research, surveys and studies generally indicate that their information has been obtained from sources believed to be reliable, although they do not guarantee the accuracy or completeness of such information. This Directors’ Report also includes data based on our own internal estimates and research. Our internal estimates and research have not been verified by any independent source, and, while we believe the industry publications and third-party research, surveys and studies are reliable, we have not independently verified such data. Such third-party data and our internal estimates and research are necessarily subject to a high degree of uncertainty and risk due to a variety of factors, including those described in the "Principal Risks" section of this Directors' Report. These and other factors could cause results to differ materially from those expressed in this Directors' Report.

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 product candidates focused on central nervous system ("CNS") disorders such as schizophrenia, depression, addiction and multiple sclerosis ("MS") and oncology. 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 Directors' Report for information with respect to the intellectual property protection for these marketed products.

Summary information regarding our proprietary products:

Product	Indication(s)	Licensee	Territory
ARISTADA INITIO	Initiation or reinitiation of ARISTADA for the treatment of Schizophrenia	None	Commercialized by Alkermes in the U.S.
ARISTADA	Schizophrenia	None	Commercialized by Alkermes in the U.S.
VIVITROL	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:			
RISPERDAL CONSTA	Schizophrenia and Bipolar I disorder	Janssen Pharmaceutica Inc. ("Janssen, Inc.") and Janssen Pharmaceutica International, a division of Cilag International AG ("Janssen International")	Worldwide
INVEGA SUSTENNA	Schizophrenia and Schizoaffective disorder	Janssen Pharmaceutica N.V. (together with Janssen, Inc. Janssen International and their affiliates "Janssen")	U.S.
XEPLION	Schizophrenia	Janssen	All countries outside the U.S. ("ROW")
INVEGA TRINZA	Schizophrenia	Janssen	U.S.
TREVICTA	Schizophrenia	Janssen	ROW
AMPYRA	Treatment to improve walking in patients with MS, as demonstrated by an increase in walking speed	Acorda	U.S.
FAMPYRA		Biogen, under sublicense from Acorda	ROW

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 four dosing options—once-monthly (441 mg, 662 mg, 882 mg), once-every-six-weeks (882 mg) and once-every-two-months (1064 mg)—to deliver and maintain therapeutic levels of medication in the body. ARISTADA is packaged in a ready-to-use, pre-filled product format. We developed ARISTADA and manufacture and commercialize it in the U.S.

ARISTADA INITIO

ARISTADA INITIO (aripiprazole lauroxil), in combination with a single 30 mg dose of oral aripiprazole, is indicated for the initiation of ARISTADA when used for the treatment of schizophrenia in adults. ARISTADA INITIO leverages our proprietary NanoCrystal technology and provides an extended-release formulation of aripiprazole lauroxil in a smaller particle size compared to ARISTADA. This smaller particle size enables faster dissolution and leads to more rapid achievement of relevant levels of aripiprazole. The ARISTADA INITIO regimen, consisting of a single injection of 675 mg ARISTADA INITIO in combination with a single 30 mg dose of oral aripiprazole, when used to initiate onto any dose of ARISTADA, provides patients with relevant levels of aripiprazole within four days of treatment initiation. The first ARISTADA dose may be administered on the same day as the ARISTADA INITIO regimen or up to 10 days thereafter. We developed ARISTADA INITIO and exclusively 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. Approximately 3.5 million people are diagnosed with schizophrenia in the U.S., 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.

For a discussion of legal proceedings related to the patents covering VIVITROL, see Note 18, *Commitments and Contingent Liabilities* in the "Notes to Consolidated Financial Statements" in this Directors' Report, and for information about risks relating to such legal proceedings, see "Principal Risks" in this Directors' Report and specifically the sections entitled "—Patent protection for our products is important and uncertain," "—Uncertainty over intellectual property in the biopharmaceutical industry has been the source of litigation, which is inherently costly and unpredictable, could significantly delay or prevent approval or commercialization of our products, and could adversely affect our business" and "—Litigation, arbitration or regulatory action (such as citizens petitions) filed against regulatory agencies related to our product or Alkermes, including securities litigation, may result in financial losses, harm our reputation, divert management resources, negatively impact the approval of our products, or otherwise negatively impact our business."

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 2017 U.S. National Survey on Drug Use and Health, an estimated 2.0 million people aged 18 or older in the U.S. had an opioid use disorder. In 2013, with the publication of the Diagnostic Statistical Manual (DSM) V, the DSM IV diagnoses of substance use disorders as either dependence or abuse (i.e., opioid dependence), were combined into one diagnostic category of "substance use disorders" (i.e., opioid use disorder) with three categories of disorder severity—either mild, moderate or severe. It is believed that the DSM IV diagnoses of opioid dependence corresponds to the DSM V diagnosis of either moderate or severe 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 2017 U.S. National Survey on Drug Use and Health, an estimated 7.8 million people 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/TREVICTA (paliperidone palmitate 3-month 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. For a discussion of legal proceedings related to the patents covering INVEGA SUSTENNA, see Note 18, *Commitments and Contingent Liabilities* in the "Notes to Consolidated Financial Statements" and for information about risks relating to such legal proceedings, 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/TREVICTA 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/TREVICTA 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. For a discussion of legal proceedings related to one of the patents covering RISPERDAL CONSTA, see Note 18, *Commitments and Contingent Liabilities* in the "Notes to Consolidated Financial Statements" section of this Directors' Report and for information about risks relating to such legal proceedings, see the "Principal Risks" section of 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."

Revenues from Janssen accounted for approximately 29% and 33% of our consolidated revenues for the years ended December 31, 2018 and 2017, respectively. See "Collaborative Arrangements" in this Directors' 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 and affects approximately one percent of the American adult population in any given year. The median age of onset for bipolar I 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. FAMPYRA is approved in the EU for the improvement of walking in adults with MS. AMPYRA and FAMPYRA incorporate our oral controlled-release technology. AMPYRA (including the authorized generic version of AMPYRA) and FAMPYRA are manufactured by us.

For a discussion of legal proceedings related to the patents covering AMPYRA, see Note 18, *Commitments and Contingent Liabilities* in the "Notes to Consolidated Financial Statements" in this Directors' Report and for information about risks relating to such legal proceedings, 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 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.

Starting in September 2018, generic versions of AMPYRA, including the authorized generic version of AMPYRA, began to enter the U.S. market.

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.

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, and in oncology. 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 "Principal Risks" of this Directors' Report. Refer to the "Patents and Proprietary Rights" section in this Directors' Report for information with respect to the intellectual property protection for our development candidates.

Diroximel Fumarate (BIIB098)

Diroximel fumarate ("BIIB098"), formerly referred to as ALKS 8700, is a novel, oral fumarate in development for the treatment of relapsing forms of MS. Diroximel fumarate is designed to rapidly convert to monomethyl fumarate in the body and may have the potential to offer differentiated gastrointestinal tolerability due to its chemical structure as compared to the currently marketed dimethyl fumarate, TECFIDERA.

The pivotal clinical program for diroximel fumarate consists of pharmacokinetic bridging studies comparing diroximel fumarate and TECFIDERA and a two-year, multicenter, open-label study designed to assess the safety of BIIB098, which we initiated in December 2015. We submitted a 505(b)(2) NDA for diroximel fumarate in December 2018. In addition, EVOLVE-MS-2, an elective, randomized, head-to-head phase 3 study of the gastrointestinal tolerability of diroximel fumarate versus TECFIDERA is ongoing, with topline results expected in mid-2019.

In November 2017, we entered into an exclusive license and collaboration agreement with Biogen relating to diroximel fumarate. Revenues from Biogen related to this license and collaboration agreement accounted for approximately 10% and less than 10% of our consolidated revenues for the years ended December 31, 2018 and 2017, respectively. For more information about the license and collaboration agreement with Biogen, see the section entitled "Collaborative Arrangements" in this Directors' Report.

ALKS 3831

ALKS 3831 is an investigational, novel, once-daily, oral atypical antipsychotic drug candidate for the treatment of schizophrenia. ALKS 3831 is composed of samidorphan, a novel, new molecular entity, co-formulated with the established antipsychotic agent, olanzapine, in a single bilayer tablet. ALKS 3831 is designed to provide the strong antipsychotic efficacy of olanzapine with a favorable weight profile.

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

In June 2017, we announced positive 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 over a four-week period 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.

In November 2018, we announced positive topline results from ENLIGHTEN-2, a multicenter, double-blind, randomized, phase 3 study that evaluated the weight gain profile of ALKS 3831 compared to olanzapine in patients with stable schizophrenia over a six-month period. ALKS 3831 met the prespecified co-primary endpoints, demonstrating both a lower mean percent weight gain from baseline at six months compared to the olanzapine group, and a lower proportion of patients who gained 10% or more of their baseline body weight at six months compared to the olanzapine group. We plan to present ENLIGHTEN-2 data at a medical meeting in the first half of 2019.

We will request a pre-NDA meeting with the FDA to discuss its key requirements including the efficacy, safety, weight and metabolic profile of ALKS 3831, and plan to submit an NDA for ALKS 3831 in mid-2019.

ALKS 4230

ALKS 4230 is a novel, engineered fusion protein designed to selectively activate tumor-killing immune cells while avoiding the expansion of immunosuppressive cells by preferentially binding to the intermediate affinity interleukin-2 ("IL-2") receptor complex. The selectivity of ALKS 4230 is designed to leverage the proven anti-tumor effects of existing IL-2 therapy, while mitigating certain limitations. Our phase 1 study for ALKS 4230 is designed to evaluate ALKS 4230 as a monotherapy agent and in combination with the anti-PD-1 therapy, pembrolizumab.

A dose-escalation stage designed to determine a maximum tolerated dose of ALKS 4230 in a monotherapy setting and to identify the optimal dose range of ALKS 4230 based on measures of immunological-pharmacodynamic effects is ongoing. Upon completion of the dose-escalation stage, we expect to initiate a monotherapy dose-expansion stage of the phase 1 study in patients with renal cell carcinoma or melanoma. Initial data from the dose-escalation stage of the phase 1 study, demonstrating dose-dependent pharmacodynamic effects on circulating CD8+ T cells and natural killer cells with minimal and non-dose dependent effect on immunosuppressive regulatory T cells, were presented at the 2018 Society for Immunotherapy of Cancer meeting.

In September 2018, we initiated the combination therapy stage of the phase 1 study, designed to assess the safety profile and anti-tumor activity of ALKS 4230 with pembrolizumab in patients with select advanced solid tumors.

ALKS 5461 Update

ALKS 5461 is a proprietary, once-daily, oral investigational medicine with a novel mechanism of action for the adjunctive treatment of major depressive disorder ("MDD") in patients with an inadequate response to standard antidepressant therapies. 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.

The clinical development program for ALKS 5461 included 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. Our NDA for ALKS 5461, submitted to the FDA in January 2018, and accepted for review by the FDA in April 2018 after the issuance, and then rescission, of a refusal to file letter, was 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.

As previously disclosed, on November 1, 2018, the FDA convened an advisory committee meeting for the ALKS 5461 NDA. The Psychopharmacologic Drugs Advisory Committee and the Drug Safety and Risk

Management Advisory Committee jointly voted that the benefit-risk profile was not adequate to support approval of ALKS 5461. On February 1, 2019, we announced receipt of a complete response letter, or CRL, from the FDA for the ALKS 5461 NDA. The CRL states that the FDA is unable to approve the ALKS 5461 NDA in its present form and requests additional clinical data to provide substantial evidence of effectiveness of ALKS 5461 for the adjunctive treatment of MDD. We plan to meet with the FDA to discuss the contents of the CRL and potential next steps for ALKS 5461. This interaction with the Agency will inform whether there is a viable path forward for the ALKS 5461 program.

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%. 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 (including the authorized generic version of AMPYRA) and 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 upon 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.

Biogen

In November 2017, we entered into a license and collaboration agreement with Biogen, under which 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. We amended the license and collaboration agreement in October 2018 and in January 2019.

Upon entering into this agreement in November 2017, we received an up-front cash payment of $28.0 million. In June 2018, we received an additional cash payment of $50.0 million following Biogen's review of preliminary gastrointestinal tolerability data from the ongoing clinical development program for BIIB098. We are also eligible to receive an additional cash payment of $150.0 million 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 developmental 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 such products and the minimum annual payments for BIIB098 are subject to reductions as set forth in the agreement.

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, since January 1, 2018, Biogen is 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, if in part B of the head-to-head phase 3 gastrointestinal tolerability clinical trial, BIIB098 demonstrates a greater rate of discontinuations as compared to TECFIDERA and TECFIDERA demonstrates statistical superiority to BIIB098 on the primary endpoint, then "GI Inferiority" shall be deemed to 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) GI Inferiority was not deemed to exist or (ii) GI Inferiority was deemed to exist 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 ARISTADA and ARISTADA INITIO, and microspheres for RISPERDAL CONSTA and VIVITROL, in our Wilmington, Ohio facility. We are currently operating one RISPERDAL CONSTA line, two VIVITROL lines and two ARISTADA lines at commercial scale. We source our packaging operations for

VIVITROL, ARISTADA and ARISTADA INITIO to third-party contractors. 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 (including the authorized generic version of 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. In 2018, the FDA 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.

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, ARISTADA and ARISTADA INITIO, we hold the appropriate regulatory documentation ourselves.

Marketing, Sales and Distribution

We are responsible for the marketing of VIVITROL, ARISTADA and ARISTADA INITIO in the U.S. We focus our sales and marketing efforts on physicians in private practice and in public treatment systems. We believe that we use customary pharmaceutical company practices to market our products and to educate physicians, including through advertisements, professional symposia, selling initiatives and other methods. Our education initiatives extend to individual physicians, nurses, social workers, counselors and other stakeholders involved in the treatment of opioid dependence, alcohol dependence and schizophrenia. We provide, and 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 primarily sold to pharmaceutical wholesalers, pharmacies, specialty distributors and treatment providers. Product sales of VIVITROL during the year ended December 31, 2018 to Cardinal Health, AmerisourceBergen Corporation ("AmerisourceBergen") and McKesson Corporation represented approximately 23%, 20% and 19%, respectively, of total VIVITROL net sales.

Our sales force for ARISTADA in the U.S. consists of approximately 300 individuals. ARISTADA is primarily sold to pharmaceutical wholesalers. Product sales of ARISTADA and ARISTADA INITIO during the year ended December 31, 2018 to Cardinal Health, McKesson Corporation and AmerisourceBergen represented approximately 47%, 23% and 19%, respectively, of total ARISTADA net sales.

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

Under our license agreements with Janssen, 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 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. In the treatment of schizophrenia, ARISTADA, INVEGA SUSTENNA/XEPLION, 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.; PERSERIS (risperidone for extended release injectable suspension), a once-monthly formulation of risperidone marketed by Indivior plc; 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, VRAYLAR, ABILIFY MAINTENA, risperidone, quetiapine, 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 SUBLOCADE (once-monthly buprenorphine extended-release injection), each of which is marketed and sold by Indivior plc, and BUNAVAIL buccal film (buprenorphine and naloxone) marketed by BioDelivery Sciences, PROBUPHINE (buprenorphine) from Titan Pharmaceuticals, Inc., ZUBSOLV (buprenorphine and naloxone) marketed by Orexo US, Inc., and once launched, will compete with BRIXADI, which will be marketed by Braeburn, 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.

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 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.

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, which includes numerous patents in the U.S. and in other countries directed to compositions of matter, methods of treatment and formulations, as well as processes of preparation. 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. In addition, our licensees may own additional patents that cover those products owned by such licensees that incorporate our proprietary technologies and for which we receive royalties.

ARISTADA and ARISTADA INITIO

We have several U.S. patents and patent applications, and a number of corresponding foreign counterparts, that cover ARISTADA and/or ARISTADA INITIO. Our principal U.S. patents for ARISTADA and/or ARISTADA INITIO and their expirations dates are as follows:

U.S. Patent No.	Product(s) Covered	Expiration Date
8,431,576	ARISTADA; ARISTADA INITIO	2030
8,796,276	ARISTADA; ARISTADA INITIO	2030
10,112,903	ARISTADA; ARISTADA INITIO	2030
10,023,537	ARISTADA	2030
9,034,867	ARISTADA	2032
9,193,685	ARISTADA	2033
9,861,699	ARISTADA	2033
9,452,131	ARISTADA	2035
9,526,726	ARISTADA	2035
10,064,859	ARISTADA	2035
10,016,415	ARISTADA INITIO	2035

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

VIVITROL and RISPERDAL CONSTA

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 and RISPERDAL CONSTA. The latest to expire of our patents covering VIVITROL and RISPERDAL CONSTA, expire in the U.S. in 2029 and 2023, respectively, and in the EU in 2021, and we own 13 and 4 unexpired Orange-Book listed U.S. patents covering VIVITROL and RISPERDAL CONSTA, respectively. For a discussion of legal proceedings related to certain of the patents covering VIVITROL and RISPERDAL CONSTA, see Note 18, *Commitments and Contingent Liabilities* in the “Notes to Consolidated Financial Statements” in this Directors’ Report.

INVEGA SUSTENNA/XEPLION and INVEGA TRINZA/TREVICTA

Our NanoCrystal technology patent portfolio, licensed to Janssen in relation to INVEGA SUSTENNA/XEPLION and INVEGA TRINZA/TREVICTA, contains a number of granted patents and pending patent applications throughout the world, including in the U.S. and in countries outside of the U.S. The latest of the patents subject to our license agreement with Janssen covering INVEGA SUSTENNA/XEPLION expires in 2030 in the U.S. and certain other countries and in 2022 in the EU. The latest to expire of the licensed patents covering INVEGA TRINZA/TREVICTA in the U.S. expired in 2017 and in the EU will expire in 2022. In addition, Janssen has other patents not subject to our license agreement, including one that covers INVEGA SUSTENNA in the U.S. and expires in 2031 and one that covers INVEGA TRINZA in the U.S. and expires in 2036. For a discussion of legal proceedings related to the patents covering INVEGA SUSTENNA, see Note 18, *Commitments and Contingent Liabilities* in the “Notes to Consolidated Financial Statements” in this Directors’ Report.

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, etc.). AMPYRA/FAMPYRA incorporates our matrix drug absorption system technology. All of the U.S. patents covering AMPYRA have expired or have been revoked. Acorda has a number of European patents covering FAMPYRA (with regulatory exclusivity in the EU until 2021), the latest of which expires in 2025. For a discussion of legal proceedings related to the patents covering AMPYRA, see Note 18, *Commitments and Contingent Liabilities* in the "Notes to Consolidated Financial Statements" in this Directors' Report.

We also have worldwide patent protection for our Key Development Programs:

ALKS 3831

We own or have a license to U.S. and worldwide patents and patent applications that cover a class of compounds that includes the opioid modulators in ALKS 3831. In addition, we own U.S. and worldwide patents and patent applications that claim formulations and methods of treatment that cover ALKS 3831. The principal owned or licensed U.S. patents for ALKS 3831 and their expiration dates are as follows:

U.S. Patent No.	Product Covered	Expiration Date
7,956,187	ALKS 3831	2021
8,252,929	ALKS 3831	2021
7,262,298	ALKS 3831	2025
8,680,112	ALKS 3831	2030
9,119,848	ALKS 3831	2031
10,005,790	ALKS 3831	2031
8,778,960	ALKS 3831	2031
9,126,977	ALKS 3831	2031
9,517,235	ALKS 3831	2031

Diroximel Fumarate (BIIB098)

We have U.S. patents and patent applications, and a number of corresponding foreign counterparts, that cover BIIB098. U.S. Patent Nos. 8,669,281 and 9,090,558, each expiring in 2033, cover compositions of or methods for BIIB098.

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, expiring in 2033, covers compositions of 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, ARISTADA and ARISTADA INITIO, 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 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 4, 2019, we had approximately 2,300 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, ARISTADA and ARISTADA INITIO, 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. In 2018, these key marketed products consisted of VIVITROL; ARISTADA and ARISTADA INITIO; INVEGA SUSTENNA/XEPLION, INVEGA TRINZA/TREVICTA; RISPERDAL CONSTA; and AMPYRA/FAMPYRA. Revenues from these key products accounted for 80% of our total revenues during 2018, as compared to 86% during 2017.

In 2018, we incurred an operating loss of $99.1 million, as compared to $147.9 million in 2017. Revenues increased by 21% in 2018, as compared to 2017, which was primarily due to revenue earned under our license and collaboration agreement with Biogen for BIIB098 and increased sales of ARISTADA. This was partially offset by a 14% increase in operating expenses, which were primarily in support of the increase in sales of our proprietary products and continued 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 for products that incorporate our technologies, except for those from Janssen related to RISPERDAL CONSTA, are recognized over time as products move through the manufacturing process, using an input method based on costs as a measure of progress. Manufacturing revenue from RISPERDAL CONSTA is recognized at the point in time the product has been fully manufactured. 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, 2018 and 2017:

(In millions)	Year Ended December 31, 2018	Year Ended December 31, 2017	Change Favorable/ (Unfavorable)
Manufacturing and royalty revenues:			
INVEGA SUSTENNA/XEPLION & INVEGA TRINZA/TREVICTA	$241.4	$214.9	$ 26.5
AMPYRA/FAMPYRA	107.1	117.0	(9.9)
RISPERDAL CONSTA	71.1	84.9	(13.8)
Other	107.1	88.5	18.6
Manufacturing and royalty revenues	$526.7	$505.3	$ 21.4

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%. The increase in INVEGA SUSTENNA/XEPLION and INVEGA TRINZA/TREVICTA royalty revenues in each period was due to an increase in Janssen's end-market 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 $2.9 billion, and $2.6 billion during the years ended December 31, 2018 and 2017, respectively. The adoption of Topic 606 had no impact on the method in which we recognize royalty revenue from sales of INVEGA SUSTENNA/XEPLION and INVEGA TRINZA/TREVICTA.

