Alkermes plc.
Form 10-K
February 15, 2019
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Form 10 K

(Mark One)

ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
for the fiscal year ended December 31, 2018

OR

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the transition period from to

Commission file number: 001 35299

ALKERMES PUBLIC LIMITED COMPANY

(Exact name of registrant as specified in its charter)

Ireland	98 1007018
(State or other jurisdiction of	(I.R.S. Employer
incorporation or organization)	Identification No.)
Connaught House	(Zip code)
1 Burlington Road	

Dublin 4, Ireland
(Address of principal executive offices)

+353 1 772 8000

(Registrant's telephone number, including area code)

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

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

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

Indicate by check mark if the registrant is a well known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes No

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Exchange Act. Yes No

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes No

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files): Yes No

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S K (§ 229.405 of this chapter) is not contained herein, and will not be contained, to the best of the registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10 K or any amendment to this Form 10 K.

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company" and "emerging growth company" in Rule 12b 2 of the Exchange Act. (Check one):

Large accelerated filer	Accelerated filer
Non-accelerated filer	Smaller reporting company
	Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the

Exchange Act.

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

The aggregate market value of the registrant's ordinary shares held by non affiliates of the registrant (without admitting that any person whose shares are not included in such calculation is an affiliate) computed by reference to the price at which the ordinary shares were last sold as of the last business day of the registrant's most recently completed second fiscal quarter was $6,322,607,110.

As of February 4, 2019, 156,039,212 ordinary shares were outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the definitive proxy statement for our 2019 Annual General Meeting of Shareholders are incorporated by reference into Part III of this report.

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ALKERMES PLC AND

SUBSIDIARIES

ANNUAL REPORT ON FORM 10 K

FOR THE YEAR ENDED DECEMBER 31, 2018

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CAUTIONARY NOTE CONCERNING FORWARD LOOKING STATEMENTS

This document contains and incorporates by reference "forward looking statements" within the meaning of Section 27A of the Securities Act of 1933, as amended (the "Securities Act"), and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). 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 other similar words. These statements discuss future expectations and contain projections of results of operations or of financial condition, or state trends and known uncertainties or other forward looking information. Forward looking statements in this Annual Report on Form 10 K ("Annual Report") include, without limitation, statements regarding:

- our expectations regarding our financial performance, including revenues, expenses, gross margins, liquidity, capital expenditures and income taxes;
- our expectations regarding our products, including 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 Annual Report.

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

This Annual 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 Annual 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 “Item 1A—Risk Factors” in this Annual Report. These and other factors could cause results to differ materially from those expressed in this Annual Report.

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NOTE REGARDING COMPANY AND PRODUCT REFERENCES

Use of the terms such as “us,” “we,” “our,” “Alkermes” or the “Company” in this Annual Report is meant to refer to Alkermes plc and its consolidated subsidiaries. Except as otherwise suggested by the context, (a) references to “products” or “our products” in this Annual Report include our marketed products, marketed products using our proprietary technologies, our product candidates, product candidates using our proprietary technologies, development products and development products using our proprietary technologies, (b) references to the “biopharmaceutical industry” in this Annual Report are intended to include reference to the “biotechnology industry” and/or the “pharmaceutical industry” and (c) references to “licensees” are used interchangeably with references to “partners.”

NOTE REGARDING TRADEMARKS

We are the owner of various United States (“U.S.”) federal trademark registrations (“®”) and other trademarks (“™”), including ALKERMES®, ARISTADA®, ARISTADA INITIO®, 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; BYDUREON®—Amylin Pharmaceuticals, LLC (“Amylin”); BYDUREON BCise™—AstraZeneca Pharmaceuticals LP;—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 Annual Report are the property of their respective owners. Solely for convenience, the trademarks and trade names in this Annual Report are referred to without the ® and ™ symbols, but such references should not be construed as any indicator that their respective owners will not assert, to the fullest extent under applicable law, their rights thereto.

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PART I

Item 1.Business

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

Overview

Alkermes plc is a fully integrated, global biopharmaceutical company that applies its scientific expertise and proprietary technologies to research, develop and commercialize, both with partners and on its own, pharmaceutical products that are designed to address unmet medical needs of patients in major therapeutic areas. 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.

Marketed Products

The key marketed products discussed below are expected to generate significant revenues for us. Refer to the “Patents and Proprietary Rights” section of this Annual Report for information with respect to the intellectual property protection for these marketed products.

Summary information regarding our proprietary products:

Product	Indication(s)	Licensee	Territory
	Initiation or re-initiation of ARISTADA for the treatment of Schizophrenia	None	Commercialized by Alkermes in the U.S.
	Schizophrenia	None	Commercialized by Alkermes in the U.S.
	Alcohol	None	Commercialized by

dependence and Opioid dependence		Alkermes in the U.S.
	Cilag GmbH International (“Cilag”)	Russia and Commonwealth of Independent States (“CIS”)

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Summary information regarding products that use our proprietary technologies:

Product	Indication(s)	Licensee	Territory
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 of the U.S. (“ROW”)

INVEGA TRINZA	Schizophrenia	Janssen	U.S.
TREVICTA	Schizophrenia	Janssen	ROW
AMPYRA FAMPYRA	Treatment to improve walking in patients with MS, as demonstrated by an increase in walking speed	Acorda Biogen, under sublicense from Acorda	U.S. ROW

Proprietary Products

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

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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 16, Commitments and Contingent Liabilities in the “Notes to Consolidated Financial Statements” and “Item 3—Legal Proceedings” in this Annual Report, and for information about risks relating to such legal 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,” “— 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.

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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 16, Commitments and Contingent Liabilities in the "Notes to Consolidated Financial Statements" and "Item 3—Legal Proceedings" in this Annual Report and for information about risks relating to such legal proceedings, see "Part I, Item 1A—Risk Factors" in this Annual 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 16, Commitments and Contingent Liabilities in the "Notes to Consolidated Financial Statements" and "Item 3—Legal Proceedings" in this Annual Report and for information about risks relating to such legal proceedings, see "Part I, Item 1A—Risk Factors" in this Annual 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%, 33% and 36% of our consolidated revenues for the years ended December 31, 2018, 2017 and 2016, respectively. See “Collaborative Arrangements” in Part I of this Annual Report for information about our relationship with Janssen.

What is bipolar I disorder?

Bipolar I disorder is a brain disorder that causes unusual shifts in a person’s mood, energy and ability to function. It is often characterized by debilitating mood swings, from extreme highs (mania) to extreme lows (depression). Bipolar I disorder is characterized based on the occurrence of at least one manic episode, with or without the occurrence of a major depressive episode 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.

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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 16, Commitments and Contingent Liabilities in the “Notes to Consolidated Financial Statements” and “Item 3—Legal Proceedings” in this Annual Report and for information about risks relating to such legal proceedings, see “Part I, Item 1A—Risk Factors” in this Annual 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 “Part I, Item 1A—Risk Factors” of this Annual Report. Refer to the “Patents and Proprietary Rights” section in “Part I, Item 1— Business” of this Annual Report for information with respect to the intellectual property protection for our development candidates.

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. For more information about 505(b)(2) NDAs, see “Part 1, Item 1—Business, Regulatory, Hatch-Waxman Act” of this Annual Report. 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 “Part 1, Item 1—Business, Collaborative Arrangements” of this Annual Report.

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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.

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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 in this "Part I, Item 1—Business" of this Annual 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.

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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.

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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.

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.

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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."

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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.

For more information about our manufacturing facilities, see “Item 2—Properties.”

Clinical Products

We have established, and are operating, facilities with the capability to produce clinical supplies of injectable extended release products as well as solid dosage and biologics products at our Wilmington, Ohio facility and NanoCrystal and OCR technology products at our Athlone, Ireland facility. We have also contracted with third party manufacturers to formulate certain products for clinical use. We require that our contract manufacturers adhere to cGMP in the manufacture of products for clinical use.

Research & Development

We devote significant resources to R&D programs. We focus our R&D efforts on developing novel therapeutics in areas of high unmet medical need. Our R&D efforts include, but are not limited to, areas such as pharmaceutical formulation, analytical chemistry, process development, engineering, scale up and drug optimization/delivery. Please see “Management’s Discussion and Analysis of Financial Condition and Results of Operations” for our R&D expenditures for our years ended December 31, 2018, 2017 and 2016.

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.

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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 gross 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 gross 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.

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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.

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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 16, Commitments and Contingent Liabilities in the “Notes to Consolidated Financial Statements” and “Item 3—Legal Proceedings” in this Annual 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 16, Commitments and Contingent Liabilities in the “Notes to Consolidated Financial Statements” and “Item 3—Legal Proceedings” in this Annual 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 16, Commitments and Contingent Liabilities in the “Notes to Consolidated Financial Statements” and “Item 3—Legal Proceedings” in this Annual 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(s) 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.

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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.

Regulatory

Regulation of Pharmaceutical Products

United States

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

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

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

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

- Phase 1 clinical trials—test for safety, dose tolerability, absorption, bio distribution, metabolism, excretion and clinical pharmacology and, if possible, to gain early evidence regarding efficacy.
- Phase 2 clinical trials—involve a relatively small sample of the actual intended patient population and seek to assess the efficacy of the drug for specific targeted indications, to determine dose response and the optimal dose range and to gather additional information relating to safety and potential adverse effects.
- Phase 3 clinical trials—consist of expanded, large scale studies of patients with the target disease or disorder to obtain definitive statistical evidence of the efficacy and safety of the proposed product and dosing regimen.

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

Once an NDA or BLA is accepted for filing, the FDA has 10 months, under its standard review process, within which to review the application (for some applications, the review process is longer than 10 months). For drugs that, if approved, would represent a significant improvement in the safety or effectiveness of the treatment, diagnosis, or prevention of serious conditions when compared to standard applications, the FDA may assign "priority review" designation and review the application within 6 months. The FDA has additional review pathways to expedite development and review of new drugs that are intended to treat serious or life threatening conditions and demonstrate the potential to address unmet medical needs, including: "Fast Track," "Breakthrough Therapy," and "Accelerated Approval." However, none of these expedited pathways ensure that a product will receive FDA approval.

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

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

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

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

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

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

Outside the United States

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

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

Good Manufacturing Processes

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

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Good Clinical Practices

The FDA, the EMA and other regulatory agencies promulgate regulations and standards, commonly referred to as Good Clinical Practices ("GCP"), for designing, conducting, monitoring, auditing and reporting the results of clinical trials to ensure that the data and results are accurate and that the trial participants are adequately protected. The FDA, the EMA and other regulatory agencies enforce GCP through periodic inspections of trial sponsors, principal investigators, trial sites, contract research organizations ("CROs") and institutional review boards. If our studies fail to comply with applicable GCP, patient safety and well-being could be impacted, the clinical data generated in our clinical trials may be deemed unreliable, and relevant regulatory agencies may require us to perform additional clinical trials before approving our marketing applications. Noncompliance can also result in civil or criminal sanctions. We rely on third parties, including CROs, to carry out many of our clinical trial related activities. Failure of such third parties to comply with GCP can likewise result in rejection of our clinical trial data or other sanctions.

Hatch Waxman Act

Under the U.S. Drug Price Competition and Patent Term Restoration Act of 1984 (the "Hatch Waxman Act"), Congress created an abbreviated FDA review process for generic versions of pioneer, or brand name, drug products. The law also provides incentives by awarding, in certain circumstances, non patent related marketing exclusivities to pioneer drug manufacturers. Newly approved drug products and changes to the conditions of use of approved products may benefit from periods of non patent related marketing exclusivity in addition to any patent protection the drug product may have. The Hatch Waxman Act provides five years of new chemical entity ("NCE") marketing exclusivity to the first applicant to gain approval of an NDA for a product that contains an active ingredient, known as the active drug moiety, not found in any other approved product. The FDA is prohibited from accepting any abbreviated NDA ("ANDA") for a generic drug or 505(b)(2) application referencing the NCE for five years from the date of approval of the NCE, or four years in the case of an ANDA or 505(b)(2) application containing a patent challenge. A 505(b)(2) application is an NDA wherein the applicant relies, in part, on data and the FDA's findings of safety and efficacy from studies not conducted by or for it and for which the applicant has not obtained a right of reference. Hatch-Waxman Act exclusivities will not prevent the submission or approval of a full NDA (e.g., under 505(b)(1)), as opposed to an ANDA or 505(b)(2) application, for any drug, including, for example, a drug with the same active ingredient, dosage form, route of administration, strength and conditions of use.

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

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

or 505(b)(2) application is triggered. The 30 month stay begins at the end of the NDA holder's data exclusivity period, or, if data exclusivity has expired, on the date that the patent holder is notified. The FDA may approve the proposed product before the expiration of the 30 month stay if a court finds the patent invalid or not infringed, or if the court shortens the period because the parties have failed to cooperate in expediting the litigation.