Under the Financial Accounting Standards Board ("FASB") Accounting Standards Update ("ASU") No. 2014-09, *Revenue From Contracts With Customers* ("Topic 606"), which we adopted on January 1, 2018, we recognize manufacturing revenue, equal to 7.5% of Janssen's unit net sales price of RISPERDAL CONSTA at the point in time when RISPERDAL CONSTA has been fully manufactured, which is when the product is approved for shipment. Prior to the adoption of Topic 606, we recognized manufacturing revenue when RISPERDAL CONSTA was shipped to Janssen. We continue to record royalty revenue, equal to 2.5% of end-market net sales, when the end-market sale of RISPERDAL CONSTA occurs.

The decrease in RISPERDAL CONSTA revenue in 2018, as compared to 2017, was due to a 19% decrease in manufacturing revenue and a 9% decrease in royalty revenue. The decrease in manufacturing revenues was due to a 19% decrease in the number of units of RISPERDAL CONSTA manufactured for Janssen. The decrease in royalty revenue was due to a decline in Janssen's end-market net sales of RISPERDAL CONSTA. Janssen's end-market net sales of RISPERDAL CONSTA were $737.0 million and $805.0 million during the years ended December 31, 2018 and 2017, respectively.

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 expires in 2030 in the U.S. and certain other countries and in 2022 in the EU. The latest of the licensed patents covering INVEGA TRINZA/TREVICTA expired in 2017 in the U.S. and will expire in 2022 in the EU. In addition, Janssen has other patents not subject to our license agreement, including one that covers INVEGA SUSTENNA in the U.S. and expires in 2031 and one that covers INVEGA TRINZA in the U.S. and expires in 2036.

In January 2018, Janssen Pharmaceuticals NV and Janssen Pharmaceuticals, Inc. initiated a patent infringement lawsuit in the U.S. 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 U.S. Patent No. 9,439,906. For further discussion of the legal proceedings related to the patents covering INVEGA SUSTENNA, see Note 18, *Commitments and Contingent Liabilities* in the "Notes to Consolidated Financial 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."

With the adoption of Topic 606, we changed the way we record certain of our manufacturing and royalty revenue for AMPYRA and FAMPYRA. For AMPYRA manufactured under our license and supply agreements with Acorda, we now record manufacturing and royalty revenue as the product is being manufactured, rather than when it is shipped to Acorda. For FAMPYRA, we record manufacturing revenue as the product is being manufactured, rather than when it is shipped to Biogen, but continue to record royalty revenue when the end-market sale of FAMPYRA occurs. See Note 3, *Turnover from Contracts with Customers*, in the "Notes to Consolidated Financial Statements" in this Directors' Report, for additional information regarding the adoption of Topic 606.

The decrease in the amount of manufacturing and royalty revenue recognized for AMPYRA and FAMPYRA in 2018, as compared to 2017, was due to a 13% decrease in revenue from AMPYRA, partially offset by an 8% increase in revenue from FAMPYRA. The decrease in AMPYRA revenues was primarily due to a 19% decrease in the amount of AMPYRA shipped to Acorda, which was due to the entry of generic forms of AMPYRA to the U.S. market in September 2018. For further discussion of the legal proceedings related to the patents covering AMPYRA, see Note 18, *Commitments and Contingent Liabilities* in this Directors' Report, and for information about risks relating to such legal proceedings see "Principal Risks" of 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.”. We expect revenues from AMPYRA to continue to decline due to the entry of generic forms of AMPYRA in the U.S. market. The increase in revenue from FAMPYRA was primarily due to a 10% increase in manufacturing revenues due to an increase in the price we received on FAMPYRA shipments to Biogen. The legal proceedings related to the patents covering AMPYRA do not involve the patents covering FAMPYRA, and the latest of the patents covering FAMPYRA expires in 2025 in the EU.

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.

Included in other manufacturing and royalty revenue in the table above is $26.7 million of royalty revenue, representing our proportional share of the proceeds of Zealand Pharma A/S’ (“Zealand”) sale to Royalty Pharma of certain royalty streams for products that utilize technology that we had previously licensed to Zealand.

Certain of our manufacturing and royalty revenues are earned in countries outside of the U.S. and are denominated in currencies in which the product is sold. See “Financial Risk Management” of this Directors’ Report for information on currency exchange rate risk related to our revenues.

Product Sales, Net

Our product sales, net consist of sales of VIVITROL, ARISTADA and ARISTADA INITIO 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, ARISTADA and ARISTADA INITIO in the U.S. during the years ended December 31, 2018 and 2017:

	Year Ended December 31, 2018		Year Ended December 31, 2017	
(In millions)	**Amount**	**% of Sales**	**Amount**	**% of Sales**
Product sales, gross	$ 846.5	100.0%	$ 657.7	100.0%
Adjustments to product sales, gross:				
Medicaid rebates	(197.0)	(23.3)%	(147.8)	(22.5)%
Chargebacks	(65.5)	(7.7)%	(47.9)	(7.3)%
Product discounts	(65.1)	(7.7)%	(51.0)	(7.8)%
Medicare Part D	(29.8)	(3.5)%	(15.1)	(2.3)%
Other	(38.8)	(4.6)%	(33.1)	(5.0)%
Total adjustments	(396.2)	(46.8)%	(294.9)	(44.8)%
Product sales, net	$ 450.3	53.2%	$ 362.8	55.2%

Our product sales, net for VIVITROL and ARISTADA/ARISTADA INITIO in 2018 were $302.6 million and $147.7 million, respectively, as compared to $269.3 million and $93.5 million in 2017.

The increase in product sales, gross in 2018, as compared to 2017, was due to a 16% increase in VIVITROL gross sales and a 69% increase in ARISTADA/ARISTADA INITIO gross sales. The increase in VIVITROL gross sales was due to a 16% increase in the number of units sold as there was no change to the selling price of VIVITROL in 2018. The increase in sales of ARISTADA/ARISTADA INITIO was primarily due to a 52% increase in the number of units sold and a 7% increase in price from December 31, 2017 to December 31, 2018. ARISTADA 441 mg, 662 mg and 882 mg launched in the U.S. in October 2015. ARISTADA 1064 mg, our two-month dosing option, launched in the U.S. in June 2017 and ARISTADA INITIO, which is approved for the initiation or re-initiation of ARISTADA for the treatment of schizophrenia, was approved by the FDA in June 2018 and launched in July 2018.

The increase in Medicare Part D rebates as a percentage of sales in 2018, as compared to 2017 was primarily due to increases in the amount of ARISTADA sold under this program.

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 generic versions of this product to enter the market 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 and ARISTADA INITIO. Increased competition and increased pricing pressure may lead to reduced unit sales of ARISTADA and ARISTADA INITIO. 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 to enter the market in the near term. We expect our product sales, net will continue to grow as VIVITROL continues to penetrate the opioid and alcohol dependence markets in the U.S., and as ARISTADA continues to gain market share in the U.S.

License Revenue

	Year Ended December 31,		Change Favorable/
(In millions)	**2018**	**2017**	**(Unfavorable)**
License revenue	$48.4	$28.0	$20.4

Amounts earned as license revenue relate to our license and collaboration agreement with Biogen for BIIB098. The amount recognized in 2018 was triggered by Biogen's decision to pay the $50.0 million option payment following Biogen's review of preliminary gastrointestinal tolerability data from the ongoing clinical development program for BIIB098, including certain data from our long-term safety clinical trial and part A of the elective, randomized, head-to-head phase 3 gastrointestinal tolerability clinical trial comparing BIIB098 and dimethyl fumarate. In 2017, we recognized the upfront cash payment of $28.0 million as license revenue under ASC Subtopic 605-25, *Multiple Element Arrangements* ("ASC 605-25").

Research and Development Revenue

	Year Ended December 31,		Change Favorable/
(In millions)	**2018**	**2017**	**(Unfavorable)**
Research and development revenue	$68.9	$7.2	$61.7

The increase in R&D revenue in 2018, as compared to 2017, was primarily due to revenue earned under our license and collaboration agreement with Biogen for BIIB098, as discussed in further detail within the *Critical Accounting Estimates* section below. Our R&D revenues earned under our license and collaboration agreement with Biogen for BIIB098 were $65.4 million and $2.3 million in 2018 and 2017, respectively.

Costs and Expenses

Cost of Goods Manufactured and Sold

	Year Ended December 31,		Change Favorable/
(In millions)	**2018**	**2017**	**(Unfavorable)**
Cost of goods manufactured and sold	$176.4	$154.7	$(21.7)

The increase in cost of goods manufactured and sold in 2018, as compared to 2017, was primarily due to a 24% and 39% increase in cost of goods sold related to VIVITROL and ARISTADA, respectively, which were driven by the increase in the sales of these products.

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 for the years ended December 31, 2018 and 2017 relating to our then-current 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, 2018	2017	Change Favorable/ (Unfavorable)
External R&D Expenses:			
Key development programs:			
ALKS 3831	$ 52.0	$ 91.9	$ 39.9
BIIB098	43.1	47.4	4.3
ALKS 5461	30.3	42.2	11.9
ALKS 4230	23.3	7.0	(16.3)
ARISTADA and ARISTADA line extensions	20.1	13.7	(6.4)
Other external R&D expenses	49.7	38.4	(11.3)
Total external R&D expenses	218.5	240.6	22.1
Internal R&D expenses:			
Employee-related	163.9	132.2	(31.7)
Depreciation	11.9	10.5	(1.4)
Occupancy	11.0	9.6	(1.4)
Other	20.1	20.0	(0.1)
Total internal R&D expenses	206.9	172.3	(34.6)
Research and development expenses	$425.4	$412.9	$(12.5)

These amounts are not necessarily predictive of future R&D expenses. In an effort to allocate our spending most effectively, we continually evaluate our 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 decrease in expenses related to ALKS 3831 in 2018, as compared to 2017, was primarily due to the decrease in activity within the ENLIGHTEN-1 and ENLIGHTEN-2 pivotal trials, which were initiated in December 2015 and February 2016, respectively, partially offset by an increase in activity within a phase 3 study of ALKS 3831 in young adults, which was initiated in June 2017. The decrease in expenses related to BIIB098 in 2018, as compared to 2017, was primarily due to the timing of activity within the two-year, multicenter, open-label phase 3 study designed to assess the safety of BIIB098, which was initiated in December 2015. In December 2018, we and Biogen announced that we submitted a NDA to the FDA seeking marketing approval of BIIB098 for the treatment of relapsing forms of MS. We also initiated an elective, randomized, head-to-head phase 3 study designed to compare the gastrointestinal tolerability of BIIB098 and TECFIDERA in patients with relapsing-remitting MS in March 2017. The decrease in expenses related to ALKS 5461 in 2018, as compared to 2017, was primarily due to a decrease in activity within the program as we completed submission of our NDA to the FDA seeking marketing approval of ALKS 5461 for the adjunctive treatment of MDD in January 2018. The increase in expenses related to ARISTADA and ARISTADA line extensions in 2018, as compared to 2017, was primarily due to an increase of activity related to the phase 3b clinical study to evaluate the efficacy and safety of ARISTADA and INVEGA SUSTENNA in patients experiencing an acute exacerbation of schizophrenia. ARISTADA 1064 mg, our two-month dosing option, was approved by the FDA in June 2017. In October 2017, we submitted an NDA to the FDA for ARISTADA INITIO, which was approved by the FDA in June 2018. The increase in expenses related to ALKS 4230 in 2018, as compared to 2017, was primarily related to the timing of the phase 1 study, as described in *Key Development Programs* above under the heading "ALKS 4230" in this Directors' Report.

The increase in other external R&D expenses in 2018, as compared to 2017, was due to activity related to our early-stage, pre-clinical development activity. The increase in employee-related expenses in both periods presented was primarily due to an increase in headcount. Our R&D-related headcount increased by 17% in 2018, as compared to 2017.

For additional detail on the status of our key development programs, refer to *Key Development Programs* within this Directors' Report.

Selling, General and Administrative Expenses

	Year Ended December 31,		Change Favorable/
(In millions)	**2018**	**2017**	**(Unfavorable)**
Selling, general and administrative expense	$526.4	$421.6	$(104.8)

The increase in selling, general and administrative ("SG&A") expense was primarily due to increases in marketing and professional services fees and employee-related expenses. Marketing and professional services fees increased by 29% and were primarily due to additional brand investments in both VIVITROL and ARISTADA, as well as an increased investment in patient access support services, such as reimbursement and transition assistance, for both of these products. Employee-related expenses increased by 21% and were primarily due to an increase in our SG&A-related headcount of 22% in 2018.

Amortization of Acquired Intangible Assets

	Year Ended December 31,		Change Favorable/
(In millions)	**2018**	**2017**	**(Unfavorable)**
Amortization of acquired intangible assets	$65.2	$62.1	$(3.1)

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, 2018 is expected to be approximately $40.0 million, $40.0 million, $40.0 million, $35.0 million and $35.0 million in the years ending December 31, 2019 through 2023, respectively.

Other (Expense) Income, Net

	Year Ended December 31,		Change Favorable/
(In millions)	**2018**	**2017**	**(Unfavorable)**
Interest income	$ 9.2	$ 4.6	$ 4.6
Interest expense	(15.4)	(12.0)	(3.4)
Change in the fair value of contingent consideration	(19.6)	21.6	(41.2)
Other expense, net	(2.0)	(9.6)	7.6
Total other (expense) income, net	$(27.8)	$ 4.6	$(32.4)

The increase in interest expense in 2018, as compared to 2017, was due to our amending and refinancing in March 2018 of our existing term loan (previously referred to as "Term Loan B-1", and as so amended and refinanced, the “2023 Term Loans”) in order to, among other things, extend the due date of the loan from September 25, 2021 to March 26, 2023, reduce the interest payable from LIBOR plus 2.75% with a LIBOR floor of 0.75% to LIBOR plus 2.25% with a 0% LIBOR floor and increase covenant flexibility (the “Refinancing”). The Refinancing resulted in a $2.3 million charge in 2018, which was included in interest expense.

In April 2015, we entered into the Gainesville Transaction with Recro Pharma, Inc. (“Recro”) and Recro Pharma LLC and received $54.0 million in cash, $2.1 million in warrants to acquire Recro common stock and $57.6 million in contingent consideration tied to low double digit royalties on net sales of the IV/IM and parenteral forms of Meloxicam and any other product with the same active ingredient as Meloxicam IV/IM that is discovered or identified using certain of our intellectual property to which Recro was provided a right of use, through license or transfer, pursuant to the Gainesville Transaction (the “Meloxicam Products”), and up to $120.0 million in milestone payments upon the achievement of certain regulatory and sales milestones related to the Meloxicam Products. We determined the fair value of the contingent consideration through three valuation approaches, which are described in greater detail in See Note 7, *Fair Value*, in the “Notes to Consolidated Financial Statements” in this Directors’ Report. At each reporting date, we update our assessment of the fair value of this contingent consideration and reflect any changes to the fair value within the consolidated statements of operations and comprehensive loss and will continue to do so until the milestones and/or royalties included in the contingent consideration have been settled.

During the years ended December 31, 2018 and 2017, we determined that the fair value of the contingent consideration decreased by $19.6 million and increased by $21.6 million, respectively. The decrease in 2018 was primarily due to the complete response letter Recro received from the FDA in May 2018 regarding its NDA for IV Meloxicam. As a result of the receipt of the complete response letter, we delayed our expectation of the anticipated date for the FDA’s approval of the IV Meloxicam NDA and reduced the amount of forecasted sales in our valuation model. Recro resubmitted the NDA for IV Meloxicam in September 2018 and the FDA assigned a PDUFA date of March 24, 2019 to the resubmitted application. In addition, in December 2018, we amended our agreements with Recro and its affiliates relating to certain development milestone payments owed to us by Recro, such that the $45.0 million previously due to us upon approval by the FDA of the IV Meloxicam NDA, was replaced with $5.0 million which was paid in the first quarter of 2019, $5.0 million to be paid in the second quarter of 2019, and if the IV Meloxicam NDA is approved by the FDA, $5.0 million to be paid within 180 days following such approval and $45.0 million payable in seven equal annual installments of approximately $6.4 million beginning on the first anniversary of such NDA approval date.

The decrease in other expense, net in 2018, as compared to 2017, was primarily due to an impairment charge related to our investment in Synchronicity Pharma, Inc. (“Synchronicity”), formerly Reset Therapeutics, Inc., 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 Synchronicity, as we believed that Synchronicity was unable to generate future earnings that justified the carrying amount of the investment.

Provision for Income Taxes

(In millions)	Year Ended December 31, 2018	Year Ended December 31, 2017	Change Favorable/ (Unfavorable)
Provision for income taxes	$(12.3)	$(14.7)	$2.4

The income tax provision in 2018 and 2017 was primarily due to U.S. federal and state taxes. The favorable change in income taxes in 2018, as compared to 2017, was due to the one-off nature of a $21.5 million tax expense in 2017 from the enactment of the Tax Cuts and Jobs Act (the “Act” or “Tax Reform”), partially offset by increased taxes on income earned in the U.S. No provision for income tax has been provided on undistributed earnings of our foreign subsidiaries because such earnings are permanently reinvested or may be repatriated to Ireland without incurring any tax liability. Cumulative unremitted earnings of overseas subsidiaries totaled approximately $327.1 million at December 31, 2018.

As of December 31, 2017, a deferred tax asset of $13.3 million was recorded as a provisional amount related to performance-based compensation to covered employees prior to November 2, 2017. We have since completed our review of the Act and have determined the performance-based compensation was provided pursuant to binding arrangements and should be deductible. We concluded that it had met the requirements for recognition of the tax benefit and we no longer consider this item a provisional amount in our financial statements in accordance with Staff Accounting Bulletin 118 ("SAB 118"). 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, 2018, we maintained a valuation allowance of $11.7 million against certain U.S. state deferred tax assets and $207.4 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, 2018, we had $1.4 billion of Irish NOL carryforwards, $2.5 million of U.S. state NOL carryforwards, $44.8 million of federal R&D credits, $2.0 million of alternative minimum tax ("AMT") credits and $14.8 million of U.S. state tax credits which either expire on various dates through 2038 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 AMT 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, 2018	December 31, 2017
Cash and cash equivalents	$266.8	$191.3
Investments—short-term	272.5	242.2
Investments—long-term	80.7	157.2
Total cash and investments	$620.0	$590.7
Outstanding borrowings—short and long-term	$279.3	$281.4

At December 31, 2018, our investments consisted of the following:

(In millions)	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Investments—short-term available-for-sale	$272.3	$0.3	$(0.6)	$272.0
Investments—short-term held-to-maturity	0.5	—	—	0.5
Investments—long-term available-for-sale	77.4	—	(0.3)	77.1
Investments—long-term held-to-maturity	3.5	0.1	—	3.6
Total	$353.7	$0.4	$(0.9)	$353.2

Sources and Uses of Cash

We generated $99.3 million and $19.2 million of cash from operating activities during the years ended December 31, 2018 and 2017, 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, the 2023 Term Loans have an incremental facility capacity in an amount of $175.0 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, 2018, 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, 2018 and 2017:

(In millions)	Year Ended December 31, 2018	Year Ended December 31, 2017
Cash and cash equivalents, beginning of period	$191.3	$186.4
Cash flows provided by operating activities	99.3	19.2
Cash flows used in investing activities	(22.2)	(18.4)
Cash flows (used in) provided by financing activities	(1.6)	4.1
Cash and cash equivalents, end of period	$266.8	$191.3

Operating Activities

The increase in cash provided by operating activities in 2018, as compared to 2017, was primarily due to a 21% increase in the amount of cash collected from our customers. This was partially offset by a 20% increase in the amount of cash paid to our employees and a 4% 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 as compared to the prior period. 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 2018, as compared to 2017, was primarily due to an increase in property, plant and equipment additions. Cash paid for the addition to property, plant and equipment increased by 35% and was primarily due to 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, 2018 primarily include capital expenditures at our manufacturing facility in Wilmington, Ohio. We expect to spend approximately $95.0 million during the year ended December 31, 2019 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.

In addition to the increase in capital spending, we had an increase in the net sales of investments of 43% in 2018, as compared to 2017.

Financing Activities

The change in cash flows from financing activities in 2018, as compared to 2017, was primarily due to a $5.8 million decrease in the net cash provided from stock option exercises by our employees.

Borrowings

At December 31, 2018, our borrowings consisted of $282.1 million outstanding under the 2023 Term Loans. Please refer to Note 6, *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, 2018:

Contractual Obligations	Total	Less Than One Year (2019)	One to Three Years (2020 - 2021)	Three to Five Years (2022 - 2023)	More than Five Years (After 2023)
			(In thousands)		
2023 Term Loans—Principal	$282,118	$ 2,843	$ 5,686	$273,589	$ —
2023 Term Loans—Interest	53,690	12,844	25,298	15,548	—
Operating lease obligations	53,601	9,394	15,424	4,843	23,940
Purchase obligations	530,307	530,307	—	—	—
Total contractual cash obligations	$919,716	$555,388	$46,408	$293,980	$23,940

As interest on the 2023 Term Loans is based on a one, three or six-month LIBOR rate of our choosing, we are using the one-month LIBOR rate, which was 2.32% at December 31, 2018 as this exceeds the LIBOR rate floor under the terms of the 2023 Term Loans 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, 2018, we had $6.1 million of net liabilities associated with uncertain tax positions. We do not anticipate that the amount of existing unrecognized tax benefits will significantly increase or decrease within the next 12 months.

Off-Balance Sheet Arrangements

At December 31, 2018, 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, 2017: 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 49% and 28% of our investments at December 31, 2018 are in corporate debt securities with a minimum rating of Aa2 (Moody's)/AA (Standard and Poor's) and debt securities issued by the U.S. government or its agencies, respectively, our exposure to liquidity and credit risk is not believed to be significant.

At December 31, 2018, our borrowings consisted of $282.1 million outstanding under the 2023 Term Loans. The 2023 Term Loans bear interest at a LIBOR rate of our choosing (one, three or six months), plus 2.25% with a 0% LIBOR floor. We are currently using the one-month LIBOR rate, which was 2.32% at December 31, 2018. A 10% increase in the one-month LIBOR rate would have increased the amount of interest we owe under this agreement during the year ended December 31, 2018 by approximately $0.8 million. At December 31, 2017, a 10% increase in the three-month LIBOR rate, which was the LIBOR rate in use at the time, would have increased the amount of interest we owed by approximately $0.4 million. For a discussion about risks relating to LIBOR, see "Principal Risks" in this Directors' Report and specifically the section entitled "—Discontinuation, reform or replacement of LIBOR, or uncertainty related to the potential for any of the foregoing, may adversely affect us."

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, 2018, 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 $36.1 million, as compared to a reduction in revenues of approximately $26.8 million for the year ended December 31, 2017.

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, 2018, 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 $9.3 million, as compared to an increase in our expenses of approximately $6.9 million in the year ended December 31, 2017.

Principal Risks

You should consider carefully the risks described below in addition to the financial and other information contained in this Directors' 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 and Biogen, 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. We have no involvement in the commercialization efforts for these and other products sold by third parties to which we have licensed our proprietary technology. 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 FAMPYRA by 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 and cost-effective 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 investigations, litigation or other legal proceedings, including government investigations regarding VIVITROL, securities litigation relating to VIVITROL and ALKS 5461, and litigation or other 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 relating to INVEGA SUSTENNA and AMPYRA, inter partes reviews ("IPR") relating to VIVITROL, opposition proceedings in the EU relating to RISPERDAL CONSTA and any other litigation related to any of our products;
- regulatory developments related to the manufacture or continued use of our products, including the issuance of a Risk Evaluation and Mitigation Strategy ("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 and volume of product orders and product shipments, the timing of product launches, and product 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;
- global political changes and/or instability, including the expected exit of the United Kingdom from the European Union (commonly referred to as "Brexit"), and any related changes in applicable laws and regulations, that may impact resources and markets for our products outside of the U.S.; and
- any other material adverse developments with respect to the commercialization of our products.

These and other factors could materially adversely affect our revenues, 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 other 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.

In addition, disruptions at the FDA and other regulatory agencies that are unrelated to our company or our products could also cause delays to the regulatory approval process for our products. For example, over the last several years, including in December 2018 and January 2019, the U.S. government has shut down several times and certain regulatory agencies, including the FDA, have had to furlough critical employees and stop critical activities. If a prolonged government shutdown occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions.

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 outcomes are 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 contract research organizations ("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. 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, ARISTADA INITIO and certain of our other development products. We rely on our manufacturing facility in Athlone, Ireland for the manufacture of AMPYRA (including the authorized generic version 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. Any such shift of production among our facilities or transition of our manufacturing processes to a third party 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 and other materials used in the manufacture of products, and 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 ARISTADA, ARISTADA INITIO 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.

We endeavor to qualify and register new vendors and to develop contingency plans so that production is not impacted by issues associated with third-party providers. Nonetheless, our business could be materially and adversely affected by issues associated with third-party 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 and INVEGA TRINZA/TREVICTA) 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 such 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-party providers 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 from third-party payers of reimbursement for our products and the extent of cost-sharing arrangements for patients (e.g., patient co-payment, co-insurance, deductible obligations), and any cost-control measures imposed, reductions in payment rate or reimbursement or increases in our financial obligation to 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 payers, including 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. Similar state drug pricing initiatives were enacted in 2018 (e.g., Oregon HB 4005 with reporting requirements commencing in 2019) and we expect additional state drug pricing initiatives to be proposed and enacted in 2019. 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 2019, 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. For example, on January 31, 2019, HHS released a notice of proposed rulemaking as part of ongoing administration drug pricing reform efforts that would modify a regulatory provision that had previously protected certain pharmaceutical manufacturer rebates from criminal prosecution and financial penalties under the federal Anti-Kickback Statute and that would add new regulatory safe harbors for certain price reductions passed through to dispensing pharmacies and payments to pharmacy benefit managers. There is no assurance that such efforts and proposed legislation 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 and drug pricing 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 subject to our licensing arrangements;
- 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 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 by the time such products are commercialized, or that such patents will successfully withstand any challenges during their respective terms.

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 intellectual property 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, or patent applications filed by, third parties that relate to certain 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, contract manufacturers, potential business partners, 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, could significantly delay or prevent approval or commercialization of our products, and could adversely affect our business.

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, including in response to patent certifications required under the U.S. Drug Price Competition and Patent Term Restoration Act of 1984 (the “Hatch-Waxman Act”), 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 delay or prevent us from manufacturing and marketing our products.

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

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 be significantly impacted by our ability to successfully develop 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 develop commercial products on our own, the risks associated with such development programs may be greater than those associated with our programs that are developed 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, such as a REMS, 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 or if such requirements restrict the marketing, sale or use of 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 3831, if approved, 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, arbitration or regulatory action (such as citizens petitions) filed against regulatory agencies related to our product or Alkermes, including securities litigation, 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. For example, 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 through November 14, 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. In December 2018 and January 2019, two purported stockholders of ours filed putative class actions against us and certain of our officers on behalf of a putative class of purchasers of our securities during the period of February 17, 2017 through November 1, 2018. Such actions allege violations of Sections 10(b) and 20(a) of the Exchange Act based on allegedly false or misleading statements and omissions regarding our regulatory submission for ALKS 5461, our drug candidate for the adjunctive treatment of major depressive disorder, and the FDA's review and consideration of that submission, and seeks to recover unspecified money damages, prejudgment and postjudgment interest, reasonable attorneys' fees, expert fees and other costs. For further discussion of these putative class actions, see Note 18, *Commitments and Contingent Liabilities* in the "Notes to Consolidated Financial Statements" in this Directors' Report. These class actions and any similar future litigation could result in substantial costs and a diversion of management's attention and resources, which could harm our business.

We may be the subject of certain government inquiries or requests for documentation. For example, in June 2017 we received a subpoena from an Office of the U.S. Attorney, and in January 2019 we received a civil investigative demand from an Office of the U.S. Attorney, in each case for documents related to VIVITROL. We are cooperating with the government. If, as a result of the government's requests, 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 may 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 payers 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, which could have a negative effect on our business, financial condition, cash flows and results of operations. Further, our liability insurance coverage may not be sufficient to satisfy, or may not cover, any expenses or liabilities that may arise. Additionally, regardless of whether or not there is merit to the claims underlying any lawsuits or government inquiries of which we are subject, or whether or not we are found as a result of such lawsuits or inquiries to have violated any applicable laws, such lawsuits and inquiries can be expensive to defend or respond to, may divert the attention of our management and other resources that would otherwise be engaged in managing our business, and may further cause significant and potentially irreparable harm to our public reputation.

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 share price as well as our ability to generate revenues from the commercialization and sale of our products and products using our proprietary technologies.

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

Our activities, and the activities of our licensees and third-party providers, are subject to extensive 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 laws and regulations, applicable laws and regulations 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 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. For example, the costs of prescription pharmaceuticals in the U.S. has 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. On January 31, 2019, HHS released a notice of proposed rulemaking as part of ongoing administration drug pricing reform efforts that would modify a regulatory provision that had previously protected certain pharmaceutical manufacturer rebates from criminal prosecution and financial penalties under the federal Anti-Kickback Statute and that would add new regulatory safe harbors for certain price reductions passed through to dispensing pharmacies and payments to pharmacy benefit managers. Such changes in law, regulation and the interpretation of existing laws and regulations could have a material adverse effect on our business, financial condition, cash flows and results of operations.

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 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. 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.; PERSERIS (risperidone for extended release injectable suspension), a once-monthly formulation of risperidone marketed by Indivior plc; 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, VRYLAR, ABILIFY MAINTENA, risperidone, quetiapine, 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 SUBLOCADE (once-monthly buprenorphine extended-release injection), each of which is 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., and once launched, will compete with BRIXADI, which will be marketed by Braeburn, 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.

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 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.

For example, we and our partner Acorda received notices of numerous ANDA filings challenging the validity of one or more of the Orange Book-listed patents for AMPYRA and/or asserting that a generic form of AMPYRA would not infringe such patents, and we and Acorda engaged in Paragraph IV litigation with various ANDA filers disputing such claims. For further discussion of the legal proceedings related to the patents covering AMPYRA, see Note 18, *Commitments and Contingent Liabilities* in the "Notes to Consolidated Financial Statements" in this Directors' Report.

Similarly, Janssen Pharmaceuticals NV and Janssen Pharmaceuticals, Inc. initiated a patent infringement lawsuit against Teva Pharmaceuticals USA, Inc. ("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 18, Commitments and Contingent Liabilities in the "Notes to Consolidated Financial Statements" in this Directors' Report.

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 defense of such 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). As our development activities progress and we continue to have commercial sales, this product liability insurance coverage may be inadequate to satisfy liabilities that arise, 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, including instances of product misuse, 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, or 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, 2018, our accumulated deficit was $1,185.4 million, which was primarily the result of net losses incurred from 1987, the year Alkermes, Inc., was founded, through December 31, 2018, 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 and our licensees' ability to commercialize our products and to manufacture our products economically. Our ability to achieve sustained profitability in the future depends, in part, on our or our licensees' (as applicable) ability to:

- successfully commercialize VIVITROL, ARISTADA and ARISTADA INITIO and any other products that may be marketed in the U.S. or in other countries in which such products are approved;
- 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 successfully and cost effectively, 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 amounts 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 pre-clinical and 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 approved products that are controlled substances;
- the time and expense required to prosecute, enforce, defend 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 or intellectual property rights owned by others for proprietary products and otherwise;
- the costs related to potential litigation, arbitration or government requests for information; and
- the costs associated with recruiting, compensating and retaining 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.

In March 2018, we amended and refinanced the term loan under our credit agreement, in order to, among other things, extend the due date of the loan from September 25, 2021 to March 26, 2023, reduce the interest payable thereon from LIBOR plus 2.75% with a LIBOR floor of 0.75% to LIBOR plus 2.25% with a 0% LIBOR floor and increase covenant flexibility. As of December 31, 2018, our borrowings consisted of $282.1 million outstanding under the 2023 Term Loans.

The 2023 Term Loans are secured by a first priority lien on substantially all of the combined company assets and properties of Alkermes plc and most of its subsidiaries, which serve as guarantors. The agreements governing the 2023 Term Loans include a number of restrictive covenants that, among other things, and subject to certain exceptions and baskets, impose operating and financial restrictions on 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, commercial 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.

Discontinuation, reform or replacement of LIBOR, or uncertainty related to the potential for any of the foregoing, may adversely affect us.

In July 2017, the U.K. Financial Conduct Authority announced that LIBOR could be effectively discontinued after 2021. In addition, other regulators have suggested reforming or replacing other benchmark rates. The discontinuation, reform or replacement of LIBOR or any other benchmark rates may have an unpredictable impact on contractual mechanics in the credit markets or cause disruption to the broader financial markets. Uncertainty as to the nature of such potential discontinuation, reform or replacement may negatively impact the volatility of LIBOR rates, liquidity, our access to funding required to operate our business, or the trading market for our 2023 Term Loans.

Under our 2023 Term Loans, if the administrative agent determines that LIBOR is not reasonably ascertainable, or is notified by our lenders that LIBOR does not adequately and fairly reflect the costs to our lenders of maintaining the loans, we would be required to pay interest under an alternative base rate which could cause the amount of interest payable on the 2023 Term Loans to be materially different than expected. We may choose in the future to pursue an amendment to our 2023 Term Loans to provide for a transition mechanism or other alternative reference rate in anticipation of LIBOR's discontinuation, but we can give no assurance that we will be able to reach agreement with our lenders on any such amendment.

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 the section entitled "Currency Exchange Rate Risk" of this Directors' Report for additional information relating to our foreign currency exchange rate risk.

Our future success largely depends upon our ability to attract and retain key personnel.

Our ability to compete and succeed in the highly competitive biopharmaceutical industry and in the disease states in which we market and sell products depends largely upon the continued service of our management and scientific and commercial teams and our ability to attract, retain and motivate highly skilled technical, scientific, manufacturing, management, regulatory, compliance and selling and marketing personnel. Each of our executive officers and all of our employees are employed "at will," meaning we or each officer or employee may terminate the employment relationship at any time. 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 impact our business, including the achievement of our manufacturing, research and development, commercial and other business objectives.

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 assets that we acquire, or we are unable to integrate successfully with a company who acquires our company, business or assets, such events could materially adversely affect our business, financial condition, cash flows and results of operations.

Mergers, acquisitions and other strategic 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, which could result in significant dilution to our shareholders. 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, 2018, we had $191.0 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, 2018, we had $85.8 million in net deferred tax assets in the U.S. Included in this amount was approximately $38.7 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. 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.

Certain U.S. holders of our ordinary shares may suffer adverse tax consequences if any of our non-U.S. subsidiaries are characterized as a "controlled foreign corporation".

In December 2017, the Tax Cuts and Jobs Act was signed into law. This legislation significantly changes U.S. tax law by, among other things, changing the rules which determine whether a foreign corporation is treated for U.S. tax purposes as a controlled foreign corporation, or CFC, for taxable years ended December 31, 2017 and onwards. The impact of this change on certain holders of our ordinary shares is uncertain and could be adverse, including potential income inclusions and reporting requirements for U.S. persons (as defined in the Internal Revenue Code) who are treated as owning (directly or indirectly) at least 10% of the value or voting power of our shares. The determination of CFC status is complex and includes attribution rules, the application of which is not entirely certain. Recent changes to these attribution rules relating to the determination of CFC status make it possible that one or more of our non-U.S. subsidiaries will be classified as a CFC. Existing and prospective investors should consult their tax advisers regarding the potential application of these rules to their investments in us.

See "*Certain Irish and United States Federal Income Tax Considerations – United States Federal Income Tax Considerations*" in our Form S-1/A, filed with the U.S. Securities and Exchange Commission on February 29, 2012, for additional discussion with respect to other potential U.S. federal income tax consequences of investments in us.

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

Proxy contests and other actions by activist shareholders have been waged against many companies in the biopharmaceutical industry over the last few years. If faced with a proxy contest or other activist shareholder action, we may not be able to respond successfully to the contest or action, which could be disruptive to our business. Even if we are successful, our business could be adversely affected by any proxy contest or activist shareholder action 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 EU and other jurisdictions have adopted data protection laws and regulations, which impose significant compliance obligations. In the EU, for example, effective May 25, 2018, the GDPR replaced the prior EU Data Protection Directive (95/46) that governed the processing of personal data in the European Union. The GDPR imposes significant obligations on controllers and processors of personal data, including, as compared to the prior directive, higher standards for obtaining consent from individuals to process their personal data, more robust notification requirements to individuals about the processing of their personal data, a strengthened individual data rights regime, mandatory data breach notifications, limitations on the retention of personal data and increased requirements pertaining to health data, and strict rules and restrictions on the transfer of personal data outside of the EU, including to the U.S. The GDPR also imposes additional obligations on, and required contractual provisions to be included in, contracts between companies subject to the GDPR and their third-party processors that relate to the processing of personal data. The GDPR allows EU member states to make additional laws and regulations further limiting the processing of genetic, biometric or health data.

Adoption of the GDPR increased our responsibility and liability in relation to personal data that we process and may require us to put in place additional mechanisms to ensure compliance. Any failure to comply with the requirements of GDPR and applicable national data protection laws of EU member states, could lead to regulatory enforcement actions and significant administrative and/or financial penalties against us (fines of up to €20,000,000 or up to 4% of the total worldwide annual turnover of the preceding financial year, whichever is higher), 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 2019, 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.

Events Since the End of the Financial Year

There have been no events since the end of the financial year that require disclosure in this Directors' Report.

Directors and Secretary

The names of the persons who were directors or secretary at any time during the year ended December 31, 2018 or since December 31, 2018 are set out below.

Directors	Date of Service as a Director or Secretary
David W. Anstice	(Reappointed May 25, 2016)
Floyd E. Bloom	(Reappointed May 23, 2018)
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	(Reappointed May 23, 2018)
Nancy J. Wysenski	(Reappointed May 23, 2018)
Secretary	
David J. Gaffin	(Appointed December 12, 2017)

Acquisition or Disposal of Own Shares

Own shares held by the Company (par value, $0.01 per share) (Value in thousands)	Number	Value
January 1, 2018	2,048,176	$ 89,347
Acquired during the year	375,313	19,622
December 31, 2018	2,423,489	$108,969

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, 2017: 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 23, *Directors' Remuneration,* of the consolidated financial statements. The interests of the directors and secretary in office at January 1 and December 31, 2018 in the ordinary share capital of Alkermes plc are shown in the table below.

	Ordinary Shares[1] At December 31, 2018			Ordinary Shares[1] At January 1, 2018		
	Shares	Options	Restricted Share Units	Shares	Options	Restricted Share Units
Directors						
David W. Anstice	66,213	189,300	—	55,000	191,800	—
Floyd E. Bloom	127,923	209,300	—	147,923	191,800	—
Robert A. Breyer	7,156	164,700	—	7,156	147,200	—
Shane Cooke	84,872	434,875	—	74,708	617,500	73,100
Wendy L. Dixon	1,600	204,300	—	1,600	186,800	—
Paul J. Mitchell	8,000	200,300	—	8,000	194,800	—
Richard F. Pops	681,628	3,420,000	198,750	637,686	3,295,000	203,000
Nancy L. Snyderman	—	75,300	—	—	57,800	—
Nancy J. Wysenski	—	160,550	—	—	143,050	—
Company Secretary						
David J. Gaffin	40,518	256,500	37,600	31,407	202,275	36,700

(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 2018.

Subsidiary Companies and Branches

Information regarding our subsidiaries is provided in Note 25, *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 (the "Annual General Meeting") will take place at Connaught House, 1 Burlington Road, Dublin 4, Republic of Ireland on May 22, 2019. The notice of meeting and a description of the business to be transacted will be made available on the Company's website at www.alkermes.com in advance of the Annual General Meeting.

Audit and Risk Committee

The Company has established an Audit and Risk Committee.

Statutory Auditors

The Company's 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.

Non-Financial Statement

The European Union (Disclosure of Non-Financial and Diversity Information by certain large undertakings and groups) Regulations 2017 (S.I. 360/2017) (as amended) require us to disclose certain non-financial information in our Directors' Report:

Our success as a global biopharmaceutical company is predicated on our ability to ask the right questions and to energetically seek answers. How can a new medicine be best designed? How can patient outcomes be improved? How can we structure our company to best serve patients, employees and communities? Our culture of inquiry and collaborative problem-solving strengthens our business and underpins how we approach corporate responsibility. We are dedicated to continuous improvement in both our solutions for patients and our performance as a responsible corporate citizen.

A description of our business model can be found under "Business Overview" beginning on page 5 of this Directors' Report and a description of our risk factors, including those related to environmental, social and governance issues can be found under "Principal Risks" on pages 32-53 of this Directors' Report. The following is a summary of our key policies, actions and key performance indicators in the areas of: (a) Environmental Matters; (b) Social and Employee Matters; (c) Human Rights; (d) Health and Safety; and (e) Bribery and Corruption. A description of matters relating to our supply chain can be found under the heading entitled "Manufacturing and Product Supply" on page 15 of this Directors' Report. These policies and actions aim to ensure Alkermes manages risk in these areas and achieves its environmental, social and governmental goals.

The descriptions of our policies set forth in the sections below include references to our Code of Business Conduct and Ethics (the "Code of Conduct"). The Code of Conduct and certain other policies pertaining to our business are available on our Company website (www.alkermes.com). Our 2017 Corporate Responsibility Review ("2017 CRR") is also published on our Company website. The 2017 CRR sets out certain detailed outcomes of our policies in previous financial years. We are currently undertaking a review and update of the 2017 CRR and plan to disclose certain detailed outcomes of our policies for our 2018 financial year in the updated version of our CRR (the "2018 CRR") that will be published on our website once completed.

Environmental Matters

Alkermes is committed to operating in a way that is protective of our patients, our people, our environment and our communities. We practice our commitment through a global Environmental, Health, Safety and Security ("EHSS") Management System that helps us institute processes to meet or exceed environmental, health and safety regulations and industry best practices. We have a strong history of regulatory compliance. Through committed leadership and an engaged workforce, we are relentlessly focused on continually improving our performance and mitigating EHSS risks arising from our operations.