Sales and Marketing

We are subject to various U.S. federal and state laws pertaining to healthcare fraud and abuse, including anti kickback laws and false claims laws. Anti kickback laws make it illegal for a prescription drug manufacturer to solicit, offer, receive, or pay any remuneration in exchange for, or to induce, the referral of business, including the purchase or prescription of a particular drug. Due to the broad scope of the U.S. statutory provisions, the general absence of guidance in the form of regulations, and few court decisions addressing industry practices, it is possible that our practices might be challenged under anti kickback or similar laws. False claims laws prohibit anyone from knowingly and willingly presenting, or causing to be presented, for payment to third party payers (including Medicare and Medicaid) claims for reimbursed drugs or services that are false or fraudulent, claims for items or services not provided as claimed or claims for medically unnecessary items or services. Activities relating to the sale and marketing of our products may be subject to scrutiny under these laws. Violations of fraud and abuse laws may be punishable by criminal and/or civil

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sanctions, including fines and civil monetary penalties, as well as the possibility of exclusion from federal healthcare programs (including Medicare and Medicaid). In addition, federal and state authorities are paying increased attention to enforcement of these laws within the pharmaceutical industry and private individuals have been active in alleging violations of the laws and bringing suits on behalf of the government under the federal civil False Claims Act. If we were subject to allegations concerning, or were convicted of violating, these laws, our business could be harmed. See "Item 1A—Risk Factors" and specifically those sections entitled "—If we fail to comply with the extensive legal and regulatory requirements affecting the healthcare industry, we could face increased costs, penalties and a loss of business," "—Revenues generated by sales of our products depend on the availability of reimbursement from third party payers, and a reduction in payment rate or reimbursement or an increase in our financial obligation to governmental payers could result in decreased sales of our products and decreased revenues" and "—The commercial use of our products may cause unintended side effects or adverse reactions, or incidents of misuse may occur, which could adversely affect our business and share price."

Laws and regulations have been enacted by the federal government and various states to regulate the sales and marketing practices of pharmaceutical manufacturers. The laws and regulations generally limit financial interactions between manufacturers and healthcare providers and require disclosure to the government and public of such interactions. The laws include federal "sunshine", or open payments, provisions enacted in 2010 as part of the comprehensive federal healthcare reform legislation and supplemented as part of the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act. Such provisions apply to pharmaceutical manufacturers with products reimbursed under certain government programs and require those manufacturers to disclose annually to the federal government (for re disclosure to the public) certain payments made to, or at the request of, or on behalf of, physicians or to teaching hospitals and, commencing for information to be submitted as of January 1, 2022, certain payments made to physicians assistants, nurse practitioners, clinical nurse specialists, certified registered nurse anesthetists and certified nurse-midwives. Certain state laws also require disclosure of pharmaceutical pricing information and marketing expenditures. Given the ambiguity found in many of these laws and their implementation, our reporting actions could be subject to the penalty provisions of the pertinent federal and state laws and regulations.

Pricing and Reimbursement

United States

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

Medicaid is a joint federal and state program that is administered by the states for low income and disabled beneficiaries. Under the Medicaid rebate program, we are required to pay a rebate for each unit of product reimbursed by the state Medicaid programs. The amount of the rebate for each product is set by law as the greater of 23.1% of average manufacturer price ("AMP") or the difference between AMP and the best price available from us to any commercial or non federal governmental customer. The rebate amount must be adjusted upward where the AMP for a product's first full quarter of sales, when adjusted for increases in the Consumer Price Index—Urban, is less than the AMP for the current quarter, with this difference being the amount by which the rebate is adjusted upwards. The rebate amount is required to be recomputed each quarter based on our report of current AMP and best price for each of our products to the Centers for Medicare & Medicaid Services ("CMS"). The terms of our participation in the rebate program imposes a requirement for us to report revisions to AMP or best price within a period not to exceed 12 quarters from the quarter in which the data was originally due. Any such revisions could have the impact of increasing

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

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Medicare Part D provides coverage to enrolled Medicare patients for self administered drugs (i.e. drugs that do not need to be injected or otherwise administered by a physician) and certain physician-administered drugs reimbursed under a pharmacy benefit. Medicare Part D also covers the prescription drug benefit for dual eligible beneficiaries. Medicare Part D is administered by private prescription drug plans approved by the U.S. government and each drug plan establishes its own Medicare Part D formulary for prescription drug coverage and pricing, which the drug plan may modify from time to time. The prescription drug plans negotiate pricing with manufacturers and may condition formulary placement on the availability of manufacturer discounts. Except for dual eligible Medicare Part D beneficiaries who qualify for low income subsidies, manufacturers, including us, are required to provide a fifty percent (50%) discount on our brand name prescription drugs utilized by Medicare Part D beneficiaries when those beneficiaries reach the coverage gap in their drug benefits; the Bipartisan Budget Act of 2018, signed into law on February 9, 2018, increased this discount percentage on brand name prescription drugs to seventy percent (70%) starting in 2019.

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

We also make our products available for purchase by authorized users of the Federal Supply Schedule ("FSS") of the General Services Administration pursuant to our FSS contract with the Department of Veterans Affairs. Under the Veterans Health Care Act of 1992 (the "VHC Act"), we are required to offer deeply discounted FSS contract pricing to four federal agencies: the Department of Veterans Affairs; the Department of Defense; the Coast Guard; and the PHS (including the Indian Health Service), in order for federal funding to be made available for reimbursement of any of our products by such federal agencies and certain federal grantees. Coverage under Medicaid, the Medicare Part B program and the PHS pharmaceutical pricing program is also conditioned upon FSS participation. FSS pricing is negotiated periodically with the Department of Veterans Affairs. FSS pricing is intended not to exceed the price that we charge our most favored non federal customer for a product. In addition, prices for drugs purchased by the Department of Veterans Affairs, Department of Defense (including drugs purchased by military personnel and dependents through the TriCare retail pharmacy program), Coast Guard and PHS are subject to a cap on pricing equal to 76% of the non federal average manufacturer price ("non FAMP"). An additional discount applies if non FAMP increases more than inflation (measured by the Consumer Price Index—Urban). In addition, if we are found to have knowingly submitted false information to the government, the VHC Act provides for civil monetary penalties per false item of information in addition to other penalties available to the government.

In addition, on January 21, 2016, CMS released the final Medicaid covered outpatient drug regulation, which became effective on April 1, 2016. This regulation implements those changes made by the Patient Protection and Affordable Care Act (the "PPACA") to the Medicaid drug rebate statute in 2010 and addresses a number of other issues with respect to the Medicaid program, including, but not limited to, the eligibility and calculation methodologies for AMP and best price, and the expansion of Medicaid rebate liability to include Medicaid managed care organizations. The final Medicaid covered outpatient drug regulation established two calculation methodologies for AMP: one for drugs generally dispensed through retail community pharmacies ("RCP") and one for so-called "5i drugs" (inhaled, infused, instilled, implanted or injectable drugs) "not generally dispensed" through RCPs. The regulation further made clear that 5i drugs would qualify as "not generally dispensed" and, therefore, able to use the alternative AMP calculation, if not more than thirty percent (30%) of their sales were to RCPs or to wholesalers for RCPs. The primary difference between the two AMP calculations is the requirement to exclude from AMP, for those qualifying 5i drugs not generally dispensed through RCPs, certain payments, rebates and discounts related to sales to non-RCPs; such exclusion often leads to a lower AMP. The decision of which AMP calculation a product is eligible to use must be made and applied on a monthly basis based on the percentage of sales of such product to RCPs or to wholesalers for

RCPs.

The U.S. federal and state governments regularly consider reforming healthcare coverage and lessening healthcare costs. Such reforms may include price controls, value-based pricing and changes to the coverage and reimbursement of our products, which may have a significant impact on our business. For example, on January 31, 2019, the Department of Health and Human Services (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. In addition, emphasis on managed care in the U.S. has increased and we expect will continue to increase the pressure on drug pricing. Private insurers regularly seek to manage drug cost and utilization by implementing coverage and reimbursement limitations through means including, but not limited to, formularies, increased out of pocket obligations and various prior authorization requirements. Even if favorable coverage and reimbursement status is attained for one or more products for which we have received regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

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Outside the United States

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

Other Regulations

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

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

The General Data Protection Regulation ("GDPR"): The GDPR came into force on May 25, 2018 and replaced the previous European Union ("EU") Data Protection Directive (95/46). The GDPR, which governs the processing of personal data (including personal health data), applies to the Company and any of its subsidiaries that are established in the EU as well as any of its subsidiaries that are established outside the EU to the extent that they process personal data relating to clinical trial participants in the EU. 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, 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..

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

Employees

As of February 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.

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Available Information and Website Disclosure

Our principal executive offices are located at Connaught House, 1 Burlington Road, Dublin 4, Ireland. Our telephone number is +353 1 772 8000 and our website address is www.alkermes.com. Information that is contained in and can be accessed through, our website is not incorporated into, and does not form a part of, this Annual Report. We make available free of charge through the Investors section of our website our Annual Reports on Form 10 K, Quarterly Reports on Form 10 Q, Current Reports on Form 8 K and all amendments to those reports as soon as reasonably practicable after such material is electronically filed with, or furnished to, the SEC. We also make available on our website (i) the charters for the standing committees of our board of directors, including the Audit and Risk Committee, Compensation Committee, and Nominating and Corporate Governance Committee, and (ii) our Code of Business Conduct and Ethics governing our directors, officers and employees. We intend to disclose on our website any amendments to, or waivers from, our Code of Business Conduct and Ethics that are required to be disclosed pursuant to the rules of the SEC.

From time to time, we may use our website to distribute material information. Our financial and other material information is routinely posted to and accessible on the Investors section of our website, available at www.alkermes.com. Investors are encouraged to review the Investors section of our website because we may post material information on that site that is not otherwise disseminated by us. Information that is contained in and can be accessed through our website is not incorporated into, and does not form a part of, this Annual Report.

Item 1A. Risk Factors

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

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

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

The revenues that we receive from manufacturing fees and royalties depend primarily upon the success of our licensees, and particularly Janssen, Acorda 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.

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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 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.

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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.

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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.

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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.

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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.

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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 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.

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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

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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 16, Commitments and Contingent Liabilities in the "Notes to Consolidated Financial Statements" and "Item 3—Legal Proceedings" in this Annual 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.

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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.

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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 16, Commitments and Contingent Liabilities in the “Notes to Consolidated Financial Statements” and “Item 3—Legal Proceedings” in this Annual 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 16, Commitments and Contingent Liabilities in the “Notes to Consolidated Financial Statements” and “Item 3—Legal Proceedings” in this Annual 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.

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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;

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- 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, (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 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.

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

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

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

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

Currency exchange rates may affect revenues and expenses.

We conduct a large portion of our business in international markets. For example, we derive a majority of our RISPERDAL CONSTA revenues and all of our FAMPYRA, XEPLION and TREVICTA revenues from sales in countries other than the U.S., and these sales are denominated in non-U.S. dollar (“USD”) currencies. We also incur substantial operating costs in Ireland and face exposure to changes in the exchange ratio of the USD and the Euro arising from expenses and payables at our Irish operations that are settled in Euro. Our efforts to mitigate the impact of fluctuating currency exchange rates may not be successful. As a result, currency fluctuations among our reporting currency, USD, and the currencies in which we do business will affect our results of operations, often in unpredictable ways. Refer to “Item 7A—Quantitative and Qualitative Disclosures about Market Risk” for additional information relating to our foreign currency exchange rate risk.

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;

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- 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.

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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 SEC on February 29, 2012, for additional discussion with respect to other potential U.S. federal income tax consequences of investments in us.

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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.

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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.

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Item 1B. Unresolved Staff Comments

None.

Item 2. Properties

We lease approximately 14,600 square feet of corporate office space in Dublin, Ireland, which houses our corporate headquarters. This lease expires in 2022. We lease two properties in Waltham, Massachusetts. One facility has approximately 175,000 square feet of space and houses corporate offices, administrative areas and laboratories. This lease expires in 2021 and includes a tenant option to extend the term for up to two five-year periods. The second property we lease in Waltham, Massachusetts has approximately 67,000 square feet of office space. This lease expires in 2020 and includes a tenant option to extend the term for up to two one-year periods. We lease approximately 7,000 square feet of corporate office and administrative space in Washington, DC. This lease expires in 2029 and includes a tenant option to extend the term for an additional five-year period.