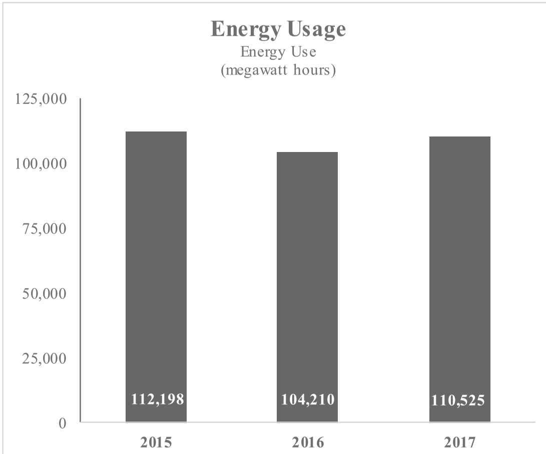
Alkermes takes proactive steps to improve air and water quality, reduce waste and optimize the use of energy and other natural resources. Examples include:

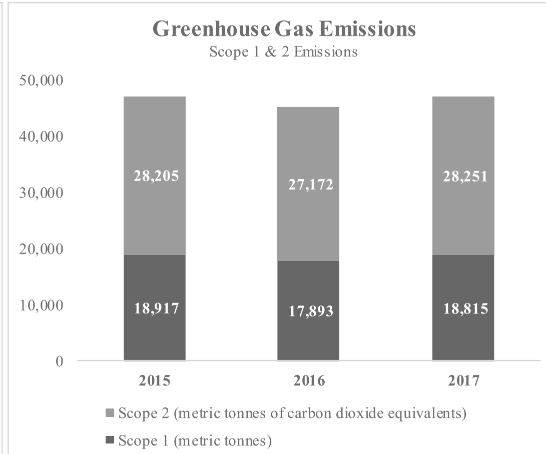
- Integrating environmental considerations into our site selections, designs and builds

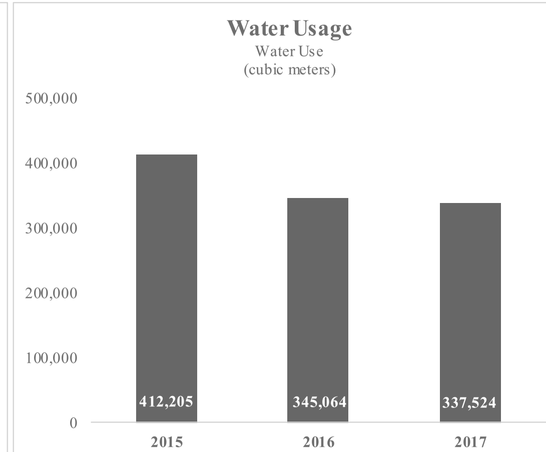
- Using building monitoring systems to collect data and make real-time adjustments
- Conducting systematic reviews of building operations and utilities to ensure systems and facilities are operating correctly and efficiently.

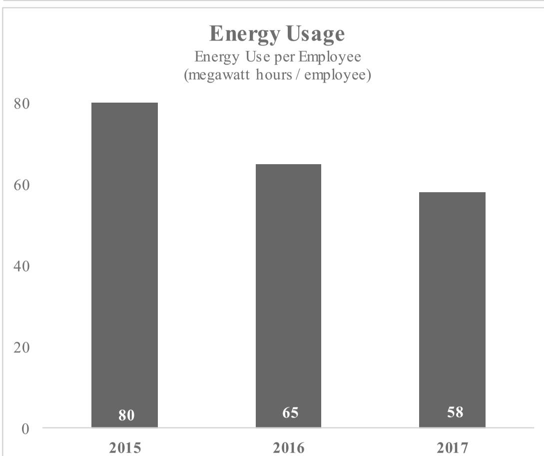
We also deploy operational excellence teams to identify potential improvements in critical areas, such as energy demand and waste stream management. In 2017, as a result of an operational excellence team review, a site replaced its existing lighting with high efficiency LED lighting. This change is expected to result in an annual savings of 107 megawatt hours—the carbon-sequestered equivalent of 1,500 trees.

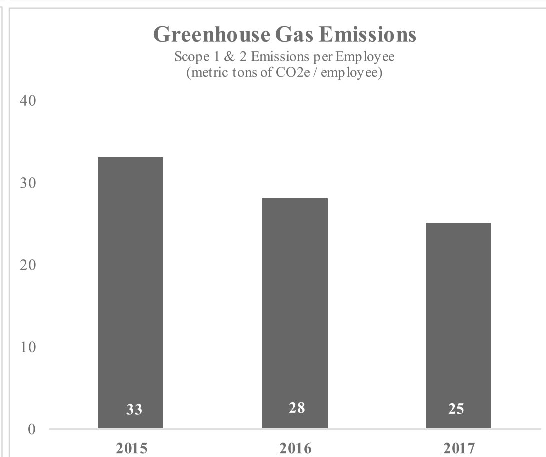
As a result of these and other efforts, we have made significant strides, including attaining an energy use intensity below the average pharmaceutical facility (1.26 megawatt hour / square meters in 2017 compared to industry average of 3.81) and achieving LEED and ISO14001 certification of select facilities. The following information was collected for financial year 2017 and published in our 2017 CRR:

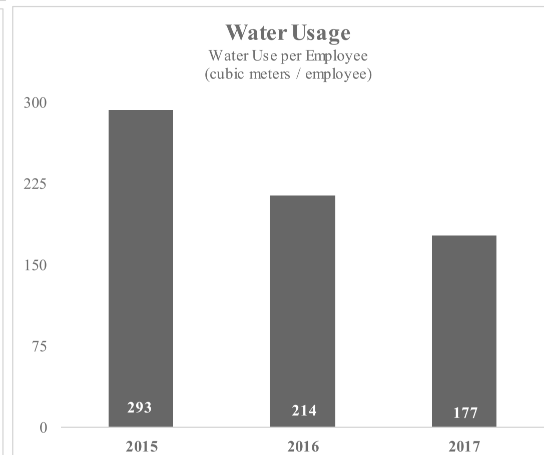












Social and Employee Matters

Our approximately 2,500 employees around the world are key to our ability to develop and advance treatment options for patients. We are an equal opportunity employer and, across our sites in Ireland and the U.S., we strive to create a work environment that reflects our values of collaboration, respect and commitment. We are proud of our unique culture where employees are encouraged to share their ideas and where teamwork is at the core of all we do. Every day, our employees have the opportunity to make an impact for patients, grow their careers and take care of themselves and their families. We are honored to have been recognized as a great place to work in rankings including The Boston Globe's 2017 Top Places to Work, Ireland's 2016 Great Place To Work, Best Large Workplaces in Ireland and Best Employers in Ohio 2015.

Across the company, we cultivate a culture of learning and development that motivates employees to reach for their career aspirations and empowers them to take charge of their careers. Our investment in our employees is what allows us to attract and retain exceptionally talented people. We conduct learning and development programs across our sites to equip employees at all levels with the tools, resources and skills to grow their careers. We offer developmental opportunities aimed at individual contributors, teams and managers at all levels. We also provide tuition benefits to assist employees with college courses.

We support the well-being of our employees and their families by providing programs that help employees maintain a healthy lifestyle. Our programs include:

- Nutrition classes
- Mindfulness programs to help reduce stress, improve sleep and increase productivity
- Speaker programs focused on providing tools to manage one's own well-being
- Weight loss and smoking cessation programs
- On-site gyms and fitness classes and discounts to nearby fitness clubs
- Employee assistance program, which includes free and confidential assessments, counseling and referrals for employees who have personal or work-related issues
- Healthful cooking demonstrations, healthy meal options in our cafeterias and vending machines and, where available, participation in farm share programs that deliver fresh, local produce

For Alkermes employees with particularly ambitious fitness goals, each year we field a team for the triAthlone—a triathlon near our Athlone, Ireland facility. Selected U.S. employees receive flights, accommodation and meals to join their Irish colleagues on the team.

Alkermes is committed to giving back to the communities where our employees live and work. We focus on efforts to increase access to health and well-being, as well as those needs unique to our communities. The following are some of the ways Alkermes and our employees contribute:

- Supporting Restorative Therapy for Local Patients
    - Alkermes supports a signature partnership with a therapeutic support center in Ireland for people living with addiction, mental illness, MS and other conditions. The center provides emotional, mental, physical and spiritual support for its clients through a range of counseling, therapy workshops and other programming. Alkermes employees contribute to the center in a variety of ways. Teams of Alkermes volunteers support the upkeep of the center, helping with gardening, construction, cleaning and painting. Other Alkermes volunteers have received special training to provide support to the center's client programming, such as mindfulness and yoga sessions. Alkermes Allegro, an all-employee choir, has lent its voice to the center's choir competition to raise funds for the center's critical mission.
- Raising Critical Funds to Support People Living with Mental Illness
    - Each year, Alkermes sponsors walks across the U.S. to raise funds for the millions of Americans affected by mental illness. Alkermes employees participate in the walks each year and, along with their fellow walkers, raise millions to support mental health advocacy, awareness and patient support programs.

- Volunteering through Alkermes in Action
  - Through Alkermes in Action, our signature U.S. employee volunteer program, our employees come together to serve their communities' most pressing needs.

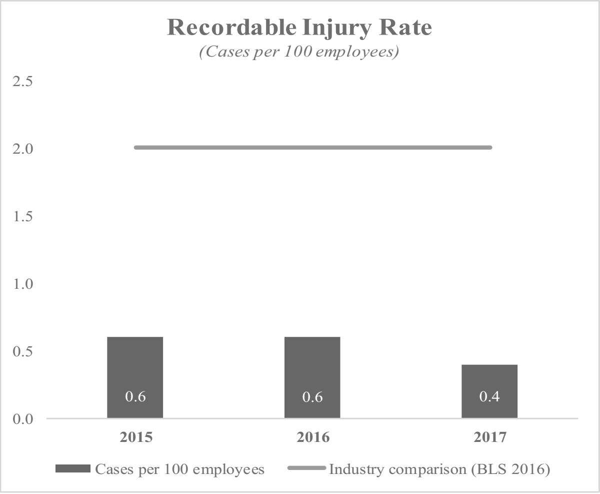
Health & Safety

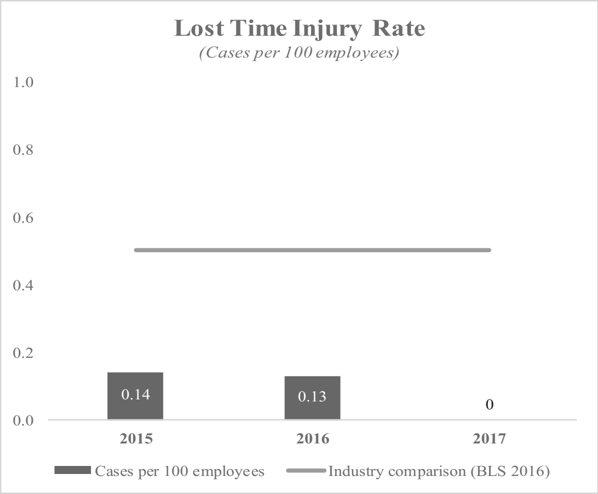
We protect and promote the health, safety and welfare of our employees by:

- Providing a safe working environment and supporting employee well-being
- Implementing processes for reporting potentially unsafe conditions or practices, so that corrective or preventative actions can be taken
- Minimizing hazardous practices and processes

Alkermes has also received awards from the National Irish Safety Organization for the past seven years recognizing our consistent achievement of a high safety standard.

The following information was collected for financial year 2017 and published in our 2017 CRR:





As part of our efforts to create a strong EHSS culture, we developed and implemented an in-house proprietary program that engages the Alkermes workforce in identifying and reducing everyday risk in the workplace. This program, CaRE® (Collaborative and Risk-focused Engagement) has become core to our EHSS approach across the enterprise, encouraging risk awareness, accountability and continuous improvement. The CaRE model includes the following elements:

- Ownership Risk Assessments: Easy-to-use tools help guide employees in evaluating whether work areas, equipment and tasks are safe before starting work.
- Good Save Awards: Monthly and quarterly awards are given to employees who flag a potential workplace hazard and take ownership of the process to address it.
- Walkthroughs: Monthly visits by randomly-selected groups of site leaders to different areas of the site to have honest and collaborative discussions about the area's work, potential risks and potential improvements. The groupings of leaders, along with the areas they visit, are changed regularly so as to maximize participation, knowledge sharing and collaboration. This also encourages interactions between colleagues who might not ordinarily meet through their daily work.

Respect for Human Rights

We are committed to respecting human rights. At Alkermes, we believe that it is our responsibility to respect and uphold the human rights of our people and any other individuals we are in contact with across the globe. We believe this is evidenced by the information summarized above in *Social and Employee Matters* as well as in our EHSS and Procurement policies and practices.

We work to establish, maintain and enforce policies and practices that seek to address the following topics relating to the protection of and respect for our global employee workforce:

- Compliance with minimum legal working age requirements.
- Establishment of working hours that comply with local law.
- Complaince with applicable wage laws, regulations, and relevant collective bargaining agreements, including those relating to minimum wages, overtime hours and legally mandated benefits.
- Maintenance of workplaces free of harassment and abuse.
- Maintenance of workplaces free of unlawful discrimination and harassment in all of its forms, including related to race, gender, sexual orientation, age, pregnancy, caste, disability, union membership, ethnicity, religious beliefs or any other factors protected by law.
- Respect for employees' voluntary freedom of association, including the right to organize and bargain collectively.
- Provision to workers' representatives of the access necessary to carry out their required functions and commitment not to discriminate against workers' representatives.

Our global supplier standards manual also requires our suppliers to treat workers with dignity and follow similar policies as outlined above for the supplier's employee workforce.

As discussed below in *Bribery and Corruption*, our employees are trained on our Code of Conduct and educated on how to report potential ethical violations or claims of harassment or discrimination without fear of retaliation. All complaints of alleged human rights violations, ethical concerns, or claims of harassment or discrimination are investigated and appropriate disciplinary action is taken if warranted.

Bribery and Corruption

Due to our global operations, Alkermes is subject to many laws governing international relations and its international operations, including but not limited to the U.S. Foreign Corrupt Practices Act ("FCPA"), the Irish Criminal Justice (Corruption Offences) Act, the U.S. Export Administration Act and U.S. and international economic sanctions and money laundering regulations. Violations of these laws, which are complex, may result in criminal penalties, sanctions and/or fines that could have an adverse effect on our business, financial condition and results of operations and reputation.

Our Code of Conduct applies to all directors, officers and employees of Alkermes plc and its subsidiaries. The Code of Conduct was established to promote, among other things:

- honest and ethical conduct by directors, officers and employees associated with the Company, including the ethical handling of actual or apparent conflicts of interest;
- full, fair, accurate, timely, and understandable disclosure in reports and documents that the Company submits to SEC and in the Company's other public communications;
- compliance with applicable governmental laws, rules, and regulations;
- the prompt internal reporting of any violations of the Code of Business Conduct to Company supervisors, or the Company's Chief Legal Officer and Chief Compliance Officer; and
- accountability for adherence to the Code of Conduct.

In addition, the Company has issued the Code of Conduct to deter wrongdoing.

We have internal policies and procedures relating to compliance with such regulations to protect us from risks associated with the improper acts of employees, agents, business partners, joint venture partners or representatives. As stated in our Code of Conduct, the Company does not permit or condone bribes, kickbacks or other improper payments, transfers or receipts. In addition to our Code of Conduct discussed above, we also implement the following compliance program elements to ensure our employees conduct business with integrity and make decisions that are legal, ethical and responsible, and that minimize risks related to bribery and corruption:

- Our policies and standards provide guidance for our employees related to our key risk areas. For example, we provide appropriate anti-corruption guidance by addressing facilitation payments, delineating appropriate government related business expenditures, requiring a review process for government related charitable contributions and political donations, and specifying appropriate behavior in respect of gifts, entertainment and travel.
- We collaborate with our senior leaders to identify employees whose job responsibilities have a higher corruption risk, including individuals within our sales teams, which facilitates targeted anti-corruption training and guidance.
- We provide ongoing business conduct and ethics training to our employees globally.
- The effectiveness of our Code of Conduct depends in part on the cooperation of all directors, officers and employees in promptly disclosing to the designated persons within the Company any conduct believed to violate the standards described in the Code of Conduct. The Company expressly prohibits retaliation of any kind against anyone who in good faith reports suspected misconduct.
- Our Chief Compliance Officer, who is also our Chief Legal Officer, is notified of any such matters and such matters are also reported to the Company's Audit and Risk Committee.

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 2018, of the arrangements and structures, referred to at 2 above.

On behalf of the directors

/s/ RICHARD F. POPS	/s/ PAUL J. MITCHELL
Richard F. Pops	Paul J. Mitchell
Chairman	*Director*

April 3, 2019

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 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 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). 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

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 31 December 2018 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 consolidated 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 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 31 December 2018;
- the Company Balance Sheet as at 31 December 2018;
- the Consolidated Profit and Loss Account and 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 Company Reconciliation of Movement in Shareholders' Funds for the year then ended; and
- the notes to the financial statements, which include a description of the significant accounting policies.

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.

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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.

Our audit approach

Overview

Materiality

$8.2 million (2017: $9 million) - Consolidated financial statements

Based on c.5% of loss before income taxes, adjusted for discrete items, primarily $26.7m of non-recurring revenue arising on Zealand Pharma A/S's licence sale.

$28 million (2017: $26 million) - Company financial statements. For group audit purposes, the lower group materiality of $8.2 million was applied to all balances and transactions that did not eliminate in the consolidated financial statements.

Based on 1% of net assets.

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. Taken together, the territories and functions where we performed our audit accounted for 100% of group revenues, 100% of loss before income taxes and 100% of group total assets.

Key audit matters

Fair value of contingent consideration receivable.

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

Recoverability of Deferred Tax Assets.

The scope of our audit

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***
Fair value of contingent consideration receivable *Refer to note 2 "summary of significant accounting policies and statement of compliance", note 7 "fair value" and note 12 "debtors".* As discussed in note 2 and note 7 to the consolidated financial statements, the group initially recognises contingent consideration that it is entitled to receive at fair value and re-values the contingent consideration at each reporting period, with changes in the fair value of contingent consideration recognized within the Consolidated Profit and Loss Account. The fair value is estimated through fair value models that incorporate probability-adjusted assumptions related to regulatory approvals, discount rates, risk-adjusted expected growth rates, and estimated expected future sales. The group utilises a third party valuation expert in to assist with the preparation of its fair value models. The group's estimate of the fair value of the contingent consideration is considered a critical accounting estimate. We focused on this area primarily due to the quantitative significance of the contingent consideration balance, which arose on the group's Gainesville Transaction ($65.2 million as of December 31, 2018) 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.	We obtained an understanding of management's process for determining the fair value of contingent consideration, including the valuation models and key assumptions. We tested key controls over management's preparation of the fair value models and approval of key assumptions. We read and considered management's valuation report that was prepared with the assistance of a third party valuation expert. We considered the appropriateness of the fair values determined for the regulatory milestone, future royalties on net sales earn-out, and commercial milestones, collectively the contingent consideration, by assessing key assumptions such as: • the likelihood and expected timing of achieving the regulatory milestone by considering events to date and industry studies; • projected net sales by considering the group's forecasts and external industry studies; and • the discount rates applied to each element of the contingent consideration by reference to external market data. 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 utilised a valuation specialist to assist with these procedures. We also tested the mathematical accuracy of the valuation models and considered the appropriateness of these valuation models. We evaluated the adequacy of the group's presentation and disclosure of the contingent consideration within the consolidated financial statements.
Rebates, discounts, chargebacks, allowances and returns in the U.S. biopharmaceutical industry, specifically Medicaid Drug Rebate Program	We obtained an understanding of management's process and methodology for determining the Medicaid rebates.

Key audit matter	How our audit addressed the key audit matter
Refer to note 2 "summary of significant accounting policies and statement of compliance" and note 16 "provisions for liabilities" 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 the recognition of a rebate liability that is included in provisions for liabilities. Refer to Note 16 for details of the provision for liabilities movement. We focused on this area due to the quantitative significance of the Medicaid Drug Rebate provision ($123.4 million as of December 31, 2018) and because in the U.S. biopharmaceutical industry estimating the rebates is complex and require significant judgement. In particular, we focused on the key assumptions utilised in the determination of the Medicaid Drug 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 tested the operating effectiveness of 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 estimate the provision to historical trends. We performed an analysis of the rebate provision 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.
Recoverability of Deferred Tax Assets *Refer to note 2 "summary of significant accounting policies and statement of compliance" and note 8 "income taxes".* As set out in note 8 net deferred tax assets recognised amount to $85.5 million. The net 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 net deferred tax assets and because there is judgement in determining whether it is more-likely-than-not that the net deferred tax assets will be recovered. In particular, we focused on the evaluation and judgements made in assessing the likely future tax consequences of events that have been recognised 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 considered in assessing the recoverability of the net deferred tax assets and utilised 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 taxable income 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 utilisations of tax credits to assess the risk that any credits would expire unutilised. We utilised our tax specialists to assist in analysing the judgements used to determine the recoverability of deferred tax asset based on their knowledge and experience of local regulations and practices. We also 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

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.

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. Taken together, the territories and functions where we performed our audit accounted for 100% of group revenues, 100% of loss before income taxes and 100% of group total assets.

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:

	Consolidated financial statements	***Company financial statements***
Overall materiality	$8.2 million (2017: $9 million).	$28 million (2017: $26 million)
How we determined it	c.5% of loss before income taxes, adjusted for discrete items, primarily $26.7m of non-recurring revenue arising on Zealand Pharma A/S's licence sale.	1% of net assets. For group audit purposes, the lower group materiality of $8.2 million was applied to all balances and transactions that did not eliminate in the consolidated financial statements.
Rationale for benchmark applied	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 we deem that net assets are the most appropriate benchmark to calculate materiality

For each component in the scope of our group audit, we allocated a materiality that is less than our overall group materiality. The range of materiality allocated across components was between €6.9 million and €7.8 million.

We agreed with the Audit Committee that we would report to them misstatements identified during our audit above $0.6 million (group audit) (2017: $0.6 million) and $1.4 million (company audit) (2017: $1.3million) as well as misstatements below that amount that, in our view, warranted reporting for qualitative reasons.

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.

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 (excluding the information included in the "Non Financial Statement" as defined by that Act on which we are not required to report) 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 (excluding the information included in the "Non-Financial Statement" on which we are not required to report) for the year ended 31 December 2018 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 (excluding the information included in the "Non-Financial Statement" on which we are not required to report).

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 63, 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 financial statements.

A further description of our responsibilities for the audit of the financial statements is located on the IAASA website at:

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.

Other required reporting

Companies Act 2014 opinions on other matters

1. We have obtained all the information and explanations which we consider necessary for the purposes of our audit.
2. In our opinion the accounting records of the company were sufficient to permit the company financial statements to be readily and properly audited.
3. The Company Balance Sheet is in agreement with the accounting records.

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
3 April 2019 (EST)

- The maintenance and integrity of the Alkermes plc website is the responsibility of the directors; the work carried out by the auditors does not involve consideration of these matters and, accordingly, the auditors accept no responsibility for any changes that may have occurred to the financial statements since they were initially presented on the website.
- Legislation in the Republic of Ireland governing the preparation and dissemination of financial statements may differ from legislation in other jurisdictions.

ALKERMES PLC

CONSOLIDATED PROFIT AND LOSS ACCOUNT

	Note	Year Ended December 31, 2018	Year Ended December 31, 2017
		(In thousands, except per share amounts)	
Manufacturing and royalty turnover	3	$ 526,675	$ 505,308
Product sales, net		450,334	362,834
Research and development turnover	3	68,895	7,232
License turnover	3	48,370	28,000
Total turnover		1,094,274	903,374
Cost of sales		176,420	154,748
Gross profit		917,854	748,626
Research and development expense		425,406	412,889
Selling, general and administrative expense		526,409	421,578
Amortization of acquired intangible assets	5	65,167	62,059
Operating loss		(99,128)	(147,900)
Interest income		9,238	4,649
Interest expense	6	(15,437)	(12,008)
Change in the fair value of contingent consideration	7	(19,600)	21,600
Other expense, net		(2,040)	(9,615)
Total other (expense) income, net		(27,839)	4,626
Loss before income taxes		(126,967)	(143,274)
Provision for income taxes	8	(12,344)	(14,671)
Loss after income taxes		$ (139,311)	$(157,945)
LOSS PER ORDINARY SHARE:			
Basic and diluted	9	$ (0.90)	$ (1.03)
WEIGHTED AVERAGE NUMBER OF ORDINARY SHARES OUTSTANDING:			
Basic and diluted	9	155,112	153,415

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

ALKERMES PLC

CONSOLIDATED STATEMENT OF COMPREHENSIVE LOSS

	Year Ended December 31,	
	2018	2017
	(In thousands)	
NET LOSS	$(139,311)	$(157,945)
Unrealized gains (losses) on marketable securities:		
Holding gains (losses), net of tax	512	(518)
Unrealized gains (losses) on marketable securities	512	(518)
COMPREHENSIVE LOSS	$(138,799)	$(158,463)

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

ALKERMES PLC

CONSOLIDATED BALANCE SHEET

	Notes	December 31, 2018	December 31, 2017
		(In thousands)	
ASSETS			
Fixed Assets			
Intangible assets—Goodwill	5	$ 92,873	$ 92,873
Intangible assets—Intellectual property	5	191,001	256,168
Tangible assets	10	309,987	284,736
Financial assets	5,13	86,212	160,581
Total fixed assets		680,073	794,358
Current Assets			
Stock	11	90,196	93,275
Debtors	12	515,443	476,090
Investments	13	272,533	242,208
Cash at bank and in-hand		266,762	191,296
Total current assets		1,144,934	1,002,869
TOTAL ASSETS		$1,825,007	$1,797,227
LIABILITIES			
Capital and Reserves			
Called-up share capital presented as equity	14	$ 1,579	$ 1,557
Share premium		570,294	549,439
Profit and loss account		171,969	312,972
Treasury shares	14	(108,969)	(89,347)
Other reserves		536,412	428,187
Total equity		1,171,285	1,202,808
Provisions for liabilities	16	163,890	117,078
Creditors			
Debt	6	279,308	281,436
Creditors	17	210,524	195,905
Total for creditors		489,832	477,341
TOTAL LIABILITIES		$1,825,007	$1,797,227

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 3, 2019 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, 2018	Year Ended December 31, 2017
	(In thousands)	
CASH FLOWS FROM OPERATING ACTIVITIES:		
Loss after tax	$(139,311)	$(157,945)
Adjustments to reconcile net loss after tax to cash flows from operating activities:		
Depreciation and amortization	103,660	98,523
Share-based compensation expense	105,357	83,917
Impairment of investment in Reset Therapeutics, Inc.	—	10,471
Deferred income taxes	10,623	7,234
Change in the fair value of contingent consideration	19,600	(21,600)
Loss on debt refinancing.	2,298	—
Payment made for debt refinancing.	(2,251)	—
Impairment of property, plant and equipment	5,746	—
Other non-cash charges	979	3,471
Changes in assets and liabilities:		
Receivables	(58,632)	(42,489)
Contract assets	880	—
Inventory	(2,665)	(30,191)
Prepaid expenses and other assets	(5,990)	(9,506)
Accounts payable and accrued expenses	46,739	72,658
Contract liabilities	3,252	(1,447)
Other long-term liabilities	8,996	6,094
Cash flows provided by operating activities	99,281	19,190
CASH FLOWS FROM INVESTING ACTIVITIES:		
Additions to property, plant and equipment	(69,431)	(51,300)
Proceeds from the sale of equipment	507	162
Purchases of investments	(397,727)	(431,712)
Sales and maturities of investments	444,456	464,494
Cash flows (used in) investing activities	(22,195)	(18,356)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from the issuance of ordinary shares for share-based compensation arrangements	20,877	23,517
Payment made in connection with debt refinancing	(743)	—
Employee taxes paid related to net share settlement of equity awards	(19,622)	(16,433)
Principal payments of long-term debt	(2,132)	(3,000)
Cash flows (used in) provided by financing activities	(1,620)	4,084
NET INCREASE IN CASH AND CASH EQUIVALENTS	75,466	4,918
CASH AND CASH EQUIVALENTS—Beginning of period	191,296	186,378
CASH AND CASH EQUIVALENTS—End of period	$ 266,762	191,296
SUPPLEMENTAL CASH FLOW DISCLOSURE:		
Cash paid for interest	$ 12,526	$ 11,143
Cash paid for taxes	$ 754	$ 2,992
Non-cash investing and financing activities:		
Purchased capital expenditures included in accounts payable and accrued expenses	$ 11,720	$ 11,151

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, 2017	$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
Net loss	—	—	(139,311)	—	—	(139,311)
Cumulative effect adjustment related to adoption of new accounting standards	—	—	(1,692)	—	—	(1,692)
Other comprehensive loss	—	—	—	—	512	512
Share-based payment reserve	—	—	—	—	107,713	107,713
Shares issued under employee stock plans	11	20,866	—	—	—	20,877
Receipt of Alkermes' shares for the purchase of share options or to satisfy minimum tax withholding obligations related to share based awards	11	(11)	—	(19,622)	—	(19,622)
BALANCE—December 31, 2018	$1,579	$570,294	$ 171,969	$(108,969)	$536,412	$1,171,285

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 focused on central nervous system ("CNS") disorders such as schizophrenia, depression, addiction, and multiple sclerosis ("MS") and oncology. 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 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 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.

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.

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

Use of Estimates

The preparation of the Company's consolidated financial statements in accordance with accounting principles generally accepted in the United States ("U.S.") ("GAAP") requires management to make estimates, judgments and assumptions that may affect the reported amounts of assets, liabilities, revenues and expenses, and related disclosure of contingent assets and liabilities. On an on-going basis, the Company evaluates its estimates and judgments and methodologies, including those related to revenue from contracts with customers and related allowances, 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, 2018, substantially all these investments were classified as available for sale and were recorded at fair value.

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

For securities with unrealized losses, the Company performs an analysis to assess whether it intends to sell or whether it would more likely than not be required to sell the security before the expected recovery of its amortized cost basis. If the Company intends to sell a security, or may be required to do so, the security's decline in fair value is deemed to be other-than-temporary and the full amount of the unrealized loss is recorded within earnings as an impairment loss. Regardless of the Company's intent to sell a security, the Company performs additional analysis on all securities with unrealized losses to evaluate losses associated with the creditworthiness of the security. Credit losses are identified where the Company does not expect to receive cash flows sufficient to recover the amortized cost basis of a security.

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

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 and are classified within the fair value hierarchy as follows:

- *Level 1*—these valuations are based on a market approach using quoted prices in active markets for identical assets. Valuations of these products do not require a significant degree of judgment. Assets utilizing Level 1 inputs at December 31, 2018 and 2017 included U.S. treasury securities, marketable securities classified as cash equivalents 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, 2018 and 2017 included U.S. government agency debt securities, debt securities issued by foreign agencies and backed by foreign governments and investments in corporate debt securities that are trading in the credit markets; and
- *Level 3*—these valuations are based on an income approach using certain inputs that are unobservable and are significant to the overall fair value measurement. Valuations of these products require a significant degree of judgment. At December 31, 2018 and 2017, assets utilizing Level 3 inputs included contingent consideration and warrants to purchase the common stock of Recro Pharma, Inc. ("Recro") and an investment in a corporate debt security.

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.

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

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:

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

Contingent Consideration

The Company records contingent consideration it is entitled to receive 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 (the "Business Combination") 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.

Consistent with U.S. GAAP, goodwill is not amortized over an arbitrary period, but is reviewed for impairment on an annual basis, as of October 31, and whenever events or changes in circumstances indicate that the carrying value of the goodwill might not be recoverable. The Company has the option to first assess qualitative factors to determine whether it is necessary to perform the quantitative impairment test. If the

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

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.

Turnover from Contracts with Customers

Effective January 1, 2018, the Company adopted the requirements of the Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC") 606, *Revenue from Contracts with Customers* ("Topic 606") using the modified retrospective method. As part of the adoption, the Company reviewed all contracts that were not yet completed as of the date of initial application in determining the cumulative-effect impact related to the adoption of Topic 606. The cumulative-effect impact recorded to retained earnings resulted in an adjustment of approximately $0.8 million, which was primarily due to the acceleration of manufacturing

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

turnover, offset by an adjustment to deferred revenue for license and milestone payments that will now be recognized over time. The following balance sheet accounts were impacted:

(In thousands):	Topic 606 Adjustment
Debtors	$ 9,110
Stock	(8,209)
Deferred tax asset	109
Creditors	(1,828)
Accumulated deficit	818
Total	$ —

When entering into arrangements with customers, the Company identifies whether its performance obligations under the arrangement represent a distinct good or service or a series of distinct goods or services. If a contract contains more than one performance obligation, the Company allocates the total transaction price to each performance obligation in an amount based on the estimated relative standalone selling prices of the promised goods or services underlying each performance obligation. The fair value of performance obligations under the arrangement may be derived using an estimate of selling price if the Company does not sell the goods or services separately.

The Company recognizes turnover when or as it satisfies a performance obligation by transferring an asset or providing a service to a customer. 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.

The Company adopted Topic 606 using the modified retrospective method. As such, the Company recognized the cumulative effect of initially applying Topic 606 as an adjustment to the opening balance of shareholders' equity at January 1, 2018. Therefore, the comparative information has not been adjusted and continues to be reported under the old turnover recognition guidance ("Topic 605"). The quantitative impacts of

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

the changes are set out below for each of the condensed consolidated balance sheet and the condensed consolidated statement of operations and comprehensive loss for the current reporting period.

ADJUSTED CONDENSED CONSOLIDATED BALANCE SHEET

	December 31, 2018		
(In thousands)	As Reported	Adjustment	Balances Without Adoption of Topic 606
Assets:			
Debtors	$515,443	$(8,230)[(1)]	$507,213
Stock	90,196	8,847[(2)]	99,043
Deferred tax asset	85,807	(133)[(3)]	85,674
Creditors:			
Debtors	$210,524	$(2,618)[(4)]	$207,906
Shareholders' Funds:			
Profit and loss account	$171,969	$ 2,156[(5)]	$174,125

The adjustments are a result of the following:

(1) Adjustment to debtors to reverse turnover recognized over time under Topic 606.

(2) Adjustment to stock to add back the cost of goods manufactured related to the turnover transactions summarized in item (1), above.

(3) Adjustment to deferred tax asset to apply the tax impact of the turnover transactions summarized in item (1), above.

(4) Adjustments to contract liabilities to recognize revenue that would have been recognized under Topic 605.

(5) Adjustment to the profit and loss account for the net impact of the transactions noted in items (1) through (3), above.

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

ADJUSTED CONDENSED CONSOLIDATED PROFIT AND LOSS ACCOUNT

	December 31, 2018		
(In thousands)	As Reported	Adjustment	Balances Without Adoption of Topic 606
Turnover:			
Manufacturing and royalty turnover	$ 526,675	$ 1,911[(1)]	$ 528,586
Product sales, net	450,334	—	450,334
Research and development turnover	68,895	48,473[(2)]	117,368
License turnover	48,370	(48,370)[(3)]	—
Total turnover	1,094,274	2,014	1,096,288
Cost of sales	176,420	(640)[(4)]	175,780
Gross profit	917,854	2,654	920,508
Research and development expense	425,406	—	425,406
Selling, general and administrative expense	526,408	—	526,408
Amortization of acquired intangible assets	65,168	—	65,168
Operating loss	(99,128)	2,654	(96,474)
Other (expense) income, net	(27,839)	—	(27,839)
Loss before income taxes	(126,967)	2,654	(124,313)
Provision for income taxes	(12,344)	(24)	(12,368)
Loss after income taxes	$ (139,311)	$ 2,630	$ (136,681)
Loss per ordinary share—basic and diluted	$ (0.90)	$ 0.02	$ (0.88)
Weighted average number of ordinary shares outstanding—basic and diluted	155,112	155,112	115,112

The adjustments are a result of the following:

(1) Adjustments to manufacturing and royalty turnover to recognize turnover under Topic 605 in the year ended December 31, 2018 that was recognized under Topic 606.

(2) Adjustments to research and development turnover during the year ended December 31, 2018 to recognize turnover under Topic 605 that was recognized under Topic 606.

(3) Adjustments to license turnover during the year ended December 31, 2018 to recognize turnover under Topic 605 that was recognized under Topic 606.

(4) Adjustments to cost of goods manufactured and sold to recognize the cost from the transactions noted in item (1) above.

The Company's changes in assets and liabilities within its condensed consolidated statement of cash flows changed as a result of the differences in the condensed consolidated balance sheet and changes in net loss in the condensed consolidated statement of operations, but the overall cash flows used in operating activities did not change.

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

The Company has entered into collaboration agreements with pharmaceutical companies including Janssen Pharmaceutica Inc. (“Janssen, Inc.”), Janssen Pharmaceutica International, a division of Cilag International AG (“Janssen International”), and Janssen Pharmaceutica N.V. (together with Janssen, Inc., Janssen International and their affiliates “Janssen”) for INVEGA SUSTENNA®/XEPLION® and INVEGA TRINZA®/TREVICTA® as well as RISPERDAL CONSTA®, Acorda Therapeutics, Inc. (“Acorda”) for AMPYRA®/FAMPYRA®, and Biogen Swiss Manufacturing GmbH (together with its affiliates, “Biogen”) for diroximel fumarate (“BIIB098”). Substantially all of the products developed under these arrangements, except for BIIB098, are currently being marketed as approved products for which the Company receives payments for manufacturing services and/or royalties on net product sales.

Manufacturing Turnover

The Company recognizes manufacturing turnover from the sale of products it manufactures for resale by its licensees. Manufacturing turnover for the Company’s partnered products, with the exception of those from Janssen related to RISPERDAL CONSTA, are recognized over time as products move through the manufacturing process, using a standard cost-based model as a measure of progress, which represents a faithful depiction of the transfer of control of the goods. The Company recognizes manufacturing turnover from these products over time as it determined, in each instance, that it would have a right to payment for performance completed to date if its customer were to terminate the manufacturing agreement for reasons other than the Company’s non-performance and the products have no alternative use. The Company invoices its licensees upon shipment with payment terms between 30 to 90 days. Prior to the adoption of Topic 606, the Company recorded manufacturing turnover from the sale of products it manufactures for resale by its partners after the Company had shipped such products and risk of loss had passed to the Company’s partner, assuming persuasive evidence of an arrangement existed, the sales price was fixed or determinable and collectability was reasonably assured.

The Company is the exclusive manufacturer of RISPERDAL CONSTA for commercial sale under its manufacturing and supply agreement with Janssen. The Company determined that it is appropriate to record turnover under this agreement at the point in time when control of the product passes to Janssen, which is determined to be when the product has been fully manufactured, since Janssen does not control the product during the manufacturing process and, in the event Janssen terminates the manufacturing and supply agreement, it is uncertain whether, and at what amount, the Company would be reimbursed for performance completed to date for product not yet fully manufactured. The manufacturing process is considered fully complete once the finished goods have been approved for shipment by both the Company and Janssen.

The sales price for certain of the Company’s manufacturing turnover is based on the end-market sales price earned by its licensees. As end-market sales generally occur after the Company has recorded manufacturing turnover, the Company estimates the sales price for such products based on information supplied to it by the Company’s licensees, its historical transaction experience and other third-party data. Differences between actual manufacturing turnover and estimated manufacturing turnover are reconciled and adjusted for in the period in which they become known, which is generally within the same quarter. The difference between the Company’s actual and estimated manufacturing turnover has not been material to date.

Royalty Turnover

The Company recognizes royalty turnover related to the sale of products by its licensees that incorporate the Company’s technologies. Royalties, with the exception of those earned on sales of AMPYRA as set forth below, qualify for the sales-and-usage exemption under Topic 606 as (i) royalties are based strictly on the sales-and-usage by the licensee; and (ii) a license of intellectual property (“IP”) is the sole or predominant item to

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

which such royalties relate. Based on this exemption, these royalties are earned in the period the products are sold by the Company's partner and the Company has a present right to payment. Royalties on AMPYRA manufactured under our license and supply agreements with Acorda are incorporated into the standard cost-based model described in the manufacturing turnover section, above, as the terms of such agreements entitle the Company to royalty turnover as the product is being manufactured, which represents a faithful depiction of the transfer of goods, and not based on the actual end-market sales of the licensee. Certain of the Company's royalty turnover are recognized by the Company based on information supplied to the Company by its licensees 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 same quarter. The difference between the Company's actual and estimated royalty turnover has not been material to date.

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 partners. The Company generally bills its partners under R&D arrangements using a full-time equivalent ("FTE") or hourly rate, plus direct external costs, if any. Turnover is recognized as the obligations under the R&D arrangements are performed.

License Turnover

The Company recognizes turnover from the grant of distinct, right-to-use licenses of intellectual property ("IP") when control of the license is transferred to the customer, which is the point in time the customer is able to direct the use of and obtain substantially all of the benefits from the license.

Product Sales, Net

The Company's product sales, net consist of sales of VIVITROL® and ARISTADA® in the U.S. primarily to wholesalers, specialty distributors and pharmacies. Product sales, net are recognized when the customer obtains control of the product, which is when the product has been received by the customer.

Turnover from product sales are recorded net of reserves established for applicable discounts and allowances that are offered within contracts with the Company's customers, health care providers or payers. The Company's process for estimating reserves established for these variable consideration components does not differ materially from historical practices. The transaction price, which includes variable consideration reflecting the impact of discounts and allowances, may be subject to constraint and is included in the net sales price only to the extent that it is probable that a significant reversal of the amount of the cumulative turnover recognized will not occur in a future period. Actual amounts may ultimately differ from the Company's estimates. If actual results vary, the Company adjusts these estimates, which could have an effect on earnings in the period of adjustment. The following are the Company's significant categories of sales discounts and allowances:

- *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 using the expected value method. 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 adjusts 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;

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

- *Chargebacks*—discounts that occur when contracted indirect customers purchase directly from wholesalers and specialty distributors. Contracted customers generally purchase a 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 contracted price paid to the wholesaler or specialty distributor by the customer. The allowance for chargebacks is made using the expected value method and 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. The reserve is made using the expected value method and to date, actual product discounts have not differed materially from the Company's estimates; and
- *Product Returns*—the Company records an estimate for product returns at the time its customers take control of the Company's product. The Company estimates this liability using the expected value method 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.
- *Medicare Part D*—the Company records accruals for Medicare Part D liabilities under the Medicare Coverage Gap Discount Program ("CGDP") as a reduction of sales. Under the CGDP, patients reaching the annual coverage gap threshold are eligible for reimbursement coverage for out-of-pocket costs for covered prescription drugs. Under an agreement with the Center for Medicare and Medicaid, manufacturers are responsible to reimburse prescription plan sponsors for the portion of out-of-pocket expenses not covered under their Medicare plans.