In March 2018, we entered into a lease agreement for approximately 220,000 square feet of office and laboratory space located in a building to be built at 900 Winter Street, Waltham, Massachusetts ("900 Winter Street"). We plan to occupy the premises in early 2020. The initial term of the lease shall commence on the earlier of (i) the Delivery Date (defined as (i) the later of January 20, 2020, or (ii) the date on which the landlord substantially completes its work in accordance with the terms of the lease), or (ii) the date we enter into possession of all or any substantial portion of 900 Winter Street for the conduct of our business (the "Commencement Date"). The initial lease term expires on the last day of the calendar month in which the fifteenth (15th) anniversary of the Commencement Date occurs, with an option to extend for an additional ten (10) years.

We own an R&D and manufacturing facility in Athlone, Ireland (approximately 400,000 square feet) and a manufacturing facility in Wilmington, Ohio (approximately 360,600 square feet).

We believe that our current and planned facilities are suitable and adequate for our current and near term pre-clinical, clinical and commercial requirements.

Item 3. Legal Proceedings

For information regarding legal proceedings, refer to Note 16, Commitments and Contingent Liabilities in the "Notes to Consolidated Financial Statements" in this Annual Report, which is incorporated into this Part I, Item 3 by reference.

Item 4. Mine Safety Disclosures

Not Applicable.

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PART II

Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities

Market and shareholder information

Our ordinary shares are traded on the Nasdaq under the symbol "ALKS." There were 119 shareholders of record for our ordinary shares on February 4, 2019. In addition, the last reported sale price of our ordinary shares as reported on the Nasdaq on February 4, 2019 was $33.18.

Dividends

No dividends have been paid on our ordinary shares to date, and we do not expect to pay cash dividends thereon in the foreseeable future. We anticipate that we will retain all earnings, if any, to support our operations and our proprietary drug development programs. Any future determination as to the payment of dividends will be at the sole discretion of our board of directors and will depend on our financial condition, results of operations, capital requirements and other factors our board of directors deems relevant.

Repurchase of equity securities

On September 16, 2011, our board of directors authorized the continuation of the Alkermes, Inc. program to repurchase up to $215.0 million of our ordinary shares at the discretion of management from time to time in the open market or through privately negotiated transactions. We did not purchase any shares under this program during the year ended December 31, 2018. As of December 31, 2018, we had purchased a total of 8,866,342 shares at a cost of $114.0 million. The 2023 Term Loans include restrictive covenants that impose certain limitations on our ability to repurchase our ordinary shares.

During the three months ended December 31, 2018, we acquired 112,733 Alkermes ordinary shares, at an average price of $34.03 per share related to the vesting of employee equity awards to satisfy withholding tax obligations.

Irish taxes applicable to U.S. holders

The following is a general summary of the main Irish tax considerations applicable to the purchase, ownership and disposition of our ordinary shares by U.S. holders. It is based on existing Irish law and practices in effect on January 15, 2019, and on discussions and correspondence with the Irish Revenue Commissioners. Legislative, administrative or judicial changes may modify the tax consequences described below.

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

Withholding tax on dividends

While we have no current plans to pay dividends, dividends on our ordinary shares would generally be subject to Irish dividend withholding tax ("DWT") at the standard rate of income tax, which is currently 20%, unless an exemption

applies. Dividends on our ordinary shares that are owned by residents of the U.S. and held beneficially through the Depositary Trust Company (“DTC”) will not be subject to DWT provided that the address of the beneficial owner of the ordinary shares in the records of the broker is in the U.S.

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

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

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Income tax on dividends

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

Irish tax on capital gains

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

Capital acquisitions tax

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

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

Stamp duty

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

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

ordinary shares or an interest in the ordinary shares, as the case may be, by the shareholder to a third party being contemplated.

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Stock performance graph

The information contained in the performance graph below shall not be deemed to be “soliciting material” or to be “filed” with the SEC, and such information shall not be incorporated by reference into any future filing under the Securities Act or the Exchange Act, except to the extent that we specifically incorporate it by reference into such filing.

The following graph compares the cumulative total shareholder return on our ordinary shares from December 31, 2013 through December 31, 2018 with the cumulative returns of the Nasdaq Composite Total Return Index and the Nasdaq Biotechnology Index. The comparison assumes $100 was invested on December 31, 2013 in our ordinary shares and in each of the foregoing indices and further assumes reinvestment of any dividends. We did not declare or pay any dividends on our ordinary shares during the comparison period.

	Nine Months Ended December 31, 2013	Year Ended December 31, 2014	2015	2016	2017	2018
Alkermes	100	144	195	137	134	73
Nasdaq Composite Total Return	100	115	123	134	173	168
Nasdaq Biotechnology Index	100	134	149	117	142	128

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Item 6. Selected Financial Data

The selected historical financial data set forth below at December 31, 2018 and 2017 and for the years ended December 31, 2018, 2017 and 2016 are derived from our audited consolidated financial statements, which are included elsewhere in this Annual Report. The selected historical financial data set forth below at December 31, 2016 and for the years ended and at December 31, 2015 and 2014 are derived from audited consolidated financial statements, which are not included in this Annual Report.

The following selected consolidated financial data should be read in conjunction with our consolidated financial statements, the related notes and "Management's Discussion and Analysis of Financial Condition and Results of Operations" included in Item 7 of Part II of this Annual Report. The historical results are not necessarily indicative of the results to be expected for any future period.

	Year Ended December 31,				
(In thousands, except per share data)	2018	2017	2016	2015	2014
Consolidated Statements of Operations Data:					
REVENUES[1]:					
Manufacturing and royalty revenues	$526,675	$505,308	$487,247	$475,288	$516,876
Product sales, net	450,334	362,834	256,146	149,028	94,160
Research and development revenue	68,895	7,232	2,301	4,019	7,753
License revenue	48,370	28,000	—	—	—
Total revenues	1,094,274	903,374	745,694	628,335	618,789
EXPENSES:					
Cost of goods manufactured and sold	176,420	154,748	132,122	138,989	175,832
Research and development	425,406	412,889	387,148	344,404	272,043
Selling, general and administrative	526,408	421,578	374,130	311,558	199,905
Amortization of acquired intangible assets	65,168	62,059	60,959	57,685	58,153
Total expenses	1,193,402	1,051,274	954,359	852,636	705,933
OPERATING LOSS	(99,128)	(147,900)	(208,665)	(224,301)	(87,144)
OTHER (EXPENSE) INCOME , NET[2]	(27,839)	4,626	(5,722)	296	73,115
LOSS BEFORE INCOME TAXES	(126,967)	(143,274)	(214,387)	(224,005)	(14,029)
PROVISION (BENEFIT) FOR INCOME TAXES	12,344	14,671	(5,943)	3,158	16,032
NET LOSS	$(139,311)	$(157,945)	$(208,444)	$(227,163)	$(30,061)
LOSS PER ORDINARY SHARE:					
BASIC AND DILUTED	$(0.90)	$(1.03)	$(1.38)	$(1.52)	$(0.21)
WEIGHTED AVERAGE NUMBER OF ORDINARY SHARES OUTSTANDING:					
BASIC AND DILUTED	155,112	153,415	151,484	149,206	145,274
Consolidated Balance Sheet Data:					
Cash, cash equivalents and investments	$620,039	$590,716	$619,165	$798,849	$801,646
Total assets[3]	1,825,007	1,797,227	1,726,423	1,855,744	1,919,058
Long-term debt[3]	279,308	281,436	283,666	349,944	355,756
Shareholders' equity	1,171,285	1,202,808	1,209,481	1,314,275	1,396,837

(1) On January 1, 2018, we adopted the Financial Accounting Standards Board's ("FASB") Accounting Standards Codification ("ASC") 606, Revenue from Contracts with Customers ("Topic 606").

(2) 2015 includes a $9.6 million gain on the sale of the Company's Gainesville, GA manufacturing facility, the related manufacturing and royalty revenue associated with certain products manufactured at the facility, and the rights to IV/IM and parenteral forms of Meloxicam (the "Gainesville Transaction"). 2014 includes a gain on the sale of property, plant and equipment of $41.9 million, a gain on the sale of an investment in Civitas Therapeutics, Inc. of $29.6 million and a gain on the sale of an investment in Acceleron Pharma Inc. of $15.3 million.

(3) In 2015, the Company retrospectively adopted the FASB's guidance simplifying the presentation of debt issuance costs. As a result, deferred financing costs of $2.2 million that were classified within "Other long-term assets" at December 31, 2014 were reclassified to "Long-term debt" to conform to the then-current period presentation.

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

The following should be read in conjunction with our consolidated financial statements and related notes beginning on page F 1 of this Annual Report. The following discussion contains forward looking statements. Actual results may differ significantly from those projected in the forward looking statements. See "Cautionary Note Concerning Forward Looking Statements" on page 3 of this Annual Report. Factors that might cause future results to differ materially from those projected in the forward looking statements also include, but are not limited to, those discussed in "Item 1A—Risk Factors" and elsewhere in this Annual Report.

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 and 2016.

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, 2017 and 2016:

	Year Ended December 31,			Change Favorable/(Unfavorable)	
(In millions)	2018	2017	2016	2018–2017	2017–2016
Manufacturing and royalty revenues:					
INVEGA SUSTENNA/XEPLION & INVEGA TRINZA/TREVICTA	$241.4	$214.9	$184.2	$ 26.5	$ 30.7
AMPYRA/FAMPYRA	107.1	117.0	114.2	(9.9)	2.8

RISPERDAL CONSTA	71.1	84.9	87.2	(13.8)	(2.3)
Other	107.1	88.5	101.6	18.6	(13.1)
Manufacturing and royalty revenues	$526.7	$505.3	$487.2	$ 21.4	$ 18.1

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, $2.6 billion and $2.2 billion during the years ended December 31, 2018, 2017 and 2016, 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 Topic 606, 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.

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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, $805.0 million and $893.0 million during the years ended December 31, 2018, 2017 and 2016, respectively. The decrease in RISPERDAL CONSTA revenue in 2017, as compared to 2016, was primarily due to a 10% decrease in royalty revenues due to the decline in Janssen's end-market net sales of RISPERDAL CONSTA. RISPERDAL CONSTA is covered by a patent until 2021 in the EU and 2023 in the U.S. For a discussion of legal proceedings related to this patent, see Note 16, Commitments and Contingent Liabilities in the "Notes to Consolidated Financial Statements" and "Item 3—Legal Proceedings" in this Annual 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 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 16, Commitments and Contingent Liabilities in the "Notes to Consolidated Financial Statements" and "Part I, Item 3—Legal Proceedings" in this Annual Report and for information about risks relating to the INVEGA SUSTENNA Paragraph IV litigation, see "Part I, Item 1A—Risk Factors" in this Annual 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, Revenue from Contracts with Customers, in the "Notes to Consolidated Financial Statements" in this Annual 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 "Part II, Item 1—Legal Proceedings" and Note 16, Commitments and Contingent Liabilities in this Annual Report, and for information about risks relating to such legal proceedings see "Part I, Item 1A—Risk Factors" of this Annual 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 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.

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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 “Part II, Item 7A—Quantitative and Qualitative Disclosures about Market Risk” of this Annual 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, 2017 and 2016:

	Year Ended December 31,					
(In millions)	2018	% of Sales	2017	% of Sales	2016	% of Sales
Product sales, gross	$846.5	100.0 %	$657.7	100.0 %	$444.6	100.0 %
Adjustments to product sales, gross:						
Medicaid rebates	(197.0)	(23.3)%	(147.8)	(22.5)%	(94.2)	(21.2)%
Chargebacks	(65.5)	(7.7)%	(47.9)	(7.3)%	(31.5)	(7.1)%
Product discounts	(65.1)	(7.7)%	(51.0)	(7.8)%	(35.1)	(7.9)%
Medicare Part D	(29.8)	(3.5)%	(15.1)	(2.3)%	(3.4)	(0.8)%
Other	(38.8)	(4.6)%	(33.1)	(5.0)%	(24.3)	(5.5)%
Total adjustments	(396.2)	(46.8)%	(294.9)	(44.8)%	(188.5)	(42.4)%
Product sales, net	$450.3	53.2 %	$362.8	55.2 %	$256.1	57.6 %

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, respectively, and $209.0 million and $47.1 million in 2016, respectively.

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. The increase in product sales, gross in 2017, as compared to 2016, was due to a 33% increase in VIVITROL gross sales and a 129% increase in ARISTADA/ARISTADA INITIO gross sales. The increase in VIVITROL gross sales was due to a 33% increase in the number of units sold as there was no change to the selling price of VIVITROL in 2017. The increase in sales of ARISTADA/ARISTADA INITIO was primarily due to a 113% increase in the number of units sold and a 5% price increase, which was effective in April 2017. ARISTADA 441 mg, 662 mg and 882 mg launched in the U.S. in October 2015. 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.

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License Revenue

	Year Ended December 31,			Change Favorable/(Unfavorable)	
(In millions)	2018	2017	2016	2018 - 2017	2017 - 2016
License revenue	$48.4	$28.0	$ —	$ 20.4	$ 28.0

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"). This is discussed in greater detail within the Critical Accounting Estimates section below.