Foreign Currency

The Company's functional and reporting currency is the U.S. dollar. Transactions in foreign currencies are recorded at the exchange rate prevailing on the date of the transaction. The resulting monetary assets and liabilities are translated into U.S. dollars at exchange rates prevailing on the subsequent balance sheet date. Gains and losses as a result of translation adjustments are recorded within "Other (expense) income, net" in the accompanying consolidated profit and loss account. During the years ended December 31, 2018 and 2017, the Company recorded a (loss) gain on foreign currency translation of $(2.3) million and $3.7 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 turnover and

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

receivables from the Company's customers exceeding 10% of the total in each category as of December 31, 2018 and 2017 and for the years ended December 31, 2018 and 2017:

	Year Ended December 31, 2018		Year Ended December 31, 2017	
Customer	**Receivables**	**Turnover**	**Receivables**	**Turnover**
Janssen	27%	29%	31%	33%
Acorda	15%	10%	14%	13%
Cardinal Health	*	13%	*	*
Biogen	*	10%	*	*

* Indicates the turnover or receivables for the customer did not exceed 10% of the Company's total in each category as of or for the years ended December 31, 2018 and 2017, as noted.

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, were as follows:

(In thousands)	Year Ended December 31, 2018	Year Ended December 31, 2017
Turnover by region:		
U.S.	$884,600	$700,090
Ireland	4,915	9,706
Rest of world	204,759	193,578
Assets by region:		
Current assets:		
U.S.	$546,533	$402,481
Ireland	433,837	403,167
Rest of world	2,882	3,196
Long-term assets:		
U.S.:		
Other	$312,243	$360,641
Ireland:		
Intangible assets	$191,001	$256,168
Goodwill	92,873	92,873
Other	245,638	278,701

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

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

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.

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, 2018 and 2017, advertising costs totaled $54.7 million and $34.4 million, respectively.

Share-Based Compensation

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

Stock Options

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

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

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:

	Year Ended December 31, 2018	Year Ended December 31, 2017
Expected option term	5 - 8 years	5 - 8 years
Expected stock volatility	44% - 49%	43% - 47%
Risk-free interest rate	2.25% - 3.10%	1.69% - 2.38%
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.

Other Reserves

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; and unrealized gains (losses) on marketable securities.

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.

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 earnings per share, the Company uses the weighted average number of ordinary shares outstanding, as adjusted for the effect of potential dilutive securities, including stock options and RSUs.

Segment Information

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

Employee Benefit Plans

401(k) Plan

The Company maintains a 401(k) retirement savings plan (the "401(k) Plan"), which covers substantially all of its U.S.-based employees. Eligible employees may contribute up to 100% of their eligible compensation, subject to certain Internal Revenue Service ("IRS") limitations. The Company matches 100% of employee contributions up to the first 5% of employee pay, up to IRS limits. Employee and Company contributions are fully vested when made. During the years ended December 31, 2018 and 2017, the Company contributed $12.1 million and $9.8 million, respectively, to match employee deferrals under the 401(k) Plan.

Defined Contribution Plan

The Company maintains a defined contribution plan for its Ireland-based employees (the "Defined Contribution Plan"). The Defined Contribution Plan provides for eligible employees to contribute up to the maximum of 40%, depending upon their age, of their total taxable earnings subject to an earnings cap of €115,000. The Company provides a match of up to 18% of taxable earnings depending upon an individual's contribution level. During the years ended December 31, 2018 and 2017, the Company contributed $4.0 million and $3.7 million, respectively, in contributions to the Defined Contribution Plan.

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

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 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 January 2016, the FASB issued ASU 2016-01, *Recognition and Measurement of Financial Assets and Financial Liabilities*, which enhances the reporting model for financial instruments by addressing certain aspects of recognition, measurement, presentation and disclosure of financial instruments. The amendments in this ASU include: requiring equity securities to be measured at fair value with changes in fair value recognized through the income statement; simplifying the impairment assessment of equity instruments without readily determinable fair values by requiring a qualitative assessment to identify impairment; eliminating the requirement to disclose the fair value of financial instruments measured at amortized cost for entities that are not public business entities; eliminating the requirement for public business entities to disclose the method(s) and significant assumptions used to estimate the fair value that is required to be disclosed for financial instruments measured at amortized cost on the balance sheet; requiring public business entities to use the exit price notion when measuring the fair value of financial instruments for disclosure purposes; requiring an entity to present separately in other comprehensive income the portion of the total change in the fair value of a liability resulting from a change in the instrument-specific credit risk when the entity has elected to measure the liability at fair value in accordance with the fair value option for financial instruments; requiring separate presentation of financial assets and financial liabilities by measurement category and form of financial asset; and clarifying that an entity should evaluate the need for a valuation allowance on a deferred tax asset related to available-for-sale securities in combination with the entity's other deferred tax assets. This ASU was effective and adopted by the Company in the year ended December 31, 2018, and the adoption of the ASU did not have an impact on its consolidated financial statements.

In February 2016, the FASB issued ASU 2016-02, *Leases*, in order 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. Numerous updates have been issued subsequent to the initial ASU that provide clarification on a number of specific issues. The main difference between previous GAAP and this ASU is the recognition of lease assets and lease liabilities by lessees for those leases classified as operating leases under previous GAAP. This ASU becomes effective for the Company in the year ending December 31, 2019. At this time, the Company is substantially complete with its assessment of the new ASU and although it hasn't concluded as to the total expected impact the adoption of this new ASU will have on its consolidated financial statements, it has determined that the adoption will have a material impact on the Company's balance sheet as it currently has, among other operating leases, two operating leases for 67,000 and 175,000 square feet of office and laboratory space in two separate locations in Waltham, Massachusetts that expire in 2020 and 2021, respectively, and an operating lease for 14,600 square feet of corporate office space in Dublin, Ireland that expires in 2022. In addition, during the three months ended March 31, 2018, the Company entered into a lease for approximately 220,000 square feet of office and laboratory space to be constructed in Waltham, Massachusetts with a delivery date of January 2020. The Company will adopt the standard retrospectively on January 1, 2019 through a cumulative-effect adjustment without adjusting comparative periods.

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

In April 2016, the FASB issued ASU 2016-09, *Improvements to Employee Share-Based Payment Accounting*, 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 ASU 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.

In June 2016, the FASB issued ASU 2016-13, *Measurement of Credit Losses on Financial Instruments*, 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 ASU 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 ASU becomes effective for the Company in the year ending December 31, 2020, with early adoption permitted for the Company in the year ending December 31, 2019. The Company is currently assessing the impact that this ASU will have on its consolidated financial statements.

In October 2016, the FASB issued ASU 2016-16, *Intra-Entity Transfers of Assets Other Than Inventory*, to simplify and improve accounting on transfers of assets between affiliated entities. This ASU eliminates the prohibition for all intra-entity asset transfers, except for inventory. Effective January 1, 2018, the Company adopted this ASU and recorded a cumulative-effect adjustment of $0.9 million to retained earnings.

In June 2018, the FASB issued ASU 2018-07, *Improvements to Nonemployee Share-Based Payment Accounting*, which addresses the accounting for nonemployee share-based payment transactions resulting from expanding the scope of Topic 718, Compensation—Stock Compensation, to include share-based payment transactions for acquiring goods and services from nonemployees. This ASU becomes effective for the Company in the year ending December 31, 2019 and early adoption is permitted. The Company does not expect that the adoption of this ASU will have a material impact on its consolidated financial statements.

In August 2018, the FASB issued ASU 2018-14, *Disclosure Framework—Changes to the Disclosure Requirements for Fair Value Measurement*, which aims to improve the effectiveness of fair value measurement disclosures. The amendments in this ASU modify the disclosure requirements on fair value measurements based on the concepts in FASB Concepts Statement, Conceptual Framework for Financial Reporting - Chapter 8: Notes to Financial Statements, including the consideration of costs and benefits. This ASU becomes effective for the Company in the year ending December 31, 2020 and early adoption is permitted. The Company is currently assessing the impact that this ASU will have on its consolidated financial statements.

In August 2018, the FASB issued ASU 2018-15, *Customer's Accounting for Implementation Costs Incurred in a Cloud Computing Arrangement That Is a Service Contract*, which aligns the requirements for capitalizing implementation costs incurred in a hosting arrangement that is a service contract with the requirements for

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

capitalizing implementation costs incurred to develop or obtain internal-use software (and hosting arrangements that include an internal-use software license). This ASU also requires the entity to expense the capitalized implementation costs of a hosting arrangement that is a service contract over the term of the hosting arrangement, which includes reasonably certain renewals. This ASU becomes effective for the Company in the year ending December 31, 2020 and early adoption is permitted. The Company is currently assessing the impact that this ASU will have on its consolidated financial statements.

In November 2018, the FASB issued ASU 2018-18, *Clarifying the Interaction Between Topic 808 and Topic 606*, which clarifies when transactions between participants in a collaborative arrangement are within the scope of the FASB's revenue standard, Topic 606. This ASU becomes effective for the Company in the year ending December 31, 2020 and early adoption is permitted. The Company is currently assessing the impact that this ASU will have on its consolidated financial statements.

3. TURNOVER FROM CONTRACTS WITH CUSTOMERS

During the years ended December 31, 2018 and 2017, the Company recorded manufacturing and royalty turnover from its collaborative arrangement as follows:

	Year Ended December 31, 2018		
	Manufacturing Turnover	Royalty Turnover	Total
		(In thousands)	
INVEGA SUSTENNA/XEPLION & INVEGA TRINZA/ TREVICTA	$ —	$241,423	$241,423
AMPYRA/FAMPYRA	53,044	54,009	107,053
RISPERDAL CONSTA	52,770	18,352	71,122
Other	27,214	79,863	107,077
Total	$133,028	$393,647	$526,675

	Year Ended December 31, 2017		
	Manufacturing Turnover	Royalty Turnover	Total
		(In thousands)	
INVEGA SUSTENNA/XEPLION & INVEGA TRINZA/ TREVICTA	$ —	$214,931	$214,931
AMPYRA/FAMPYRA	55,373	61,646	117,019
RISPERDAL CONSTA	64,793	20,129	84,922
Other	32,655	55,781	88,436
Total	$152,821	$352,487	$505,308

During the years ended December 31, 2018 and 2017, the Company recorded product sales, net, as follows:

	December 31,	
(In thousands)	2018	2017
VIVITROL	$302,609	$269,321
ARISTADA	147,725	93,513
Total product sales, net	$450,334	$362,834

3. TURNOVER FROM CONTRACTS WITH CUSTOMERS (Continued)

Research and Development Turnover and License Turnover

The research and development turnover and license turnover recorded during the years ended December 31, 2018 and 2017 primarily related to turnover earned under the Company's license and collaboration agreement with Biogen for BIIB098.

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 the agreement in November 2017, the Company received an up-front cash payment of $28.0 million. In June 2018, the Company received an additional cash payment of $50.0 million following Biogen's review of preliminary gastrointestinal tolerability data from the ongoing clinical development program for BIIB098. The Company is also eligible to receive an additional payment of $150.0 million upon an approval by the FDA on or before December 31, 2021 of a 505(b)(2) new drug application ("NDA") (or, in certain circumstances, a 505(b)(1) NDA) for BIIB098. The Company is also eligible to receive additional payments upon achievement of developmental 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 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 such products and the minimum annual payments for BIIB098 are subject to reductions as set forth in the agreement. Biogen paid a portion of the BIIB098 development costs the Company incurred in 2017 and, since January 1, 2018, Biogen is 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 Topic 606 and determined that it had four deliverables: (i) the grant of a distinct, right-to-use license of IP to Biogen; (ii) future development services; (iii) clinical supply; and (iv) participation on a joint steering committee with Biogen. The Company's participation on the joint steering committee was considered to be perfunctory and thus not recognized as a performance obligation. The deliverables, aside from the participation in the joint steering committee which was considered to be perfunctory, were determined to be separate performance obligations as the license is separately identifiable from the development services and clinical supply, and the development services are not expected to significantly modify or customize the IP.

The Company allocated the arrangement consideration to each performance obligation using the standalone selling prices based on its estimate of selling price for the license and other deliverables. The Company used a discounted cash flow model to estimate the standalone selling price of the license in order to allocate the consideration to the performance obligations. To estimate the standalone selling price 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 maintenance of the 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 estimate of selling price of the development services and clinical

3. TURNOVER FROM CONTRACTS WITH CUSTOMERS (Continued)

supply were determined through third-party evidence. The Company believes that a change in the assumptions used to determine its estimate of selling price for the license most likely would not have a significant effect on the allocation of consideration transferred.

As the license was delivered to Biogen in November 2017, under Topic 606, the Company allocated the $28.0 million upfront payment as follows: $27.0 million to the delivery of the license; $0.9 million to future development services; and $0.1 million to clinical supply. The Company allocated the $50.0 million payment received in 2018 following Biogen's review of preliminary gastrointestinal tolerability data from the ongoing clinical development program for BIIB098 as follows: $48.3 million to the delivery of the license; $1.5 million to future development services; and $0.2 million to clinical supply. The amounts allocated to the license were recognized upon receipt of the payments as delivery of the license occurred upon entry into the agreement in 2017. The Company expects to earn an additional $60.4 million in development services and clinical supply, which is expected to continue through 2021.

The Company determined that the future milestones it is entitled to receive, including the $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, and sales-based royalties, are variable consideration. The Company is using the most likely amount method for estimating the variable consideration to be received related to the milestones under this arrangement. 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. Accordingly, the Company has not included these milestones in the transaction price as it is not probable that a significant reversal in the amount of cumulative turnover recognized will not occur. The royalties are subject to the sales-based exception and will be recorded when the corresponding sale occurs.

The Company expects to earn an additional $60.4 million in research and development turnover under this agreement with Biogen through the year ended December 31, 2021.

4. COLLABORATIVE ARRANGEMENTS

The Company's significant collaborative arrangements are described below:

Janssen

<u>INVEGA SUSTENNA/XEPLION and INVEGA TRINZA/TREVICTA</u>

Under its license agreement with Janssen Pharmaceutica N.V., the Company granted Janssen a worldwide exclusive license under its NanoCrystal technology to develop, commercialize and manufacture INVEGA SUSTENNA/XEPLION and INVEGA TRINZA/TREVICTA and related products.

Under 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

4. COLLABORATIVE ARRANGEMENTS (Continued)

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.

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 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 turnover when the product is fully manufactured and approved for shipment, 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%.

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%.

4. COLLABORATIVE ARRANGEMENTS (Continued)

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 turnover and a royalty of approximately 10% based on net sales of AMPYRA (including the authorized generic version 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 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 upon 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 the amended and restated 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;

4. COLLABORATIVE ARRANGEMENTS (Continued)

- approval of the NDA by the FDA: $1.5 million; and
- the first commercial sale: $1.5 million.

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 also received 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 in 2018. The Company is also eligible to receive 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 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, 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, since January 1, 2018, Biogen is 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, if in part B of the head-to-head phase 3 gastrointestinal tolerability clinical trial, BIIB098 demonstrates a greater rate of discontinuations as compared to TECFIDERA and TECFIDERA demonstrates statistical superiority to BIIB098 on the primary endpoint, then "GI Inferiority" shall be deemed to 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.

4. COLLABORATIVE ARRANGEMENTS (Continued)

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) GI Inferiority was not deemed to exist or (ii) GI Inferiority was deemed to exist but Biogen commercialized BIIB098, then, at the Company's request, the BIIB098 program will revert to the Company.

5. GOODWILL, INTANGIBLE ASSETS AND ASSOCIATED UNDERTAKINGS

Goodwill and intangible assets consist of the following:

		Intangible Assets—Intellectual Property			
(In thousands)	Goodwill	Collaboration Agreements	NanoCrystal Technology	OCR Technology	Total
Cost:					
At January 1, 2018	$92,873	$ 465,590	$ 74,600	$ 42,560	$ 582,750
At December 31, 2018	$92,873	$ 465,590	$ 74,600	$ 42,560	$ 582,750
Accumulated Depreciation:					
At January 1, 2017	$ —	$(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)
Expensed during the year	—	(49,919)	(7,659)	(7,589)	(65,167)
At December 31, 2018	$ —	$(319,311)	$(38,942)	$(33,496)	$(391,749)
Net Book Amount:					
At December 31, 2018	$92,873	$ 146,279	$ 35,658	$ 9,064	$ 191,001
At December 31, 2017	$92,873	$ 196,198	$ 43,317	$ 16,653	$ 256,168

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 $65.2 million and $62.1 million of amortization expense related to its finite-lived intangible assets during the years ended December 31, 2018 and 2017, 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 $40.0 million, $40.0 million, $40.0 million, $35.0 million and $35.0 million in the years ending December 31, 2019 through 2023, respectively. Although the Company believes such available information and assumptions are reasonable, given the inherent risks and uncertainties underlying its expectations regarding such future turnover, there is the potential for the Company's actual results to vary significantly from such expectations. If turnover are projected to change, the related amortization of the intangible assets will change in proportion to the change in turnover.

The Company performed its annual goodwill impairment test as of October 31, 2018. The Company elected to perform a quantitative impairment test and determined that the fair value of the reporting unit exceeded its carrying value.

5. GOODWILL, INTANGIBLE ASSETS AND ASSOCIATED UNDERTAKINGS (Continued)

Associated Undertakings

In February 2016, the Company entered into a collaboration and license option agreement with Synchronicity Pharma, Inc. (“Synchronicity”) formerly 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 Synchronicity’s Series B Preferred Stock. The Company was accounting for its investment in Synchronicity under the equity method based on its percentage of ownership, its seat on the board of directors and its belief that it could exert significant influence over the operating and financial policies of Synchronicity.

In September 2017, the Company recorded an other-than-temporary impairment charge of $10.5 million within “Other (expense) income, net” in the accompanying consolidated statements of operations and comprehensive loss, which represented the Company’s remaining investment in Synchronicity, as the Company believed that Synchronicity was unable to generate future earnings that justify the carrying amount of the investment. In November 2017, the collaboration and license option agreement with Synchronicity was terminated. During the year ended December 31, 2017, the Company recorded a reduction in its investment in Synchronicity of $2.8 million, which represented the Company’s proportional share of Synchronicity’s net loss for the period.

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, 2018, the Company’s total contribution in Fountain was equal to €5.2 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, 2018 and 2017, the Company recorded an increase in its investment in Fountain of $0.5 million and a reduction in its investment in Fountain of $0.1 million, respectively, which represented the Company’s proportionate share of Fountain’s net gain (loss) for this period. At December 31, 2018 and 2017, the Company’s investment is equal to, $5.5 million (€4.8 million), and $3.4 million (€2.8 million), respectively, which is included within “Intangible assets—Associated undertaking” in the accompanying consolidated balance sheets.

6. LONG-TERM DEBT

Long-term debt consists of the following:

	December 31,	
(In thousands)	**2018**	**2017**
2023 Term Loans, due March 26, 2023	$279,308	$281,436
Less: current portion	(2,843)	(3,000)
Long-term debt	$276,465	$278,436

2023 Term Loans

In March 2018, the Company amended and refinanced its existing term loan, referred to as Term Loan B-1 (as so amended and refinanced, the “2023 Term Loans”), in order to, among other things, extend the due date of the loan from September 25, 2021 to March 26, 2023, reduce the interest payable from LIBOR plus 2.75% with a LIBOR floor of 0.75% to LIBOR plus 2.25% with a 0% LIBOR floor and increase covenant flexibility (the “Refinancing”).

6. LONG-TERM DEBT (Continued)

The Refinancing involved multiple lenders who were considered members of a loan syndicate. In determining whether the Refinancing was to be accounted for as a debt extinguishment or a debt modification, the Company considered whether creditors remained the same or changed and whether the changes in debt terms were substantial. A change in the debt terms was considered to be substantial if the present value of the remaining cash flows under the new terms of the 2023 Term Loans was at least 10% different from the present value of the remaining cash flows under the former 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. With the exception of one lender, who owned 1% of the total outstanding principal amount of Term Loan B-1 at the date of the Refinancing and was accounted for as a debt extinguishment, the Refinancing was accounted for as a debt modification.

The Refinancing resulted in a $2.3 million charge in the three months ended March 31, 2018, which was included in "Interest expense" in the accompanying consolidated statement of operations and comprehensive loss.

Scheduled maturities with respect to the 2023 Term Loans are as follows (in thousands):

Year Ended:	
2019	$ 2,843
2020	2,843
2021	2,843
2022	2,843
2023	270,746
Total	$282,118

Beginning on January 1, 2014, the Company became subject to mandatory prepayments of principal if certain excess cash flow thresholds, as defined in the 2023 Term Loans, were met.

The 2023 Term Loans have an incremental facility capacity in an amount of $175.0 million, plus additional amounts as long as the Company meets certain conditions, including a specified leverage ratio. The 2023 Term Loans include a number of restrictive covenants that, among other things and subject to certain exceptions and baskets, impose operating and financial restrictions on the Company and certain of its subsidiaries. The 2023 Term Loans also contain customary affirmative covenants and events of default. The Company was in compliance with its debt covenants at December 31, 2018.