Research and Development Revenue

	Year Ended December 31,			Change Favorable/(Unfavorable)	
(In millions)	2018	2017	2016	2018 - 2017	2017 - 2016
Research and development revenue	$68.9	$7.2	$2.3	$ 61.7	$ 4.9

The increase in R&D revenue in 2018, as compared to 2017, and in 2017, as compared to 2016, was primarily due to revenue earned under our license and collaboration agreement with Biogen for BIIB098, as discussed in further detail within the 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/(Unfavorable)	
(In millions)	2018	2017	2016	2018 - 2017	2017 - 2016
Cost of goods manufactured and sold	$176.4	$154.7	$132.1	$ (21.7)	$ (22.6)

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. The increase in cost of goods manufactured and sold in 2017, as compared to 2016, was primarily due to the increase in cost of goods sold related to VIVITROL and ARISTADA and an increase in cost of goods manufactured related to RISPERDAL CONSTA. Cost of goods sold for VIVITROL and ARISTADA

increased by 33% and 83%, respectively, in 2017, as compared to 2016 driven by increases in sales. Cost of goods manufactured for RISPERDAL CONSTA increased by 13% in 2017, as compared to 2016, which was primarily due to an increase in the number of units shipped to Janssen.

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.

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The following table sets forth our external R&D expenses for the years ended December 31, 2018, 2017 and 2016 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:

	Year Ended December 31,			Change Favorable/(Unfavorable)	
(In millions)	2018	2017	2016	2018 - 2017	2017 - 2016
External R&D Expenses:					
Key development programs:					
ALKS 3831	$52.0	$91.9	$71.0	$ 39.9	$ (20.9)
BIIB098	43.1	47.4	26.9	4.3	(20.5)
ALKS 5461	30.3	42.2	46.2	11.9	4.0
ALKS 4230	23.3	7.0	4.8	(16.3)	(2.2)
ARISTADA and ARISTADA line extensions	20.1	13.7	36.3	(6.4)	22.6
Other external R&D expenses	49.7	38.4	58.7	(11.3)	20.3
Total external R&D expenses	218.5	240.6	243.9	22.1	3.3
Internal R&D expenses:					
Employee-related	163.9	132.2	110.1	(31.7)	(22.1)
Depreciation	11.9	10.5	7.9	(1.4)	(2.6)
Occupancy	11.0	9.6	9.0	(1.4)	(0.6)
Other	20.1	20.0	16.2	(0.1)	(3.8)
Total internal R&D expenses	206.9	172.3	143.2	(34.6)	(29.1)
Research and development expenses	$425.4	$412.9	$387.1	$ (12.5)	$ (25.8)

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 increase in expenses related to ALKS 3831 in 2017, as compared to 2016, was primarily due to the timing of activity within the ENLIGHTEN-1 and ENLIGHTEN-2 pivotal trials and the initiation of the phase 3 study of ALKS 3831 in young adults.

The decrease in expenses related to BIIB098 in 2018, as compared to 2017, and in increase in expenses in 2017, as compared to 2016, were 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 decrease in expenses related to ALKS 5461 in 2017, as compared to 2016, was primarily due to the completion of the three core phase 3 studies related to the program. We announced topline results of the FORWARD-3 and FORWARD-4 studies in January 2016 and topline results from FORWARD-5 were announced in October 2016.

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. The decrease in expenses related to ARISTADA and ARISTADA line extensions in 2017, as compared to 2016, was primarily due to the timing of the phase 1 clinical study of extended dosing intervals of aripiprazole lauroxil in patients with schizophrenia. ARISTADA 1064 mg, our two-month dosing option, was approved by the FDA in June 2017. In October 2017, we submitted an NDA to the FDA for ARISTADA INITIO, which was approved by the FDA in June 2018.

The increases in expenses related to ALKS 4230 in 2018, as compared to 2017, and in 2017, as compared to 2016, were primarily related to the timing of the phase 1 study for ALKS 4230, as described in Key Development Programs above under the heading “ALKS 4230” within “Part I, Item 1—Business” in this Annual Report.

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

For additional detail on the status of our key development programs, refer to Key Development Programs within "Part I, Item 1—Business" in this Annual Report.

Selling, General and Administrative Expenses

	Year Ended December 31,			Change Favorable/(Unfavorable)	
(In millions)	2018	2017	2016	2018 - 2017	2017 - 2016
Selling, general and administrative expense	$526.4	$421.6	$374.1	$ (104.8)	$ (47.5)

The increase in selling, general and administrative ("SG&A") expense in both periods presented was primarily due to increases in marketing and professional services fees and employee-related expenses. Marketing and professional services fees increased by 29% and 27%, respectively, and were primarily due to additional brand investments in both VIVITROL and ARISTADA, as well as an increase investment in patient access support services, such as reimbursement and transition assistance, for both of these products. Employee-related expenses increased by 21% and 6%, respectively, and were primarily due to an increase in our SG&A-related headcount of 22% in 2018 and 17% in 2017.

Amortization of Acquired Intangible Assets

	Year Ended December 31,			Change Favorable/(Unfavorable)	
(In millions)	2018	2017	2016	2018 - 2017	2017 - 2016
Amortization of acquired intangible assets	$65.2	$62.1	$61.0	$ (3.1)	$ (1.1)

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/(Unfavorable)	
(In millions)	2018	2017	2016	2018 - 2017	2017 - 2016
Interest income	$9.2	$4.6	$3.8	$ 4.6	$ 0.8
Interest expense	(15.4)	(12.0)	(14.9)	(3.4)	2.9
Change in the fair value of contingent consideration	(19.6)	21.6	7.9	(41.2)	13.7
Other expense, net	(2.0)	(9.6)	(2.5)	7.6	(7.1)
Total other (expense) income, net	$(27.8)	$4.6	$(5.7)	$ (32.4)	$ 10.3

The increase in interest expense in 2018, as compared to 2017, was due to our amending and refinancing our 2023 Term Loans in March 2018 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. The decrease in interest expense in 2017, as compared to 2016, was due an amendment of our outstanding term loans at September 25, 2016. We incurred a charge of $2.1 million in connection with this transaction in 2016, which was included in interest expense.

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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 Critical Accounting Estimates, Contingent Consideration, later in "Item 7—Management's Discussion and Analysis of Financial Condition and Results of Operations" of this Annual 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, 2017 and 2016, we determined that the fair value of the contingent consideration decreased by $19.6 million and increased by $21.6 million and $7.9 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 increase in the fair value of the contingent consideration in 2017, as compared to 2016, was primarily due to a prior change in the structure of the development milestones related to approval of the IV Meloxicam NDA and a shorter time to payment and improved probability of success on the milestones and royalties included in the contingent consideration. The valuation of the contingent consideration is discussed in greater detail in Critical Accounting Estimates, Contingent Consideration, later in "Item 7—Management's Discussion and Analysis of Financial Condition and Results of Operations" of this Annual Report.

The decrease in other expense, net in 2018, as compared to 2017, and the increase in 2017, as compared to 2016, were primarily due to an impairment charge related to our investment in Synchronicity, 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 (Benefit) for Income Taxes

	Year Ended December 31,			Change Favorable/(Unfavorable)	
(In millions)	2018	2017	2016	2018 - 2017	2017 - 2016
Income tax provision (benefit)	$12.3	$14.7	$(5.9)	$ 2.4	$ (20.6)

The income tax provision (benefit) in 2018, 2017 and 2016 were 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. The unfavorable change in income taxes in 2017, as compared to 2016, was primarily due to Tax Reform and an increase in income earned in the U.S., partially offset by the recognition of excess tax benefits related to share-based compensation.

No provision for income tax has been provided on undistributed earnings of our foreign subsidiaries because such earnings 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.

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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:

	December 31, 2018			December 31, 2017		
(In millions)	U.S.	Ireland	Total	U.S.	Ireland	Total
Cash and cash equivalents	$139.3	$127.5	$266.8	$114.7	$76.6	$191.3
Investments—short-term	203.3	69.2	272.5	127.5	114.7	242.2
Investments—long-term	51.5	29.2	80.7	108.9	48.3	157.2
Total cash and investments	$394.1	$225.9	$620.0	$351.1	$239.6	$590.7
Outstanding borrowings—short and long-term	$279.3	$—	$279.3	$281.4	$—	$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 and used $63.8 million of cash from operating activities during the years ended December 31, 2018, 2017 and 2016, respectively. We expect that our existing cash and investments will be sufficient to finance our anticipated working capital and other cash requirements, such as capital expenditures and principal and interest payments on our long term debt, for at least the twelve months following the date from which our financial statements were issued. Subject to market conditions, interest rates and other factors, we may pursue

opportunities to obtain additional financing in the future, including debt and equity offerings, corporate collaborations, bank borrowings, arrangements relating to assets or other financing methods or structures. In addition, 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.

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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, 2017 and 2016:

	Year Ended December 31,		
(In millions)	2018	2017	2016
Cash and cash equivalents, beginning of period	$191.3	$186.4	$181.1
Cash flows provided by (used in) operating activities	99.3	19.2	(63.8)
Cash flows (used in) provided by investing activities	(22.2)	(18.4)	127.2
Cash flows (used in) provided by financing activities	(1.6)	4.1	(58.1)
Cash and cash equivalents, end of period	$266.8	$191.3	$186.4

Operating Activities

The increases in cash provided by operating activities in 2018, as compared to 2017, and in 2017, as compared to 2016, were primarily due to a 21% increase in the amount of cash collected from our customers. This was partially offset by a 20% and 17% increase in the amount of cash paid to our employees, respectively, and a 4% and 6% increase in the amount of cash paid to our suppliers, respectively. The increase in the amount of cash we collected from our customers is primarily due to the increase in revenues in each period 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 in each period, as compared to the prior period, and the increase in the amount of cash paid to our suppliers is due to the increase in R&D and commercial activity in each period, as compared to the prior period, as previously discussed.

Investing Activities

The increases in cash used in investing activities in 2018, as compared to 2017, and in 2017, as compared to 2016, were 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 15%, respectively, 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% and a decrease of 82% in 2018 as compared to 2017, and in 2017 as compared to 2016, respectively. In 2017, this increase was partially offset by a $15.0 million investment in Synchronicity that we made in 2016.

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. The increase in cash provided by financing activities in 2017, as compared to 2016, was primarily due to a $60.9 million principal payment for a term loan which matured in September 2016, which had an original principal balance of $75.0 million, bore interest at

LIBOR plus 2.75%, with no LIBOR floor. In 2017, our financing activities consisted of $7.1 million in cash received from our employees related to stock option exercises and $3.0 million in principal payments we made under the Term Loan B-1 (which has since been refinanced as described above into the 2023 Term Loans).

Borrowings

At December 31, 2018, our borrowings consisted of $282.1 million outstanding under the 2023 Term Loans. Please refer to Note 10, Long Term Debt, in the accompanying “Notes to Consolidated Financial Statements” for a discussion of our outstanding term loans.

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Contractual Obligations

The following table summarizes our obligations to make future payments under our current contracts at December 31, 2018:

Contractual Obligations (In thousands)	Total	Less Than One Year (2019)	One to Three Years (2020 - 2021)	Three to Five Years (2022 - 2023)	More than Five Years (After 2023)
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.

Critical Accounting Estimates

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

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

Revenue from Contracts with Customers

When entering into arrangements with customers, we identify whether our performance obligations under each arrangement represent a distinct good or service or a series of distinct goods or services. If a contract contains more than one performance obligation, we allocate 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 each arrangement may be derived using an estimate of selling price if we do not sell the goods or services separately.

We recognize revenue when or as we satisfy 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 we are expected to complete our 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 we expect to complete our aggregate performance obligations.

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Manufacturing Revenue

We recognize manufacturing revenues from the sale of products we manufacture for resale by our licensees. Manufacturing revenues for our 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. We recognize manufacturing revenue from these products over time as we determined, in each instance, that we would have a right to payment for performance completed to date if our customer were to terminate the manufacturing agreement for reasons other than our non-performance and the products have no alternative use. We invoice our licensees upon shipment with payment terms between 30 to 90 days. Prior to the adoption of Topic 606, we recorded manufacturing revenue from the sale of products we manufactured for resale by our partners after we had shipped such products and risk of loss had passed to our partner, assuming persuasive evidence of an arrangement existed, the sales price was fixed or determinable and collectability was reasonably assured.

We are the exclusive manufacturer of RISPERDAL CONSTA for commercial sale under our manufacturing and supply agreement with Janssen. We determined that it is appropriate to record revenue 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, we 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 us and Janssen.

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

Royalty Revenue

We recognize royalty revenues related to the sale of products by our licensees that incorporate our technology. 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 IP is the sole or predominant item to which such royalties relate. Based on this exemption, these royalties are earned in the period the products are sold by our partner and we have 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 revenues section, above, as the terms of such agreements entitle us to royalty revenue 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.