At December 31, 2018, the Company's balance of unamortized deferred financing costs and unamortized original issue discount costs were $0.8 million and $2.0 million, respectively. These costs are being amortized to interest expense over the estimated repayment period of the 2023 Term Loans using the effective interest method. During the years ended December 31, 2018 and 2017, the Company had amortization expense of $0.7 million and $0.8 million, respectively, related to deferred financing costs and original issue discount.

7. FAIR VALUE

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

(In thousands)	December 31, 2018	Level 1	Level 2	Level 3
Assets:				
Cash equivalents	$ 54,590	$ 54,590	$ —	$ —
U.S. government and agency debt securities	98,513	60,107	38,406	—
Corporate debt securities	173,637	—	173,145	492
International government agency debt securities	77,504	—	77,504	—
Contingent consideration	65,200	—	—	65,200
Common stock warrants	1,205	—	—	1,205
Total	$470,649	$114,697	$289,055	$66,897

(In thousands)	December 31, 2017	Level 1	Level 2	Level 3
Assets:				
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	$483,824	$126,847	$270,782	$86,195

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, 2018.

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, 2018:

(In thousands)	Fair Value
Balance, January 1, 2018	$ 86,195
Purchase of corporate debt security	492
Change in the fair value of contingent consideration	(19,600)
Increase in the fair value of warrants	(190)
Balance, December 31, 2018	$ 66,897

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

7. FAIR VALUE (Continued)

Company validated the prices developed using the market-observable data by obtaining market values from other pricing sources, analyzing pricing data in certain instances and confirming that the relevant markets are active.

On December 20, 2018, the Company entered into a Second Amendment to the Purchase and Sale Agreement ("Purchase and Sale Agreement Amendment") dated March 7, 2015 with Recro and Recro Gainesville LLC and a Second Amendment to the Asset Transfer and License Agreement dated April 10, 2015 with Recro Gainesville LLC (the "License Agreement Amendment" and, together with the Purchase and Sale Agreement Amendment, the "Amendments").

Under the terms of the Amendments, the milestone payment of $45.0 million previously due to the Company upon approval of an NDA for IV/IM and parenteral forms of Meloxicam or any other product with the same active ingredient as Meloxicam IV/IM that is discovered or identified using certain of the Company's IP to which Recro was provided a right of use, through license or transfer (the "Meloxicam Product(s)") was amended and replaced with (i) a $5.0 million payment due within 30 days of signing of the Amendments; (ii) a $5.0 million payment due by April 23, 2019; (iii) a $5.0 million payment due within 180 days following approval of an NDA for injectable Meloxicam; and (iv) an additional $45.0 million following approval of an NDA for Meloxicam Product(s), payable in seven equal annual payments of approximately $6.4 million beginning on the first anniversary of such approval.

At December 31, 2018, the Company determined the value of the contingent consideration receivable using the following valuation approaches:

- Based upon the terms of the Amendments, the fair value of the regulatory milestone was estimated based on the likelihood of achieving this regulatory milestone and applying a discount rate from the expected time the milestone occurs to the balance sheet date. The Company received the first $5.0 million milestone payment in January 2019 and expects to receive the second $5.0 million in April 2019. Additionally, the Company expects the regulatory milestone event to occur in the first quarter of 2019 and to receive milestone payments on the subsequent seven anniversary years thereafter. A discount rate of 15.8% was utilized in this analysis;
- The Company is entitled to receive future royalties on net sales of Meloxicam Products. To estimate the fair value of the future royalties, the Company assessed the likelihood of a Meloxicam Product being approved for sale and estimated the expected future sales of such Meloxicam Product assuming approval and IP protection. The Company then discounted these expected payments using a discount rate of 16.0%, which it believes captures a market participant's view of the risk associated with the expected payments; and
- The Company is entitled to receive payments of up to $80.0 million upon achieving certain sales milestones on future sales of the Meloxicam Products. The fair value of the sales milestones were determined through the use of a real options approach, where net sales are simulated in a risk-neutral world. To employ this methodology, the Company used a risk-adjusted expected growth rate based on its assessments of expected growth in net sales of the approved 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 was 15.8%.

At December 31, 2018 and 2017, the Company determined that the value of the contingent consideration was $65.2 million and $84.8 million, respectively. The Company recorded a decrease of $19.6 million and an increase of $21.6 million during the years ended December 31, 2018 and 2017, respectively, within "Change in the fair value of contingent consideration" in the accompanying consolidated statements of profit and loss.

7. FAIR VALUE (Continued)

In addition to the signing of the Amendments, as described above, on December 20, 2018, the Company and Recro entered into a First Amendment to the Warrant to Purchase Stock (the "Warrant Amendment"), pursuant to which the exercise price of the warrant to purchase 350,000 shares of Recro's common stock, was decreased to a per share exercise price of $8.26 from $19.46, subject to adjustment as set forth therein. The Company used a Black-Scholes model with the following assumptions to determine the fair value of these warrants at December 31, 2018:

	Year Ended December 31, 2018
Closing stock price at December 31, 2018	$7.10
Warrant strike price	$8.26
Expected term (years)	3.27
Risk-free interest rate	2.46%
Volatility	75.0%

The decrease of $0.2 million and the increase in the fair value of the warrants of less than $0.1 during the years ended December 31, 2018 and 2017, respectively, was recorded within "Other (expense) income, net" in the accompanying consolidated profit and loss account.

The estimated fair value of the 2023 Term Loans, 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 $274.7 million and $285.7 million at December 31, 2018 and 2017, respectively.

8. PROVISION FOR INCOME TAXES

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

	Year Ended	
(In thousands)	December 31, 2018	December 31, 2017
Current income tax benefit (provision):		
U.S. federal	$ 53	$ (6,964)
U.S. state	(1,774)	(350)
Rest of world	—	(123)
Deferred income tax (provision) benefit:		
U.S. federal	(10,624)	(8,188)
Ireland	(62)	933
U.S. state	63	21
Provision for income taxes	$(12,344)	$(14,671)

The income tax provision in 2018 and 2017 was primarily due to U.S. federal and state taxes. The favorable change in income taxes in 2018, as compared to 2017, was due to the one-off nature of a $21.5 million tax expense in 2017 from the enactment of the Tax Cuts and Jobs Act (The "Act" or "Tax Reform"), partially offset by increased taxes on income earned in the U.S.

No provision for income tax has been provided on undistributed earnings of the Company's foreign subsidiaries because such earnings are indefinitely reinvested in the foreign operations or may be repatriated to

8. PROVISION FOR INCOME TAXES (Continued)

Ireland without incurring any tax liability. Cumulative unremitted earnings of overseas subsidiaries totaled approximately $327.1 million at December 31, 2018. In the event of a repatriation of those earnings in the form of dividends or otherwise, the Company may be liable for income taxes, subject to adjustment, if any, for foreign tax credits and foreign withholding taxes payable to foreign tax authorities. The Company estimates that approximately $8.3 million of income taxes would be payable on the repatriation of the unremitted earnings to Ireland.

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

	Year Ended	
(In thousands)	**December 31, 2018**	**December 31, 2017**
Ireland	$(180,195)	$(172,363)
U.S.	53,287	2,414
Rest of world	(59)	26,675
Loss before provision for income taxes	$(126,967)	$(143,274)

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

(In thousands)	**December 31, 2018**	**December 31, 2017**
Deferred tax assets:		
Irish NOL carryforwards	$ 198,633	$ 177,435
Tax credits	52,395	71,366
Share-based compensation	44,873	40,048
Other	24,561	13,239
Less: valuation allowance	(219,093)	(172,797)
Total deferred tax assets	101,369	129,291
Deferred tax liabilities:		
Intangible assets	—	(18,184)
Property, plant and equipment	(14,533)	(12,040)
Other	(1,274)	(818)
Total deferred tax liabilities	(15,807)	(31,042)
Net deferred tax assets	$ 85,562	$ 98,249

As of December 31, 2017, a deferred tax asset of $13.3 million was recorded as a provisional amount in respect of performance-based compensation provided to covered employees prior to November 2, 2017. The Company has since completed its review of the Act and has determined that the performance-based compensation was provided pursuant to binding arrangements and should be deductible. The Company concluded that it had met the requirements for recognition of the tax benefit, and no longer considers this item a provisional amount in the financial statements under Staff Accounting Bulletin 118 ("SAB 118").

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

8. PROVISION FOR INCOME TAXES (Continued)

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:

(In thousands)	Balance at Beginning of Year	Additions(1)	Balance at End of Year
Deferred tax asset valuation allowance for the year ended December 31, 2017	$(141,859)	$(30,938)	$(172,797)
Deferred tax asset valuation allowance for the year ended December 31, 2018	$(172,797)	$(46,296)	$(219,093)

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

At December 31, 2018, the Company maintained a valuation allowance of $11.7 million against certain U.S. state deferred tax assets and $207.4 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.

As of December 31, 2018, the Company had $1.4 billion of Irish NOL carryforwards, $2.5 million of state NOL carryforwards, $44.8 million of federal R&D credits, $2.0 million of alternative minimum tax ("AMT") credits and $14.8 million of state tax credits which will either expire on various dates through 2038 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 AMT 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)	December 31, 2018	December 31, 2017
Prepaid expenses and other current assets	$—	$188
Other assets—long-term	—	686
Total deferred charges	$—	$874

The Company adopted 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 recorded a $17.8 million deferred tax asset to take account of certain basis differences on intangible assets, with a corresponding adjustment to valuation allowance.

8. PROVISION FOR INCOME TAXES (Continued)

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

(In thousands, except percentage amounts)	Year Ended December 31, 2018	Year Ended December 31, 2017
Statutory tax rate	12.5%	12.5%
Income tax provision, at statutory rate	$ 15,871	$ 17,909
Change in valuation allowance	(28,371)	(26,771)
Federal tax law change[1]	—	(21,453)
Impairment on equity method investment	—	(1,662)
Foreign rate differential[2]	(5,405)	682
Share-based compensation	(1,163)	1,205
U.S. state income taxes, net of U.S. federal benefit	(1,732)	558
Intercompany amounts[3]	751	5,041
Irish rate differential[4]	2,350	2,675
R&D credit	7,698	9,326
Other permanent items[5]	(2,343)	2,181
Income tax (provision) benefit	$(12,344)	$(14,671)
Effective tax rate	(9.7)%	(10.2)%

(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.

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

(In thousands)	Unrecognized Tax Benefits
Balance, January 1, 2017	$4,688
Reductions based on tax positions related to prior periods	(47)
Additions based on tax positions related to the current period	877
Balance, December 31, 2017	$5,518
Additions based on tax positions related to prior periods	4
Additions based on tax positions related to the current period	559
Balance, December 31, 2018	$6,081

8. PROVISION FOR INCOME TAXES (Continued)

The unrecognized tax benefits at December 31, 2018, 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, 2018, 2017 and 2016, 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 2015 through 2018 fiscal years remain subject to examination by the respective tax authorities. In Ireland, the years 2014 to 2018 remain subject to examination by the Irish tax authorities. Additionally, because of the Company's Irish and U.S. loss carryforwards and credit carryforwards, certain tax returns from fiscal years 1999 onward may also be examined. These years generally remain open for three to four years after the loss carryforwards and credit carryforwards have been utilized.

The years ended December 31, 2015 and 2014 for Alkermes U.S. Holdings, Inc. are currently under examination by the State of Illinois.

9. 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, 2018 and 2017, 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. 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:

	Year Ended December 31,	
(In thousands)	**2018**	**2017**
Stock options	11,331	9,540
Restricted stock units	2,592	2,119
Total	13,923	11,659

10. 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)		
Cost:					
At January 1, 2017	$158,784	$ 251,437	$ 19,241	$ 41,254	$ 470,716
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	$161,491	$ 289,455	$ 19,578	$ 54,270	$ 524,794
Additions at cost	2,091	25,017	567	36,451	64,126
Transfers	(7)	1,745	—	(1,738)	—
Disposals	(36)	(1,386)	(40)	—	(1,462)
At December 31, 2018	$163,539	$ 314,831	$ 20,105	$ 88,983	$ 587,458
Accumulated Depreciation:					
At January 1, 2017	$ (53,899)	$(142,705)	$ (9,327)	$ —	$(205,931)
Charged during the year	(5,474)	(28,563)	(2,427)	—	(36,464)
Disposals	—	2,337	—	—	2,337
At December 31, 2017	$ (59,373)	$(168,931)	$(11,754)	$ —	$(240,058)
Charged during the year	(5,537)	(30,388)	(2,567)	—	(38,492)
Disposals	36	1,012	31	—	1,079
At December 31, 2018	(64,874)	(198,307)	(14,290)	—	(277,471)
Net Book Amount:					
At December 31, 2018	$ 98,665	$ 116,524	$ 5,815	$ 88,893	$ 309,987
At December 31, 2017	$102,118	$ 120,524	$ 7,824	$ 54,270	$ 284,736

Depreciation expense was $38.5 million and $36.5 million for the years ended December 31, 2018 and 2017, respectively. Also, during the years ended December 31, 2018 and 2017, the Company wrote off furniture, fixtures and equipment that had a carrying value of $0.5 million and $0.1 million, respectively, at the time of disposition.

Amounts included as construction in progress in the consolidated balance sheets primarily include capital expenditures at the Company's manufacturing facility in Wilmington, Ohio. The Company 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.

In 2016, the Company began an expansion of its Wilmington, Ohio manufacturing facility to meet forecasted manufacturing demand for VIVITROL. The original expansion project included constructing a separate facility adjacent to the existing Wilmington, Ohio facility. In December 2018, the Company determined that it could expand its existing facility rather than build a separate facility and wrote-off to SG&A expense $5.7 million of design and other miscellaneous costs that had been capitalized but it was determined had no future value.

11. STOCK

Stock consists of the following:

(In thousands)	December 31, 2018	December 31, 2017
Raw materials	$31,824	$29,883
Work in process	38,019	38,964
Finished goods[(1)]	20,353	24,428
Total stock	$90,196	$93,275

(1) At December 31, 2018 and 2017, the Company had $11.0 million and $8.7 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, 2018 and 2017, the Company had a provision for stock obsolescence of $0.7 million and $2.8 million, respectively.

12. DEBTORS

	December 31, 2018	December 31, 2017
	(In thousands)	
Amounts falling due within one year		
Trade receivables	$292,223	$233,590
Contract assets	8,230	—
Prepaid expenses and other current assets	53,308	48,475
	$353,761	$282,065
Amounts falling due after more than one year		
Contingent consideration	$ 65,200	$ 84,800
Deferred income taxes	85,807	98,560
Other debtors	10,675	10,665
Total	$515,443	$476,090

Included in accounts receivable at December 31, 2018 and 2017, are unbilled receivables of $4.7 million and $5.3 million, respectively. The Company's allowance for doubtful accounts was $0.2 million at December 31, 2018 and 2017.

Contract assets include unbilled amounts resulting from sales under certain of the Company's manufacturing contracts where revenue is recognized over time. The products included in the contract assets table below complete the manufacturing process in ten days to eight weeks. Contract assets are classified as current.

Contract assets consisted of the following:

(In thousands)	Contract Assets
Balance, January 1, 2018	$ 9,110
Additions	57,617
Transferred to trade receivables, net	(58,497)
Balance, December 31, 2018	$ 8,230

13. INVESTMENTS

Investments consist of the following:

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
	(In thousands)			
December 31, 2018				
Short-term investments:				
Available-for-sale securities:				
Corporate debt securities	$120,197	$ 57	$ (336)	$119,918
U.S. government and agency debt securities	80,055	115	(98)	80,072
International government agency debt securities	72,091	85	(125)	72,051
	272,343	257	(559)	272,041
Held-to-maturity securities:				
Corporate debt securities	492	—	—	492
Total short-term investments	272,835	257	(559)	272,533
Long-term investments:				
Available-for-sale securities:				
Corporate debt securities	53,505	—	(278)	53,227
U.S. government and agency debt securities	18,474	—	(33)	18,441
International government agency debt securities	5,457	—	(4)	5,453
	77,436	—	(315)	77,121
Held-to-maturity securities:				
Fixed term deposit account	1,820	—	—	1,820
Certificates of deposit	1,667	136	—	1,803
	3,487	136	—	3,623
Total long-term investments	80,923	136	(315)	80,744
Total investments	$353,758	$393	$ (874)	$353,277
December 31, 2017				
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	242,703	5	(500)	242,208
Long-term investments:				
Available-for-sale securities:				
U.S. government and agency debt securities	48,948	—	(341)	48,607
Corporate debt securities	83,924	—	(334)	83,590
International government agency debt securities	21,453	—	(118)	21,335
	154,325	—	(793)	153,532
Held-to-maturity securities:				
Fixed term deposit account	1,667	222	—	1,889
Certificates of deposit	1,791	—	—	1,791
	3,458	222	—	3,680
Total long-term investments	157,783	222	(793)	157,212
Total investments	$400,486	$227	$(1,293)	$399,420

13. 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, 2018	2017
Proceeds from the sales and maturities of marketable securities	$444,456	$464,494
Realized gains	$ 4	$ 9
Realized losses	$ 268	$ 3

The Company's available-for-sale and held-to-maturity securities at December 31, 2018 had contractual maturities in the following periods:

	Available-for-sale		Held-to-maturity	
(In thousands)	Amortized Cost	Estimated Fair Value	Amortized Cost	Estimated Fair Value
Within 1 year	$184,841	$184,304	$2,312	$2,312
After 1 year through 5 years	164,938	164,858	1,667	1,803
Total	$349,779	$349,162	$3,979	$4,115

At December 31, 2018, 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 agency 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.

14. SHARE CAPITAL PRESENTED AS EQUITY

Share Capital

(In thousands, except per share amounts)	December 31, 2018	2017
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 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

14. SHARE CAPITAL PRESENTED AS EQUITY (Continued)

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

Issued Ordinary Shares (par value, $0.01 per share) (Value in thousands)	**Number**	**Value**
Balance at January 1, 2017	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
Issuance of ordinary shares under employee stock plans	2,123,201	22
Balance at December 31, 2018	158,180,833	$1,579

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, 2018, 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, 2018 and 2017, the Company did not acquire any ordinary shares under the repurchase program.

14. SHARE CAPITAL PRESENTED AS EQUITY (Continued)

Treasury Shares

Treasury Shares (par value, $0.01 per share) (Value in thousands)	**Number**	**Value**
Balance at January 1, 2017	1,760,767	$ 72,639
Acquired during the year	287,409	16,708
Balance at December 31, 2017	2,048,176	$ 89,347
Acquired during the year	375,313	19,622
Balance at December 31, 2018	2,423,489	$108,969

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.

15. SHARE-BASED COMPENSATION

Share-based Compensation Expense

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

	Year Ended	
(In thousands)	**December 31, 2018**	**December 31, 2017**
Cost of goods manufactured and sold	$ 9,174	$ 7,596
Research and development	32,943	22,635
Selling, general and administrative	63,240	53,686
Total share-based compensation expense	$105,357	$83,917

During the years ended December 31, 2018 and 2017, $2.7 million and $0.4 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 one compensation plan pursuant to which awards are currently being made: the 2011 Stock Option and Incentive Plan (the "2011 Plan"). The Company has one compensation plan pursuant to which awards are eligible to be made, but from which no awards have been made to date: the 2018 Stock Option and Incentive Plan (the "2018 Plan"). The Company has one share-based compensation plan pursuant to which outstanding awards have been made, but from which no further awards can or will be made: the 2008 Stock Option and Incentive Plan (the "2008 Plan"). The 2018 Plan and the 2011 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 2018 Plan and the 2011 Plan.

At December 31, 2018, there were 11.1 million ordinary shares authorized for issuance under the Company's stock plans. The 2018 Plan and the 2011 Plan provide that awards other than stock options will be

15. SHARE-BASED COMPENSATION (Continued)

counted against the total number of shares available under the plan in a 1.8-to-1 ratio and the 2008 Plan provides that awards other than stock options will be counted against the total number of shares available under the plan in a 2-to-1 ratio.

Stock Options

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

	Number of Shares	Weighted Average Exercise Price
Outstanding, January 1, 2018	14,773,412	$36.64
Granted	2,269,830	$61.45
Exercised	(1,087,815)	$19.19
Forfeited	(924,343)	$51.88
Expired	(178,627)	$59.83
Outstanding, December 31, 2018	14,852,457	$40.48
Exercisable, December 31, 2018	10,506,897	$34.26

The weighted average grant date fair value of stock options granted during the years ended December 31, 2018 and 2017 was $30.47 and $25.81, respectively. The aggregate intrinsic value of stock options exercised during the years ended December 31, 2018 and 2017 was $35.5 million and $40.4 million, respectively.

At December 31, 2018, there were 4.2 million stock options expected to vest with a weighted average exercise price of $55.46 per share, a weighted average contractual remaining life of 8.3 years with no aggregate intrinsic value. At December 31, 2018, the aggregate intrinsic value of stock options exercisable was $64.8 million with a weighted average remaining contractual term of 4.5 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, 2018, there was $51.4 million of unrecognized compensation cost related to unvested stock options, which is expected to be recognized over a weighted average period of 2.0 years. Cash received from option exercises under the Company's award plans during the years ended December 31, 2018 and 2017 was $20.9 million and $23.5 million, respectively.