In anticipation of the entry of generic forms of AMPYRA to the U.S. market, during the three months ended September 30, 2018, we supplied five batches of AMPYRA to Acorda for which we agreed to defer the receipt of royalties on end-market sales of the product until the product was sold by Acorda, rather than as it was manufactured. Upon delivery of these five batches, royalty revenue for AMPYRA reverted to being recognized as the product is manufactured.

Certain of our royalty revenues are recognized based on information supplied to us by our licensees and require estimates to be made. Differences between actual royalty revenues and estimated royalty revenues are reconciled and

adjusted for in the period in which they become known, which is generally within the same quarter. The difference between our actual and estimated royalty revenues has not been material to date.

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Research and Development Revenue and License Revenue

In November 2017, we 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, 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 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. 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. 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.

We evaluated the agreement under Topic 606 and determined that we had four deliverables: (i) the grant of a distinct, right-to-use license of intellectual property to Biogen; (ii) future development services; (iii) clinical supply; and (iv) participation on a joint steering committee with Biogen. Our 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.

We allocated the arrangement consideration to each performance obligation using standalone selling prices based on an estimate of selling price for the license and other deliverables. We 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, we 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. We then discounted these cash flows using a discount rate of 8.0%, which we believed captured 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 supply were determined through third-party evidence. We believe that a change in the assumptions used to determine our estimate of selling price for the license most likely would not have a significant effect on the allocation of consideration transferred.

Under Topic 606, we allocated the upfront payment of $28.0 million 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. We allocated the $50.0 million payment received 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 and the amounts allocated to the development services and clinical supply will be recognized over the course of the development work and as clinical supply is delivered to Biogen, which is expected to continue through 2019.

We determined that the future milestones we are 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. We are 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, we have not included these milestones in the transaction price as it is not probable that a significant reversal in the amount of cumulative revenue recognized will not occur. The royalties are subject to the sales-based exception and will be recorded as revenue when the corresponding sale occurs.

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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. Product sales, net are recognized when the customer obtains control of the product, which is when the product has been received by the customer.

Revenues from product sales are recorded net of reserves established for applicable discounts and allowances that are offered within contracts with our customers, health care providers or payers. Our 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 revenues recognized will not occur in a future period. Actual amounts may ultimately differ from our estimates. If actual results vary, we adjust these estimates, which could have an effect on earnings in the period of adjustment. The following are our significant categories of sales discounts and allowances:

- Medicaid Rebates—we record accruals for rebates to states under the Medicaid Drug Rebate Program as a reduction of sales when the product is shipped into the distribution channel using the expected value. We rebate individual states for all eligible units purchased under the Medicaid program based on a rebate per unit calculation, which is based on our average manufacturer prices. We estimate expected unit sales and rebates per unit under the Medicaid program and adjusts our rebate based on actual unit sales and rebates per unit. To date, actual Medicaid rebates have not differed materially from our estimates;
- 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 us 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 and is based on actual and expected utilization of these programs. Chargebacks could exceed historical experience and our estimates of future participation in these programs. To date, actual chargebacks have not differed materially from our estimates;
- Product Discounts—cash consideration, including sales incentives, given by us 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 and to date, actual product discounts have not differed materially from our estimates; and
- Product Returns—we record an estimate for product returns at the time our customers take control of our product. We estimate this liability using the expected value based on our 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— We record 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.

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

(In millions)	Medicaid Rebates	Chargebacks	Product Discounts	Product Returns	Medicare Part D	Other	Total
Balance, December 31, 2016	$ 43.8	$ 1.1	$ 5.6	$ 13.5	$ 1.3	$ 1.9	$ 67.2
Provision:							
Current year	153.5	47.9	51.2	7.5	16.0	25.8	301.9
Prior year	(5.7)	—	(0.2)	(0.8)	—	(0.3)	(7.0)
Total	147.8	47.9	51.0	6.7	16.0	25.5	294.9
Actual:							
Current year	(66.0)	(46.3)	(42.0)	(0.1)	(12.6)	(20.8)	(187.8)
Prior year	(35.7)	(0.8)	(6.0)	(1.3)	(0.8)	(2.0)	(46.6)
Total	(101.7)	(47.1)	(48.0)	(1.4)	(13.4)	(22.8)	(234.4)
Balance, December 31, 2017	$ 89.9	$ 1.9	$ 8.6	$ 18.8	$ 3.9	$ 4.6	$ 127.7
Provision:							
Current year	203.1	65.5	65.2	6.6	29.8	32.1	402.3
Prior year	(6.1)	—	(0.1)	—	—	—	(6.2)
Total	197.0	65.5	65.1	6.6	29.8	32.1	396.1
Actual:							
Current year	(80.5)	(63.7)	(51.1)	—	(17.8)	(27.5)	(240.6)
Prior year	(83.0)	(1.4)	(10.4)	(3.5)	(4.8)	(3.7)	(106.8)
Total	(163.5)	(65.1)	(61.5)	(3.5)	(22.6)	(31.2)	(347.4)
Balance, December 31, 2018	$ 123.4	$ 2.3	$ 12.2	$ 21.9	$ 11.1	$ 5.5	$ 176.4

Investments

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

Substantially all of our investments are classified as “available for sale” and are recorded at their estimated fair value. The valuation of our available for sale securities for purposes of determining the amount of gains and losses is based on the specific identification method. Our held to maturity investments are restricted investments held as collateral under certain letters of credit related to our lease arrangements and are recorded at amortized cost.

The earnings on our investment portfolio may be adversely affected by changes in interest rates, credit ratings, collateral value, the overall strength of credit markets and other factors that may result in other than temporary declines in the value of the securities. On a quarterly basis, we review the fair market value of our investments in comparison to amortized cost. If the fair market value of a security is less than its carrying value, we perform an analysis to assess whether we intend to sell or whether we would more likely than not be required to sell the security before the expected recovery of the amortized cost basis. Where we intend to sell a security, or may be required to do so, the security’s decline in fair value is deemed to be other than temporary, and the full amount of the unrealized loss is recorded within earnings as an impairment loss. Regardless of our intent to sell a security, we perform additional analysis on all securities with unrealized losses to evaluate losses associated with the creditworthiness of the security. Credit losses are identified where we do not expect to receive cash flows sufficient to recover the amortized cost basis of a security.

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

Share Based Compensation

Our share based compensation plans provide for compensation in the form of incentive stock options, non qualified stock options and restricted stock units. See Note 2, Summary of Significant Accounting Policies, and Note 13, Share Based Compensation, in our "Notes to Consolidated Financial Statements" for a complete discussion of our share based compensation plans.

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The fair value of restricted stock units is equal to the closing price of our shares on the date of grant. The fair value of stock option awards is determined through the use of a Black Scholes option pricing model. The Black Scholes model requires us to estimate certain subjective assumptions. These assumptions include the expected option term, which takes into account both the contractual term of the option and the effect of our employees' and non-employee directors' expected exercise and post vesting termination behavior, expected volatility of our ordinary shares over the option's expected term, which is developed using both the historical volatility of our ordinary shares and implied volatility from our publicly traded options, the risk free interest rate over the option's expected term and an expected annual dividend yield. Due to the differing exercise and post vesting termination behaviors of our employees and non employee directors, we establish separate Black Scholes input assumptions for three distinct employee populations: our senior management; our non employee directors; and all other employees. For the years ended December 31, 2018, 2017 and 2016, the ranges in weighted average assumptions were as follows:

	Year Ended December 31,		
	2018	2017	2016
Expected option term	5 - 8 years	5 - 8 years	5 - 7 years
Expected stock volatility	44 % - 49 %	43 % - 47 %	39 % - 53 %
Risk-free interest rate	2.25 % - 3.10 %	1.69 % - 2.38 %	0.95 % - 2.14 %
Expected annual dividend yield	—	—	—

In addition to the above, we apply judgment in developing estimates of award forfeitures. For the year ended December 31, 2018, we used an estimated forfeiture rate of zero for our non employee directors, 2.25% for members of senior management and 6.0% for all other employees.

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

Amortization and Impairment of Long Lived Assets

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

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

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

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

Based on our most recent analysis, amortization of intangible assets included within our consolidated balance sheet at December 31, 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. Although we believe such available information and assumptions are reasonable, given the inherent risks and uncertainties underlying our expectations regarding such future revenues, there is the potential for our actual results to vary significantly from such expectations. If revenues are projected to change, the related amortization of the intangible asset will change in proportion to the change in revenue.

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If there are any indications that the assumptions underlying our most recent analysis would be different than those utilized within our current estimates, our analysis would be updated and may result in a significant change in the anticipated lifetime revenue of the products associated with our amortizable intangible assets. For example, the occurrence of an adverse event could substantially increase the amount of amortization expense associated with our acquired intangible assets as compared to previous periods or our current expectations, which may result in a significant negative impact on our future results of operations.

Goodwill

We evaluate goodwill for impairment for our reporting units annually, as of October 31, and whenever events or changes in circumstances indicate its carrying value may not be recoverable. A reporting unit is an operating segment, as defined by the segment reporting accounting standards, or a component of an operating segment. A component of an operating segment is a reporting unit if the component constitutes a business for which discrete financial information is available and is reviewed by management. Two or more components of an operating segment may be aggregated and deemed a single reporting unit for goodwill impairment testing purposes if the components have similar economic characteristics. As of December 31, 2018, we have one operating segment and two reporting units. Our goodwill, which solely relates to the Business Combination, has been assigned to one reporting unit which consists of the former EDT business.

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

In 2017, we elected to early adopt guidance issued by the FASB in January 2017 that simplifies the test for goodwill impairment. This guidance removes Step 2 of the goodwill impairment test, which requires a hypothetical purchase price allocation. Under the amended guidance, a goodwill impairment charge will now be recognized for the amount by which the carrying value of a reporting unit exceeds its fair value, not to exceed the carrying amount of goodwill.

On October 31, 2018, we elected to perform a quantitative impairment test and determined that the fair value of the reporting unit exceeded its carrying value.

Contingent Consideration

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

The period over which we discount contingent consideration is based on the current development stage of the product candidates, the specific development plan for that product candidate adjusted for the probability of completing the development step, and the date on which contingent payments would be triggered. In estimating the probability of

success, we utilize data regarding similar milestone events from several sources, including industry studies and our own experience. These fair value measurements are based on significant inputs not observable in the market. Significant judgment was employed in determining the appropriateness of these assumptions at the acquisition date and for each subsequent period. Accordingly, changes in assumptions described above could have a material impact on the increase or decrease in the fair value of contingent consideration recorded in any given period.

At December 31, 2018, our contingent consideration related to consideration to be received as part of the Gainesville Transaction. We received one $5.0 million payment in the first quarter of 2019 and will receive another $5.0 million payment in the second quarter of 2019; we are eligible to receive low double-digit royalties on net sales of IV/IM and parenteral forms of Meloxicam and any other Meloxicam Product(s); and we are eligible to receive up to $130.0 million in milestone payments upon the achievement of certain regulatory and sales milestones related to the Meloxicam Products.

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

- We received $5.0 million in the first quarter of 2019 and will receive another $5.0 million in the second quarter of 2019; we are entitled to receive $5.0 million upon regulatory approval of an NDA for the first Meloxicam Product; and $45.0 million in seven equal, annual installments beginning on the first anniversary of such approval. The fair value of the regulatory milestone was estimated based on applying the likelihood of achieving the regulatory milestone and applying a discount rate from the expected time the milestone occurs to the balance sheet date. We expect the regulatory milestone event to occur in the first quarter of 2019 and used a discount rate of 15.8%;
- We are entitled to receive future royalties on net sales of Meloxicam Products. To estimate the fair value of the future royalties, we assessed the likelihood of a Meloxicam Product being approved for sale and estimated the expected future sales given approval and IP protection. We then discounted these expected payments using a discount rate of 16.0%, which we believe captures a market participant's view of the risk associated with the expected payments; and
- We are entitled to receive payments of up to $80.0 million upon achieving certain sales milestones on future sales of the Meloxicam Product. The sales milestones were determined through the use of a real options approach, where net sales are simulated in a risk-neutral world. To employ this methodology, we used a risk-adjusted expected growth rate based on our 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 of 15.8%.

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

Valuation of Deferred Tax Assets

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

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

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

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

We utilize a rolling three years of actual and current year anticipated results as the primary measures of cumulative losses in recent years.

The evaluation of deferred tax assets requires judgment in assessing the likely future tax consequences of events that have been recognized in our financial statements or tax returns and future profitability. Our accounting for deferred tax consequences represents our best estimate of those future events. Changes in our current estimates, due to unanticipated events or otherwise, could have a material effect on our financial condition and results of operations.

For information related to risks surrounding our deferred tax assets, see “Item 1A—Risk Factors” and specifically the section entitled “—Our deferred tax assets may not be realized.”

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Recent Accounting Pronouncements

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

Item 7A. Quantitative and Qualitative Disclosures about Market Risk

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

We do not believe that inflation and changing prices have had a material impact on our results of operations, and as approximately 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 “Part I, Item 1A—Risk Factors” in this Annual 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.

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Item 8. Financial Statements and Supplementary Data

Selected Quarterly Financial Data (unaudited)

(In thousands, except per share data)	First Quarter	Second Quarter	Third Quarter	Fourth Quarter	Total
Year Ended December 31, 2018					
REVENUES:					
Manufacturing and royalty revenues	$ 114,601	$ 128,241	$ 116,411	$ 167,422	$526,675
Product sales, net	91,842	109,807	116,035	132,650	450,334
Research and development revenue	18,707	18,344	16,274	15,570	68,895
License revenues	—	48,250	—	120	48,370
Total revenues	225,150	304,642	248,720	315,762	1,094,274
EXPENSES:					
Cost of goods manufactured and sold	44,476	43,417	39,410	49,117	176,420
Research and development	108,346	106,823	101,265	108,972	425,406
Selling, general and administrative	118,147	138,257	128,777	141,227	526,408
Amortization of acquired intangible assets	16,069	16,247	16,426	16,426	65,168
Total expenses	287,038	304,744	285,878	315,742	1,193,402
OPERATING (LOSS) INCOME	(61,888)	(102)	(37,158)	20	(99,128)
OTHER (EXPENSE) INCOME, NET	(5,110)	(24,343)	3,325	(1,711)	(27,839)
LOSS BEFORE INCOME TAXES	(66,998)	(24,445)	(33,833)	(1,691)	(126,967)
INCOME TAX (BENEFIT) PROVISION	(4,493)	8,204	611	8,022	12,344
NET LOSS	$ (62,505)	$ (32,649)	$ (34,444)	$ (9,713)	$(139,311)
LOSS PER SHARE—BASIC AND DILUTED	$ (0.40)	$ (0.21)	$ (0.22)	$ (0.06)	$(0.90)

	First Quarter	Second Quarter	Third Quarter	Fourth Quarter	Total
Year Ended December 31, 2017					
REVENUES:					
Manufacturing and royalty revenues	$ 114,679	$ 129,252	$ 122,677	$ 138,700	$505,308
Product sales, net	76,456	88,756	93,681	103,941	362,834
License revenues	—	—	—	28,000	28,000
Research and development revenue	643	833	1,027	4,729	7,232
Total revenues	191,778	218,841	217,385	275,370	903,374
EXPENSES:					
Cost of goods manufactured and sold	40,412	39,775	36,054	38,507	154,748
Research and development	104,835	99,153	104,411	104,490	412,889
Selling, general and administrative	102,099	108,950	99,633	110,896	421,578
Amortization of acquired intangible assets	15,302	15,472	15,643	15,642	62,059
Total expenses	262,648	263,350	255,741	269,535	1,051,274
OPERATING (LOSS) INCOME	(70,870)	(44,509)	(38,356)	5,835	(147,900)
OTHER INCOME (EXPENSE), NET	(1,720)	(1,171)	2,566	4,951	4,626
(LOSS) EARNINGS BEFORE INCOME TAXES	(72,590)	(45,680)	(35,790)	10,786	(143,274)
INCOME TAX (BENEFIT) PROVISION	(3,709)	(2,681)	486	20,575	14,671
NET LOSS	$ (68,881)	$ (42,999)	$ (36,276)	$ (9,789)	$(157,945)

LOSS PER SHARE—BASIC AND DILUTED	$ (0.45)	$ (0.28)	$ (0.24)	$ (0.06)	$(1.03)

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

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

Not applicable.

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Item 9A. Controls and Procedures

Disclosure Controls and Procedures and Internal Control Over Financial Reporting

Controls and Procedures

Our management has evaluated, with the participation of our principal executive officer and principal financial officer, the effectiveness of our disclosure controls and procedures (as defined in Rules 13a 15(e) and 15d 15(e) under the Exchange Act), as of December 31, 2018. Based upon that evaluation, our principal executive officer and principal financial officer concluded that, as of the end of the period covered by this report, our disclosure controls and procedures were effective to provide reasonable assurance that (a) the information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms, and (b) such information is accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate to allow timely decisions regarding required disclosure. In designing and evaluating our disclosure controls and procedures, our management recognized that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives, and our management necessarily was required to apply its judgment in evaluating the cost benefit relationship of possible controls and procedures.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting during the quarter ended December 31, 2018 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Management's Annual Report on Internal Control over Financial Reporting

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

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

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

Our management assessed the effectiveness of our internal control over financial reporting as of December 31, 2018. In making this assessment, management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission ("COSO") in its 2013 Internal Control—Integrated Framework.

Based on this assessment, our management has concluded that, as of December 31, 2018, our internal control over financial reporting was effective.

The effectiveness of our internal control over financial reporting as of December 31, 2018 has been audited by PricewaterhouseCoopers LLP, an independent registered public accounting firm, as stated in their report, which is included in this Annual Report, beginning on page F-1.

Item 9B. Other Information

None.

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PART III

Item 10. Directors, Executive Officers and Corporate Governance

The information required by this item is incorporated herein by reference to the Proxy Statement for our 2019 Annual General Meeting of Shareholders.

Item 11. Executive Compensation

The information required by this item is incorporated herein by reference to the Proxy Statement for our 2019 Annual General Meeting of Shareholders.

Item 12. Security Ownership of Certain Beneficial Owners and Management

The information required by this item is incorporated herein by reference to the Proxy Statement for our 2019 Annual General Meeting of Shareholders.

Item 13. Certain Relationships and Related Transactions and Director Independence

The information required by this item is incorporated herein by reference to the Proxy Statement for our 2019 Annual General Meeting of Shareholders.

Item 14. Principal Accounting Fees and Services

The information required by this item is incorporated herein by reference to the Proxy Statement for our 2019 Annual General Meeting of Shareholders.

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PART IV

Item 15. Exhibits and Financial Statement Schedules

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

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

(3) The exhibits listed in the below Exhibit Index are filed or furnished as part of this Annual Report or are incorporated into this Annual Report by reference.

EXHIBIT INDEX

		Incorporated by reference herein	
Exhibit No.	Description of Exhibit	Form	Date
2.1 *	Purchase and Sale Agreement, dated March 7, 2015, by and among Alkermes Pharma Ireland Limited, Daravita Limited, Eagle Holdings USA, Inc., Recro Pharma, Inc., and Recro Pharma LLC.	Exhibit 2.1 of the Alkermes plc Current Report on Form 8-K/A (File No. 001-35299)	April 16, 2015
2.1.1	First Amendment to Purchase and Sale Agreement, dated December 8, 2016 by and among Alkermes	Exhibit 2.1.1 to the Alkermes plc Annual Report on Form 10-K (File No. 001-35299)	February 17, 2017

	Pharma Ireland Limited, Daravita Limited, Eagle Holdings USA, Inc., Recro Pharma, Inc., and Recro Gainesville LLC.		
2.1.2 #	Second Amendment to Purchase and Sale Agreement, dated December 20, 2018, by and among Alkermes Pharma Ireland Limited, Daravita Limited, Alkermes US Holdings, Inc. (as successor in interest to Eagle Holdings USA, Inc.), Recro Pharma, Inc. and Recro Gainesville LLC.		
3.1	Memorandum and Articles of Association of Alkermes plc.	Exhibit 3.1 to the Alkermes plc Current Report on Form 8-K (File No. 001-35299)	May 26, 2016
10.1	Lease between	Exhibit 10.5 to the Alkermes, Inc. Annual Report on Form 10-K (File No. 001-14131)	May 28, 2009

	Alkermes, Inc. and PDM Unit 850, LLC, dated as of April 22, 2009.		
10.1.1	First Amendment to Lease between Alkermes, Inc. and PDM Unit 850, LLC, dated as of June 18, 2009.	Exhibit 10.2 to the Alkermes, Inc. Quarterly Report on Form 10-Q (File No. 001-14131)	August 6, 2009
10.1.2	Second Amendment to Lease between Alkermes, Inc. and PDM Unit 850, LLC, dated as of November 12, 2013.	Exhibit 10.74 of the Alkermes plc Transition Report on Form 10-KT (File No. 001-35299)	February 27, 2014
10.1.3	Third Amendment to Lease between Alkermes, Inc. and PDM 850 Unit, LLC, dated as of May 15, 2014.	Exhibit 10.2 of the Alkermes plc Quarterly Report on Form 10-Q (File No. 001-35299)	July 31, 2014
10.1.4	Fourth Amendment to Lease between Alkermes, Inc. and Gl TC 850 Winter Street, LLC, dated as of December	Exhibit 10.7 to the Alkermes plc Quarterly Report on Form 10-Q (File No. 001-35299)	July 30, 2015

	30, 2014.		
10.1.5 #	Fifth Amendment to Lease between Alkermes, Inc. and GI TC 850 Winter Street, LLC, dated as of October 31, 2018.		
10.2	License Agreement, dated as of February 13, 1996, between Medisorb Technologies International L.P. and Janssen Pharmaceutica Inc. (United States) (assigned to Alkermes, Inc. in July 2006).	Exhibit 10.2 to the Alkermes plc Annual Report on Form 10-K (File No. 001-35299)	February 25, 2016

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Exhibit No.	Description of Exhibit	Incorporated by reference herein Form	Date
10.2.1 *	Third Amendment To Development Agreement, Second Amendment To Manufacturing and Supply Agreement and First Amendment To License Agreements by and between Janssen Pharmaceutica International, Janssen Pharmaceutica Inc. and Alkermes Controlled Therapeutics Inc. II, dated April 1, 2000 (assigned to Alkermes, Inc. in July 2006).	Exhibit 10.5 to the Alkermes, Inc. Quarterly Report on Form 10-Q (File No. 001-14131)	February 8, 2005
10.2.2 *	Second Amendment, dated as of August 16, 2012, to the License Agreement, dated as of February 13, 1996, as amended, by and between Alkermes, Inc. and	Exhibit 10.3 of the Alkermes plc Quarterly Report on Form 10-Q (File No. 001-35299)	November 1, 2012

	Janssen Pharmaceutica Inc. and the License Agreement, dated as of February 21, 1996, as amended, by and between Alkermes, Inc. and JPI Pharmaceutica International, and the Fifth Amendment, dated as of August 16, 2012, to the Manufacturing and Supply Agreement, dated as of August 6, 1997, as amended, by and between Alkermes, Inc., Janssen Pharmaceutica Inc. and JPI Pharmaceutica International.		
10.3	License Agreement, dated as of February 21, 1996, between Medisorb Technologies International L.P. and Janssen Pharmaceutica International (worldwide except United States) (assigned to	Exhibit 10.3 to the Alkermes plc Annual Report on Form 10-K (File No. 001-35299)	February 25, 2016

	Alkermes, Inc. in July 2006).		
10.4	Manufacturing and Supply Agreement, dated August 6, 1997, by and among JPI Pharmaceutica International, Janssen Pharmaceutica, Inc. and Alkermes Controlled Therapeutics Inc. II (assigned to Alkermes, Inc. in July 2006).	Exhibit 10.4 to the Alkermes plc Annual Report on Form 10-K (File No. 001-35299)	February 25, 2016
10.4.1 *	Fourth Amendment To Development Agreement and First Amendment To Manufacturing and Supply Agreement by and between Janssen Pharmaceutica International, Janssen Pharmaceutica Products, L.P. and Alkermes Controlled Therapeutics Inc. II, dated December 20, 2000 (assigned to Alkermes,	Exhibit 10.4 to the Alkermes, Inc. Quarterly Report on Form 10-Q (File No. 001-14131)	February 8, 2005

	Inc. in July 2006).		
10.4.2	Addendum to the Manufacturing and Supply Agreement by and among JPI Pharmaceutica International, Janssen Pharmaceutica Inc. and Alkermes Controlled Therapeutics Inc. II, dated August 1, 2001.	Exhibit 10.4.2 to the Alkermes plc Annual Report on Form 10-K (File No. 001-35299)	February 25, 2016
10.4.3	Letter Agreement and Exhibits to Manufacturing and Supply Agreement, dated February 1, 2002, by and among JPI Pharmaceutica International, Janssen Pharmaceutica Inc. and Alkermes Controlled Therapeutics Inc. II (assigned to Alkermes, Inc. in July 2006).	Exhibit 10.4.3 to the Alkermes plc Annual Report on Form 10-K (File No. 001-35299)	February 25, 2016
10.4.4 *	Amendment to Manufacturing and Supply Agreement by and between JPI	Exhibit 10.6 to the Alkermes plc Quarterly Report on Form 10-Q (File No. 011-35299)	July 30, 2015

	Pharmaceutica International, Janssen Pharmaceutica Inc. and Alkermes Controlled Therapeutics Inc. II, dated December 22, 2003 (assigned to Alkermes, Inc. in July 2006).		
10.4.5 *	Fourth Amendment To Manufacturing and Supply Agreement by and between JPI Pharmaceutica International, Janssen Pharmaceutica Inc. and Alkermes Controlled Therapeutics Inc. II, dated January 10, 2005 (assigned to Alkermes, Inc. in July 2006).	Exhibit 10.9 to the Alkermes, Inc. Quarterly Report on Form 10-Q (File No. 001-14131)	February 8, 2005
10.4.6 *	Sixth Amendment to Manufacturing and Supply Agreement by and between JPI Pharmaceutica International, Janssen Pharmaceutica Inc. and	Exhibit 10.11 to the Alkermes plc Quarterly Report on Form 10-Q (File No. 011-35299)	October 23, 2018

	Alkermes Controlled Therapeutics Inc. II (assigned to Alkermes, Inc. in July 2006), effective as of July 1, 2018.