Time-Vested Restricted Stock Units

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

	Number of Shares	Weighted Average Grant Date Fair Value
Unvested, January 1, 2018	1,936,808	$46.72
Granted	1,367,710	$63.01
Vested	(723,473)	$47.72
Forfeited	(314,759)	$53.09
Unvested, December 31, 2018	2,266,286	$55.32

15. SHARE-BASED COMPENSATION (Continued)

The weighted average grant date fair value of time-vested RSUs granted during the years ended December 31, 2018 and 2017 were $63.01 and $54.85, respectively. The total fair value of time-vested RSUs that vested during the years ended December 31, 2018 and 2017, was $34.5 million and $31.5 million, respectively.

At December 31, 2018, there was $57.5 million of total unrecognized compensation cost related to unvested time-vested RSUs, which will be recognized over a weighted average remaining contractual term of 2.0 years.

Performance-Based Restricted Stock Units

In February 2017, the compensation committee of the Company's board of directors approved awards of RSUs to all employees employed by the Company during 2017, in each case subject to vesting on the achievement of the following performance criteria: (i) FDA approval of the NDA for ALKS 5461, (ii) the achievement of the pre-specified primary efficacy endpoints in each of two phase 3 studies of ALKS 3831, and (iii) revenues equal to or greater than a pre-specified amount for the year ending December 31, 2019. These performance criteria are being assessed over a performance period of three years from the date of the grant.

In December 2018, the Company achieved the pre-specified primary efficacy endpoints on its second of the two phase 3 studies of ALKS 3831, resulting in the vesting of a portion of the granted performance-based RSUs and the recognition of $17.1 million in share-based compensation expense related to these awards. The Company recognized $2.1 million, $6.7 million and $8.3 million of this expense in cost of goods manufactured and sold; R&D expense; and SG&A expense, respectively.

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

	Number of Shares	Weighted Average Grant Date Fair Value
Unvested, January 1, 2018	1,108,653	$54.72
Granted	6,065	$55.89
Vested	(176,637)	$54.64
Forfeited	(311,913)	$54.74
Unvested, December 31, 2018	626,168	$54.75

The grant date fair value of the performance-based RSUs was equal to the market value of the Company's stock on the date of grant. At December 31, 2018, the Company does not consider it probable that the performance criteria will be met on the remaining two performance obligations and has not recognized any additional share-based compensation expense related to these performance-based RSUs. At December 31, 2018, there was $34.3 million of unrecognized compensation cost related to the remaining unvested portion of the performance-based RSUs, 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. The unvested awards will expire if the performance conditions have not been met on or before the three-year anniversary of the grant date.

16. PROVISIONS FOR LIABILITIES

Provisions for liabilities consists of the following:

	Medicaid Rebates	Product Returns	Other	Total
	(In thousands)			
Balance, January 1, 2017	$ 43,772	$13,542	$ 2,447	$ 59,761
Additions	147,755	6,676	32,540	186,971
Amounts utilized	(101,726)	(1,450)	(26,478)	(129,654)
Balance, December 31, 2017	$ 89,801	$18,768	$ 8,509	$ 117,078
Additions	197,002	6,615	53,855	257,472
Amounts utilized	(163,374)	(3,483)	(43,803)	(210,660)
Balance, December 31, 2018	$ 123,429	$21,900	$ 18,561	$ 163,890

17. CREDITORS

	December 31, 2018	December 31, 2017
	(In thousands)	
Amounts falling due within one year		
Accrued expenses	$144,313	$124,388
Trade creditors	39,767	55,526
Contract liabilities	3,169	1,956
Payroll taxes	2,684	2,413
Accrued interest on long-term debt	822	844
Value added tax	876	999
Corporate tax	911	21
Other taxes	91	147
	$192,633	$186,294
Amounts falling due after more than one year		
Deferred income taxes	$ 245	$ 308
Contract liabilities	9,525	5,657
Other long-term liabilities	8,121	3,646
Total	$210,524	$195,905

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.

Contract liabilities, which consist of contractual obligations related to deferred revenue, consisted of the following:

(In thousands)	Contract Liabilities
Balance, January 1, 2018	$ 9,442
Additions	6,381
Amounts recognized into turnover	(3,129)
Balance, December 31, 2018	$12,694

18. COMMITMENTS AND CONTINGENT LIABILITIES

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 December 31, 2018, the total future annual minimum lease payments under the Company's non-cancelable operating leases are as follows:

(In thousands)	Payment Amount
Years Ending December 31,:	
2019	$ 9,394
2020	10,717
2021	4,706
2022	2,455
2023	2,389
Thereafter	23,940
Total future minimum lease payments	$53,601

Rent expense related to operating leases charged to operations was $10.8 million and $9.4 million for the years ended December 31, 2018 and 2017, respectively. In addition to its lease commitments, the Company had open purchase orders totaling $530.3 million at December 31, 2018.

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, 2018, there were no potential material losses from claims, asserted or unasserted, or legal proceedings that the Company determined were probable of occurring.

INVEGA SUSTENNA ANDA Litigation

In January 2018, Janssen Pharmaceuticals NV and Janssen Pharmaceuticals, Inc. initiated a patent infringement lawsuit in the U.S. District Court for the District of New Jersey against Teva Pharmaceuticals USA, Inc. ("Teva"), who filed an abbreviated new drug application ("ANDA") seeking approval to market a generic version of INVEGA SUSTENNA before the expiration of U.S. 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 the Principal Risks section of 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."

18. COMMITMENTS AND CONTINGENT LIABILITIES (Continued)

AMPYRA ANDA Litigation

Eleven 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”); MicroLabs Limited (“MicroLabs”); 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 (collectively with Accord, Actavis, Alkem, Apotex, Aurobindo, MicroLabs, Mylan, Par, Roxane and Sun, the “ANDA Filers”) advising that each of the ANDA Filers had submitted an 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 one or more 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 asserting infringement of one or more of the Orange Book-listed patents for AMPYRA. Requested judicial remedies included recovery of litigation costs and injunctive relief.

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 first 30-month stay 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, MicroLabs, Par and Sun to resolve the patent litigation that the Company and/or Acorda brought against these settling ANDA Filers. The settlements with these settling ANDA Filers did not impact the patent litigation that the Company and Acorda brought against the remaining ANDA Filers, including as described below.

In March 2017, after a bench trial, the U.S. District Court for the District of Delaware (the “Delaware Court”) issued an opinion (the “Delaware Court Decision”), which, among other things, invalidated U.S. Patent Nos. 8,007,826; 8,354,437; 8,440,703; and 8,663,685. The Delaware Court also upheld the validity of the U.S. Patent No. 5,540,938, which pertains to the formulation of AMPYRA, but that patent expired on July 30, 2018. In May 2017, Acorda filed an appeal with the Federal Circuit of the Delaware Court Decision with respect to the findings on U.S. Patent Nos. 8,007,826; 8,354,437; 8,440,703; and 8,663,685. On July 27, 2018, Acorda and the Company entered into a settlement agreement with Mylan, pursuant to which, among other things, Mylan was permitted to market an authorized generic version of AMPYRA in the U.S. in the event of an affirmance by the Federal Circuit of the Delaware Court Decision. On September 10, 2018, the Federal Circuit affirmed the Delaware Court Decision, which invalidated U.S. Patent Nos. 8,007,826; 8,354,437; 8,440,703; and 8,663,685. On October 24, 2018, Acorda filed a petition for rehearing and rehearing en banc of the Federal Circuit’s decision. On January 4, 2019, the Federal Circuit denied Acorda’s petition. Acorda has until April 4, 2019 to file a petition for writ of certiorari to the Supreme Court of the United States.

For information about risks relating to the AMPYRA Paragraph IV litigations and other proceedings see the Principal Risks section of 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.”

18. COMMITMENTS AND CONTINGENT LIABILITIES (Continued)

VIVITROL IPR Proceeding

On April 20, 2018, Amneal Pharmaceuticals LLC filed a petition with the Patent Trial and Appeal Board (the "PTAB") of the U.S. Patent and Trademark Office seeking an inter partes review ("IPR") of U.S. Patent Number 7,919,499 (the "'499 Patent"), which is an Orange Book-listed patent for VIVITROL, challenging the validity of the '499 Patent. On November 7, 2018, the PTAB issued an order instituting an IPR of claims 1-13 of the '499 Patent. On February 7, 2019, the Company filed its patent owner's response. Amneal's reply is due on May 7, 2019. A decision on the matter is expected by November 7, 2019. The Company will vigorously defend the '499 Patent in the IPR proceedings. For information about risks relating to the '499 Patent IPR proceedings see the Principal Risks section in this Directors' Report and specifically the sections entitled "—Patent protection for our products is important and uncertain" and "—Uncertainty over intellectual property in the biopharmaceutical industry has been the source of litigation, which is inherently costly and unpredictable, could significantly delay or prevent approval or commercialization of our products, and could adversely affect our business."

RISPERDAL CONSTA European Opposition Proceedings

In December 2016, Nanjing Luye Pharmaceutical Co Ltd, Pharmathen SA, Teva Pharmaceutical Industries Ltd and Dehns Ltd (a law firm representing an unidentified opponent) filed notices of opposition with the European Patent Office (the "EPO") in respect of EP 2 269 577 B (the "EP '577" Patent), which is a patent directed to certain risperidone microsphere compositions, including RISPERDAL CONSTA. Following a hearing on the matter on January 23, 2019, the Opposition Division (the "OD") of the EPO verbally advised the parties of its interlocutory decision to revoke the EP '577 Patent. The Company expects a written decision to be issued within a few months of the hearing date, following which the Company will have two months to appeal the decision to the EPO's Technical Boards of Appeal. The Company will vigorously defend the EP '577 Patent in the opposition proceedings. For information about risks relating to the EP '577 Patent opposition proceedings see "Part I, Item 1A—Risk Factors" in this Annual Report and specifically the sections entitled "— Patent protection for our products is important and uncertain" and "— Uncertainty over intellectual property in the biopharmaceutical industry has been the source of litigation, which is inherently costly and unpredictable, could significantly delay or prevent approval or commercialization of our products, and could adversely affect our business."

Government Matters

On June 22, 2017 and January 17, 2019, the Company received a subpoena and a civil investigative demand, respectively, each 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 (collectively, the "Defendants") 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. This complaint has been amended twice since its initial filing. The second amended complaint was filed on behalf of a putative class of purchasers of Alkermes securities during the period of February 24, 2015 through November 14, 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

18. COMMITMENTS AND CONTINGENT LIABILITIES (Continued)

securities, and reasonable costs and expenses, including attorneys' fees. On June 29, 2018, Defendants filed a motion to dismiss the second amended complaint. Oral arguments on this motion were heard on October 23, 2018. For information about risks relating to this action, see the Principal Risks section 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."

On December 27, 2018, 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 Eastern District of New York captioned *Karimian v. Alkermes plc, et al.*, No. 1:18-cv-07410. On January 31, 2019, a purported stockholder of the Company filed a similar putative class action against the Company and the same officers in the United States District Court for the Eastern District of New York captioned *McDermott v. Alkermes plc, et al.*, No. 1:19-cv-00624. The complaints were filed on behalf of putative classes of purchasers of Alkermes securities during the period of February 17, 2017 through November 1, 2018 and allege 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 regulatory submission for ALKS 5461 and the FDA's review and consideration of that submission. The lawsuits seek, among other things, unspecified money damages, prejudgment and postjudgment interest, reasonable attorneys' fees, expert fees and other costs. For information about risks relating to these actions, see the Principal Risks section 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."

19. CAPITAL EXPENDITURE COMMITMENTS

The directors have authorized the Company to spend $95.0 million for capital expenditures in the year ending December 31, 2019.

20. RELATED PARTY DISCLOSURES

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

Subsidiaries and Associates

The consolidated financial statements include the results of operations, financial positions and cash flows of the Company and its subsidiaries and associates over which the Company has control. A listing of principal subsidiaries and associates is provided in Note 25, *Subsidiaries,* 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 23, *Directors' Remuneration*.

21. 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.

22. EMPLOYEES

The average number of persons employed by the Company during the years ended December 31, 2018 and 2017, respectively, was as follows:

	December 31, 2018	December 31, 2017
Manufacturing	781	707
Research and development	497	438
Selling, general and administrative	862	719
Total	2,140	1,864

Employee costs included in profit and loss during the years ended December 31, 2018 and 2017 consisted of the following:

	December 31, 2018	December 31, 2017
	(In thousands)	
Wages and salaries	$334,725	$279,779
Share-based compensation	105,357	83,916
Social insurance costs[1]	53,460	44,080
Defined contribution plan contributions	17,298	14,440
Total	$510,840	$422,215

(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, 2018 and 2017, the Company capitalized $0.1 million and $0.5 million, respectively, as part of its tangible fixed assets and $59.1 million and $47.6 million, respectively, as part of its stock.

23. 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").

	December 31, 2018	December 31, 2017
	(In thousands)	
Managerial Services:		
Emoluments	$2,155	$2,078
Benefits under long term incentive schemes	3,891	3,161
Company contribution to 401(k) plan	14	14
Total	$6,060	$5,253
Director Services:		
Fees paid in cash	$ 713	$ 658
Total	$ 713	$ 658

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, 2018 was $11.5 million (December 31, 2017: $8.3 million). The Company considers its directors to be key management personnel.

24. AUDITORS' REMUNERATION

Total auditors' remuneration, including expenses, accrued and paid to PricewaterhouseCoopers and its affiliated firms for the years ended December 31, 2018 and 2017, respectively, were as follows:

	December 31, 2018	December 31, 2017
	(In thousands)	
Audit and review of group financial statements(1)	$2,072	$1,860
Audit-related fees(2)	—	263
Tax fees(3)	631	517
All other fees(4)	3	2
Total	$2,706	$2,642

(1) Consists of fees for services related to the audit of the Company's annual consolidated financial statements, statutory audits and the review of the Company's quarterly consolidated financial statements, including the review of the Company's internal controls over financial reporting, and other engagements related to the fiscal year. Included in the years ended December 31, 2018 and 2017 are expenses of $92 thousand and $85 thousand, respectively.

(2) Consists of fees for general advisory services.

(3) Consists of fees for tax advisory services, other than those related to the audit of our annual consolidated financial statements and review of our quarterly consolidated financial statements.

(4) Consists of fees for access to the PricewaterhouseCoopers on-line accounting research database.

24. AUDITORS' REMUNERATION (Continued)

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, 2018 and 2017, respectively. In addition, PricewaterhouseCoopers Ireland received $0.1 million for tax advisory services during both the years ended December 31, 2018 and 2017.

25. SUBSIDIARIES

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

Name	Nature of Business	Registered Office and Country of Incorporation	Percent of Ownership
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%

26. SUBSEQUENT EVENTS

In March 2019, Recro received a second complete response letter ("CRL") from the FDA regarding their NDA seeking approval for Meloxicam. Recro intends to continue to pursue regulatory approval for Meloxicam and will request a meeting with the FDA and work closely with them to resolve the issues highlighted in the CRL.

ALKERMES PLC

COMPANY BALANCE SHEET

	Note	December 31, 2018	December 31, 2017
		(In thousands)	
ASSETS			
Fixed Assets			
Financial assets	7	$2,005,008	$1,987,201
Associated undertakings	8	5,463	3,369
Total fixed assets		2,010,471	1,990,570
Current Assets			
Debtors	9	795,478	695,361
Cash at bank and in-hand		49,110	38,971
TOTAL ASSETS		$2,855,059	$2,724,902
LIABILITIES			
Creditors			
Creditors	10	$ 46,331	$ 2,535
Total for creditors		46,331	2,535
Equity Shareholders' Funds			
Share capital, $0.01 par value	11	1,579	1,557
Share premium	12	566,670	545,803
Profit and loss account	12	1,825,243	1,847,862
Treasury shares	12	(108,969)	(89,347)
Other reserves	12	524,205	416,492
Total equity shareholders' funds		$2,808,728	$2,722,367
TOTAL EQUITY AND LIABILITIES		$2,855,059	$2,724,902

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

The consolidated financial statements were approved by the board of directors on April 3, 2019 and signed on its behalf by:

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

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

ALKERMES PLC

COMPANY RECONCILIATION OF MOVEMENT IN SHAREHOLDERS' FUNDS

	Share Capital	Share Premium	Profit and Loss Account	Treasury Shares	Other Reserves	Total
			(In thousands)			
BALANCE—January 1, 2017	$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
Net loss	—	—	(22,619)	—	—	(22,619)
Share-based payment reserve	—	—	—	—	107,713	107,713
Shares issued under employee stock plans	11	20,878	—	—	—	20,889
Receipt of Alkermes' shares for the purchase of share options or to satisfy minimum tax withholding obligations related to share based awards	11	(11)	—	(19,622)	—	(19,622)
BALANCE—December 31, 2018	$1,579	$566,670	$1,825,243	$(108,969)	$524,205	$2,808,728

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 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 convention.

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*.

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.

3. Summary of Significant Accounting Policies (Continued)

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.

Associated Undertakings

The Company accounts for its associated undertakings at cost, less impairment. Refer to Note 8, *Associated Undertakings*, for further discussion.

Dividend Income from Shares in Group Undertakings

Dividend income from group undertakings is recognized in the period in which it is received.

3. Summary of Significant Accounting Policies (Continued)

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, 2018, 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' 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

3. Summary of Significant Accounting Policies (Continued)

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 15, *Share-Based Compensation,* of the 2018 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.

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.

3. Summary of Significant Accounting Policies (Continued)

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, 2018 and 2017, determined in accordance with Irish GAAP, was $22.6 million and $29.2 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, turnover 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.

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 23, *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.

	(In thousands)
Balance—January 1, 2017, at cost	$1,986,070
Capital contribution in respect of share-based payment plans	80,659
Reduction—equity recharge from subsidiaries	(79,528)
Balance—December 31, 2017, at cost	$1,987,201
Capital contribution in respect of share-based payment plans	104,014
Reduction—equity recharge from subsidiaries	(86,207)
Balance—December 31, 2018, at cost	$2,005,008

7. Financial Assets (Continued)

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 25, *Subsidiaries,* in the consolidated financial statements for the list of direct subsidiaires.

8. Associated Undertakings

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, 2018, the Company's total contribution in Fountain was equal to €5.2 million, and its commitment represents approximately 7% of the partnership's total funding. The Company is accounting for its investment in Fountain under the cost method. At December 31, 2018 and 2017, the Company's investment is equal to, $5.5 million (€4.8 million), and $3.7 million (€2.8 million), respectively, which is included within "Associated undertakings" in the accompanying balance sheets.

9. Debtors

	December 31, 2018	December 31, 2017
	(In thousands)	
Amounts falling due within one year		
Trade receivables	$ —	$ 1,180
Prepaid expenses and other current assets	2,180	715
Intercompany notes and loans receivable	113,298	307,466
	$115,478	$309,361
Amounts falling due after one year		
Intercompany loans receivable	680,000	386,000
Total	$795,478	$695,361

9. Debtors (Continued)

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

Borrower	Maturity	Interest Rate	Balance at December 31, 2018	Balance at December 31, 2017
			(in thousands)	
Alkermes Science Six Limited	Repayable upon demand	None	$ 10,500	$ 10,500
Daravita Pharma Ireland Limited	Repayable upon demand	None	3,600	3,600
Alkermes Pharma Ireland Limited	January 1, 2018	3.25%	—	130,000
Alkermes Finance Ireland No.3 Limited	Repayable upon demand	Variable	—	163,266
Alkermes Finance Ireland No.3 Limited	Repayable upon demand	Variable	99,098	—
Alkermes Science Six Limited	Repayable upon demand	None	100	100
Total			$113,298	$307,466

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

Borrower	Maturity	Interest Rate	Balance at December 31, 2018	Balance at December 31, 2017
			(in thousands)	
Alkermes Pharma Ireland Limited	July 8, 2022	7.00%	$284,000	$160,000
Alkermes Pharma Ireland Limited	September 27, 2022	7.00%	396,000	226,000
Total			$680,000	$386,000

10. Creditors

	December 31, 2018	December 31, 2017
	(In thousands)	
Amounts falling due within one year		
Accrued expenses	$ 720	$ 745
Trade creditors	41	9
Intercompany payables	45,570	1,781
Total	$46,331	$2,535

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.

11. Share Capital

(In thousands, except per share amounts)	December 31, 2018	December 31, 2017
Authorized:		
40,000 ordinary shares of €1 par value	$ 40,000	$ 40,000
50,000,000 preferred shares of $0.01 par value	500,000	500,000
450,000,000 ordinary shares of $0.01 par value	4,500,000	4,500,000
Share Capital	$5,040,000	$5,040,000

Issued Ordinary Shares (par value, $0.01 per share) (Value in thousands)	Number	Value
Balance at January 1, 2017	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
Issuance of ordinary shares under employee stock plans	2,123,201	22
Balance at December 31, 2018	158,180,833	$1,579

See Note 14, *Called up Share Capital Presented as Equity,* to the Consolidated Financial Statements for additional information regarding equity shareholder's funds.

12. 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.

13. 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 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.

14. 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, 2018, there were no potential losses from claims, asserted or unasserted, or legal proceedings the Company felt were probable of occurring (at December 31, 2017: none).

15. 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, 2018	Year Ended December 31, 2017
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 24, *Auditors' Remuneration,* to the Consolidated Financial Statements for additional information regarding fees paid to PricewaterhouseCoopers and its affiliated firms by the Company.

16. Approval of the Financial Statements

The financial statements were approved and authorized for issue by the board of directors on April 3, 2019 and were signed on its behalf on that day.