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		Incorporated by reference herein	
Exhibit No.	Description of Exhibit	Form	Date
10.5 *	Development and License Agreement, dated as of May 15, 2000, by and between Alkermes Controlled Therapeutics Inc. II and Amylin Pharmaceuticals, Inc., as amended on October 24, 2005 and July 17, 2006 (assigned, as amended, to Alkermes, Inc. in July 2006).	Exhibit 10.28 to the Alkermes, Inc. Annual Report on Form 10-K (File No. 001-14131)	May 21, 2010
10.5.1 *	Third Amendment to Development and License Agreement, dated March 20, 2018, by and between Amylin Pharmaceuticals, LLC and Alkermes Pharma Ireland Limited (as successor-in-interest to Alkermes Controlled Therapeutics Inc. II), amending that certain Development and License Agreement, by and between ACTII and Amylin, dated	Exhibit 10.3 to the Alkermes plc Quarterly Report on Form 10-Q (File No. 011-35299)	April 26, 2018

	May 15, 2000, as amended on October 24, 2005 and July 17, 2006.		
10.6 *	Agreement by and between JPI Pharmaceutica International, Janssen Pharmaceutica Inc. and Alkermes Controlled Therapeutics Inc. II, dated December 21, 2002 (assigned to Alkermes, Inc. in July 2006).	Exhibit 10.6 to the Alkermes, Inc. Quarterly Report on Form 10-Q (File No. 001-14131)	February 8, 2005
10.6.1 *	Amendment to Agreement by and between JPI Pharmaceutica International, Janssen Pharmaceutica Inc. and Alkermes Controlled Therapeutics Inc. II, dated December 16, 2003 (assigned to Alkermes, Inc. in July 2006).	Exhibit 10.7 to the Alkermes, Inc. Quarterly Report on Form 10-Q (File No. 001-14131)	February 8, 2005
10.7	Amended and Restated License Agreement, dated September 26, 2003, by and between Acorda Therapeutics, Inc. and Elan Corporation, plc.	Exhibit 10.14 of the Acorda Therapeutics, Inc. Quarterly Report on Form 10-Q/A (File No.000-50513; film No. 11821367)	July 20, 2011
10.7.1 *	Supply Agreement, dated September 26, 2003, by and	Exhibit 10.22 of the Alkermes plc Annual Report on Form 10-K (File No. 001-35299)	May 23, 2013

	between Acorda Therapeutics, Inc. and Elan Corporation, plc.		
10.7.2	Amendment No. 1 Agreement, dated June 30, 2009, to the Amended and Restated License Agreement dated September 26, 2003 and the Supply Agreement dated September 26, 2003, and Consent to Sublicense, by and among Elan Pharma International Limited (as successor in interest to Elan Corporation, plc), Acorda Therapeutics, Inc. and Biogen Idec International GmbH.	Exhibit 10.56 to Acorda Therapeutics, Inc.'s Quarterly Report on Form 10-Q (File No.000-50513; film No. 09999376)	August 10, 2009
10.7.3	Amendment No. 2, dated March 29, 2012, to the Amended and Restated License Agreement, dated September 26, 2003, as amended, and the Supply Agreement, dated September 26, 2003, as amended, in each case by and between Acorda Therapeutics, Inc. and Alkermes	Exhibit 10.46 of the Acorda Therapeutics, Inc. Annual Report on Form 10-K (File No.000-50513; film no. 13653677)	February 28, 2013

	Pharma Ireland Limited (as successor in interest to Elan Corporation, plc).		
10.7.4	Amendment No. 3, dated February 14, 2013, to the Amended and Restated License Agreement, dated September 26, 2003, as amended and the Supply Agreement, dated September 26, 2003, as amended, in each case by and between Acorda Therapeutics, Inc. and Alkermes Pharma Ireland Limited (as successor in interest to Elan Corporation, plc).	Exhibit 10.1 of the Acorda Therapeutics, Inc. Quarterly Report on Form 10-Q (File No. 000-50513; film No. 13831684)	May 10, 2013
10.8 *	License Agreement by and among Elan Pharmaceutical Research Corp., d/b/a Nanosystems and Elan Pharma International Limited and Janssen Pharmaceutica N.V. dated as of March 31, 1999.	Exhibit 10.23 of the Alkermes plc Annual Report on Form 10-K (File No. 001-35299)	May 23, 2013

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Exhibit No.	Description of Exhibit	Incorporated by reference herein Form	Date
10.8.1	First Amendment, dated as of July 31, 2003, to the License Agreement by and among Elan Drug Delivery, Inc. (formerly Elan Pharmaceutical Research Corp.) and Elan Pharma International Limited and Janssen Pharmaceutica NV dated March 31, 1999.	Exhibit 10.24 of the Alkermes plc Annual Report on Form 10-K (File No. 001-35299)	May 23, 2013
10.8.2 *	Agreement Amendment No. 2, dated as of July 31, 2009, to the License Agreement by and among Elan Pharmaceutical Research Corp., d/b/a Nanosystems and Elan Pharma International Limited and Janssen Pharmaceutica N.V. dated as of March	Exhibit 10.25 of the Alkermes plc Annual Report on Form 10-K (File No. 001-35299)	May 23, 2013

	31, 1999, as amended by the First Amendment, dated as of July 31, 2003.		
10.9	Amendment to First Lien Credit Agreement, dated September 25, 2012, among Alkermes, Inc., Alkermes plc, the guarantors party thereto, the lenders party thereto, Morgan Stanley Senior Funding, Inc. as Administrative Agent and Collateral Agent and the arrangers and agents party thereto.	Exhibit 10.1 of the Alkermes plc Current Report on Form 8-K (File No. 011-35299)	September 25, 2012
10.9.1	Amendment No. 2, dated as of February 14, 2013, to Amended and Restated Credit Agreement, dated as of September 16, 2011, as amended and restated on September 25, 2012,	Exhibit 10.1 of the Alkermes plc Current Report on Form 8-K (File No. 011-35299)	February 19, 2013

	among Alkermes, Inc., Alkermes plc, the guarantors party thereto, the lenders party thereto, Morgan Stanley Senior Funding, Inc. as Administrative Agent and Collateral Agent and the arrangers and agents party thereto.		
10.9.2	Amendment No. 3 and Waiver to Amended and Restated Credit Agreement, dated as of May 22, 2013, among Alkermes, Inc., Alkermes plc, Alkermes Pharma Ireland Limited, Alkermes US Holdings, Inc., Morgan Stanley Senior Funding, Inc. as Administrative Agent and Collateral Agent and the lenders	Exhibit 10.52 of the Alkermes plc Annual Report on Form 10-K (File No. 011-35299)	May 23, 2013

	party thereto.		
10.9.3	Amendment No. 4, dated as of October 12, 2016, to Amended and Restated Credit Agreement, dated as of September 16, 2011, as amended and restated on September 25, 2012, as further amended by Amendment No. 2 on February 14, 2013 and as amended by Amendment No. 3 and Waiver to Amended and Restated Credit Agreement dated as of May 22, 2013, among Alkermes, Inc., Alkermes plc, the guarantors party thereto, the lenders party thereto and Morgan Stanley Senior Funding, Inc. as Administrative Agent and Collateral Agent.	Exhibit 10.2 of the Alkermes plc Quarterly Report on Form 10-Q (File No. 011-35299)	November 2, 2016
10.9.4			April 26, 2018

Amendment No. 5, dated as of March 26, 2018, to Amended and Restated Credit Agreement, dated as of September 16, 2011, as amended and restated on September 25, 2012, as further amended by Amendment No. 2 on February 14, 2013, as amended by Amendment No. 3 and Waiver to Amended and Restated Credit Agreement dated as of May 22, 2013, and as amended by Amendment No. 4, dated as of October 12, 2016, among Alkermes, Inc., Alkermes plc, the guarantors party thereto, the lenders party thereto and Morgan Stanley Senior Funding, Inc. as	Exhibit 10.5 to the Alkermes plc Quarterly Report on Form 10-Q (File No. 011-35299)

	Administrative Agent and Collateral Agent.		
10.10 *	License and Collaboration Agreement, dated November 27, 2017, by and between Alkermes Pharma Ireland Limited and Biogen Swiss Manufacturing GmbH.	Exhibit 10.10 of the Alkermes plc Annual Report on Form 10-K (File No. 011-35299)	February 16, 2018

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Exhibit No.	Description of Exhibit	Incorporated by reference herein Form	Date
10.10.1 *	First Amendment to License and Collaboration Agreement between Alkermes Pharma Ireland Limited and Biogen Swiss Manufacturing GmbH, effective as of October 3, 2018.	Exhibit 10.12 to the Alkermes plc Quarterly Report on Form 10-Q (File No. 011-35299)	October 23, 2018
10.11	Lease between Alkermes, Inc. and PDM 900 Unit, LLC, dated March 23, 2018.	Exhibit 10.4 to the Alkermes plc Quarterly Report on Form 10-Q (File No. 011-35299)	April 26, 2018
10.11.1	First Amendment to Lease, dated June 21, 2018, by and between Alkermes, Inc. and PDM 900 Unit, LLC.	Exhibit 10.2 to the Alkermes plc Quarterly Report on Form 10-Q (File No. 001-35299)	July 26, 2018
10.12 †	Employment agreement, dated as of December 12, 2007, by and between Richard F. Pops and Alkermes, Inc.	Exhibit 10.1 to the Alkermes, Inc. Quarterly Report on Form 10-Q (File No. 001-14131)	February 11, 2008

10.12.1 †	Amendment to Employment Agreement, dated as of October 7, 2008, by and between Alkermes, Inc. and Richard F. Pops.	Exhibit 10.5 to the Alkermes, Inc. Current Report on Form 8-K (File No. 001-14131)	October 7, 2008
10.12.2 †	Amendment No. 2 to Employment Agreement by and between Alkermes, Inc. and Richard F. Pops, dated September 10, 2009.	Exhibit 10.2 to the Alkermes, Inc. Current Report on Form 8-K (File No. 001-14131)	September 11, 2009
10.13 †	Form of Employment Agreement, dated as of December 12, 2007, entered into by and between Alkermes, Inc. and each of Kathryn L. Biberstein, James M. Frates and Michael J. Landine.	Exhibit 10.3 to the Alkermes, Inc. Quarterly Report on Form 10-Q (File No. 001-14131)	February 11, 2008
10.13.1 †	Form of Amendment to Employment Agreement entered into by and between Alkermes,	Exhibit 10.7 to the Alkermes, Inc. Current Report on Form 8-K (File No. 001-14131)	October 7, 2008

	Inc. and each of Kathryn L. Biberstein, James M. Frates and Michael J. Landine.		
10.14 †	Form of Covenant Not to Compete, of various dates, by and between Alkermes, Inc. and each of Kathryn L. Biberstein and James M. Frates.	Exhibit 10.15 to the Alkermes, Inc. Annual Report on Form 10-K (File No. 001-14131)	May 30, 2008
10.15 †	Form of Covenant Not to Compete, of various dates, by and between Alkermes, Inc. and Michael J. Landine.	Exhibit 10.15(a) to the Alkermes, Inc. Annual Report on Form 10-K (File No. 001-14131)	May 30, 2008
10.16 †	Offer Letter between Alkermes, Inc. and Mark P. Stejbach, effective as of February 15, 2012.	Exhibit 10.2 to the Alkermes plc Current Report on Form 8-K (File No. 011-35299)	March 5, 2012
10.16.1 †	Employment Agreement by and between Alkermes, Inc. and Mark P. Stejbach, dated as of	Exhibit 10.1 to the Alkermes plc Current Report on Form 8-K (File No. 011-35299)	March 5, 2012

	February 29, 2012.		
10.16.2 †	Amendment to Employment Agreement, dated as of July 21, 2015, by and between Mark P. Stejbach and Alkermes, Inc.	Exhibit 10.2 to the Alkermes plc Quarterly Report on Form 10-Q (File No. 011-35299)	July 30, 2015
10.17 †	Form of Employment Agreement entered into by and between Alkermes, Inc. and each of Iain M. Brown, David J. Gaffin, Craig C. Hopkinson, M.D. and James R. Robinson, Jr.	Exhibit 10.1 to the Alkermes plc Quarterly Report on Form 10-Q (File No. 011-35299)	November 2, 2016
10.17.1†	Offer Letter between Alkermes, Inc. and Craig C. Hopkinson M.D., effective as of April 24, 2017.	Exhibit 10.17.1 of the Alkermes plc Annual Report on Form 10-K (File No. 011-35299)	February 16, 2018

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		Incorporated by reference herein	
Exhibit No.	Description of Exhibit	Form	Date
10.17.2 †	Offer Letter between Alkermes, Inc. and James R. Robinson, Jr., dated February 28, 2018.	Exhibit 10.1 of the Alkermes plc Quarterly Report on Form 10-Q (File No. 011-35299)	April 26, 2018
10.18 †	Form of Indemnification Agreement by and between Alkermes, Inc. and each of its directors and executive officers.	Exhibit 10.1 to the Alkermes, Inc. Current Report on Form 8-K (File No. 001-14131)	March 25, 2010
10.19 †	Form of Deed of Indemnification for Alkermes plc Officers.	Exhibit 10.1 to the Alkermes plc Current Report on Form 8-K (File No. 011-35299)	September 20, 2011
10.20 †	Form of Deed of Indemnification for Alkermes plc Directors/Secretary.	Exhibit 10.2 to the Alkermes plc Current Report on Form 8-K (File No. 011-35299)	September 20, 2011
10.21 †	Form of Deed of Indemnification for Alkermes, Inc. and Subsidiaries Directors/Secretary.	Exhibit 10.3 to the Alkermes plc Current Report on Form 8-K (File No. 011-35299)	September 20, 2011
10.22†	Alkermes plc Amended and Restated 2008 Stock Option and Incentive Plan, as amended.	Exhibit 10.1 to the Alkermes plc Quarterly Report on Form 10-Q for the quarter ended March 31, 2017 (File No. 001-35299)	April 27, 2017
10.22.1 †	Form of Stock Option Award Certificate (Non-Employee Director) under	Exhibit 10.4 to the Alkermes plc Quarterly Report on Form 10-Q for the quarter ended March 31, 2016 (File No. 001-35299)	April 28, 2016

	the Alkermes plc Amended and Restated 2008 Stock Option and Incentive Plan, as amended.		
10.22.2 †	Form of Restricted Stock Unit Award Certificate (Time Vesting Only – Irish) under the Alkermes plc Amended and Restated 2008 Stock Option and Incentive Plan, as amended.	Exhibit 10.5 to the Alkermes plc Quarterly Report on Form 10-Q for the quarter ended March 31, 2016 (File No. 001-35299)	April 28, 2016
10.22.3 †	Form of Restricted Stock Unit Award Certificate (Time Vesting Only – U.S.) under the Alkermes plc Amended and Restated 2008 Stock Option and Incentive Plan, as amended.	Exhibit 10.6 to the Alkermes plc Quarterly Report on Form 10-Q for the quarter ended March 31, 2016 (File No. 001-35299)	April 28, 2016
10.22.4 †	Form of Stock Option Award Certificate (Time Vesting Non-Qualified Option – Irish) under the Alkermes plc Amended and Restated 2008 Stock Option and Incentive Plan, as amended.	Exhibit 10.7 to the Alkermes plc Quarterly Report on Form 10-Q for the quarter ended March 31, 2016 (File No. 001-35299)	April 28, 2016
10.22.5 †	Form Stock Option Award	Exhibit 10.8 to the Alkermes plc Quarterly Report on Form 10-Q for the quarter ended March 31, 2016 (File No. 001-35299)	April 28, 2016

	Certificate (Time Vesting Non-Qualified Option – U.S.) under the Alkermes plc Amended and Restated 2008 Stock Option and Incentive Plan, as amended.		
10.22.6 †	Form of Stock Option Award Certificate (Incentive Stock Option – U.S.) under the Alkermes plc Amended and Restated 2008 Stock Option and Incentive Plan, as amended.	Exhibit 10.9 to the Alkermes plc Quarterly Report on Form 10-Q for the quarter ended March 31, 2016 (File No. 001-35299)	April 28, 2016

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		Incorporated by reference herein	
Exhibit No.	Description of Exhibit	Form	Date
10.22.7 †	Form of 2008 Restricted Stock Unit Award Certificate (Performance Vesting Only) under the Alkermes plc Amended and Restated 2008 Stock Option and Incentive Plan, as amended.	Exhibit 10.2 to the Alkermes, Inc. Current Report on Form 8-K (File No. 001-14131)	May 22, 2009
10.23†	Alkermes plc 2011 Stock Option and Incentive Plan, as amended.	Exhibit 10.1 to the Alkermes plc Current Report on Form 8-K (File No. 011-35299)	May 24, 2017
10.23.1 †	Form of Incentive Stock Option Award Certificate under the Alkermes plc 2011 Stock Option and Incentive Plan, as amended.	Exhibit 10.1 to the Alkermes plc Quarterly Report on Form 10-Q (File No. 001-35299)	October 23, 2018
10.23.2 †	Form of Non-Qualified Stock Option (Employee) Award Certificate under the Alkermes plc 2011 Stock Option and Incentive Plan, as amended.	Exhibit 10.2 to the Alkermes plc Quarterly Report on Form 10-Q (File No. 001-35299)	October 23, 2018
10.23.3 †	Form of Restricted Stock Unit (Time-Vesting) Award Certificate under the Alkermes plc 2011 Stock Option and Incentive Plan, as amended.	Exhibit 10.3 to the Alkermes plc Quarterly Report on Form 10-Q (File No. 001-35299)	October 23, 2018
10.23.4 †	Form of Restricted Stock Unit (Performance-Vesting) Award Certificate	Exhibit 10.4 to the Alkermes plc Quarterly Report on Form 10-Q (File No. 001-35299)	October 23, 2018

	under the Alkermes plc 2011 Stock Option and Incentive Plan, as amended.		
10.23.5 †	Form of Non-Qualified Stock Option (Non-Employee Director) Award Certificate under the Alkermes plc 2011 Stock Option and Incentive Plan, as amended.	Exhibit 10.5 to the Alkermes plc Quarterly Report on Form 10-Q (File No. 001-35299)	October 23, 2018
10.24 †	Alkermes plc 2018 Stock Option and Incentive Plan.	Exhibit 10.1 to the Alkermes plc Current Report on Form 8-K (File No. 011-35299)	May 23, 2018
10.24.1 †	Form of Incentive Stock Option Award Certificate under the Alkermes plc 2018 Stock Option and Incentive Plan.	Exhibit 10.6 to the Alkermes plc Quarterly Report on Form 10-Q (File No. 001-35299)	October 23, 2018
10.24.2 †	Form of Non-Qualified Stock Option (Employee) Award Certificate under the Alkermes plc 2018 Stock Option and Incentive Plan.	Exhibit 10.7 to the Alkermes plc Quarterly Report on Form 10-Q (File No. 001-35299)	October 23, 2018
10.24.3 †	Form of Restricted Stock Unit (Time-Vesting) Award Certificate under the Alkermes plc 2018 Stock Option and Incentive Plan.	Exhibit 10.8 to the Alkermes plc Quarterly Report on Form 10-Q (File No. 001-35299)	October 23 ,2018
10.24.4 †	Form of Restricted Stock Unit (Performance-Vesting) Award Certificate under the Alkermes plc 2018 Stock Option and Incentive Plan.	Exhibit 10.9 to the Alkermes plc Quarterly Report on Form 10-Q (File No. 001-35299)	October 23, 2018
10.24.5 †	Form of Non-Qualified	Exhibit 10.10 to the Alkermes plc Quarterly Report on Form 10-Q (File No. 001-35299)	October 23, 2018

	Stock Option (Non-Employee Director) Award Certificate under the Alkermes plc 2018 Stock Option and Incentive Plan.
21.1 #	List of subsidiaries
23.1 #	Consent of PricewaterhouseCoopers LLP, an independent registered public accounting firm
24.1 #	Power of Attorney (included on the signature pages hereto)
31.1 #	Certification Pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934
31.2 #	Certification Pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934
32.1 ‡	Certification Pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
101.INS +#	XBRL Instance Document
101.SCH +#	XBRL Taxonomy Extension Schema Document

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Exhibit No.	Description of Exhibit	Incorporated by reference herein Date
101.CAL +#	XBRL Taxonomy Extension Calculation Linkbase Document	
101.DEF +#	XBRL Taxonomy Extension Definition Linkbase Document	
101.LAB +#	XBRL Taxonomy Extension Label Linkbase Document	
101.PRE +#	XBRL Taxonomy Extension Presentation Linkbase Document	

†	Indicates a management contract or any compensatory plan, contract or arrangement.
+	XBRL (Extensible Business Reporting Language).
#	Filed herewith.
‡	Furnished herewith.
*	

	Confidential treatment has been granted or requested for certain portions of this exhibit. Such portions have been filed separately with the SEC pursuant to a confidential treatment request.

Item 16. Form 10-K Summary

Not applicable.

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SIGNATURES

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

ALKERMES PLC

By: /s/ Richard F. Pops

Richard F. Pops

Chairman and Chief Executive Officer

February 15, 2019

POWER OF ATTORNEY

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

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

Signature	Title	Date
/s/ Richard F. Pops Richard F. Pops	Chairman and Chief Executive Officer (Principal Executive Officer)	February 15, 2019
/s/ James M. Frates James M. Frates	Senior Vice President and Chief Financial Officer (Principal Financial Officer)	February 15, 2019
/s/ Iain M. Brown Iain M. Brown	Senior Vice President and Chief Accounting Officer (Principal Accounting Officer)	February 15, 2019
/s/ David W. Anstice David W. Anstice	Director	February 15, 2019

/s/ Robert A. Breyer Robert A. Breyer	Director	February 15, 2019
/s/ Shane Cooke Shane Cooke	Director	February 15, 2019
/s/ Wendy L. Dixon Wendy L. Dixon	Director	February 15, 2019
/s/ Paul J. Mitchell Paul J. Mitchell	Director	February 15, 2019
/s/ Nancy L. Snyderman Nancy L. Snyderman	Director	February 15, 2019
/s/ Nancy J. Wysenski Nancy J. Wysenski	Director	February 15, 2019

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Report of Independent Registered Public Accounting Firm

To the Board of Directors and Shareholders of Alkermes plc

Opinions on the Financial Statements and Internal Control over Financial Reporting

We have audited the accompanying consolidated balance sheets of Alkermes plc and its subsidiaries (the “Company”) as of December 31, 2018 and 2017, and the related consolidated statements of operations and comprehensive loss, of shareholders’ equity and of cash flows for each of the three years in the period ended December 31, 2018, including the related notes (collectively referred to as the “consolidated financial statements”). We also have audited the Company's internal control over financial reporting as of December 31, 2018, based on criteria established in Internal Control - Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO).

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of the Company as of December 31, 2018 and 2017, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2018 in conformity with accounting principles generally accepted in the United States of America. Also in our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2018, based on criteria established in Internal Control - Integrated Framework (2013) issued by the COSO.

Change in Accounting Principles

As discussed in Note 2 to the consolidated financial statements, the Company changed the manner in which it accounts for revenue from contracts with customers in 2018 and the manner in which it accounts for share-based compensation in 2017.

Basis for Opinions

The Company's management is responsible for these consolidated financial statements, for maintaining effective internal control over financial reporting, and for its assessment of the effectiveness of internal control over financial reporting, included in Management's Annual Report on Internal Control over Financial Reporting appearing under Item 9A. Our responsibility is to express opinions on the Company’s consolidated financial statements and on the Company's internal control over financial reporting based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud, and whether effective internal control over financial reporting was maintained in all material respects.

Our audits of the consolidated financial statements included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. Our audit of internal control over financial reporting included obtaining an understanding of

internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audits also included performing such other procedures as we considered necessary in the circumstances. We believe that our audits provide a reasonable basis for our opinions.

Definition and Limitations of Internal Control over Financial Reporting

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

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

/s/PricewaterhouseCoopers LLP

Boston, Massachusetts

February 15, 2019

We have served as the Company's auditor since 2007.

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ALKERMES PLC AND SUBSIDIARIES

CONSOLIDATED BALANCE SHEETS

December 31, 2018 and 2017

	December 31, 2018	December 31, 2017
	(In thousands, except share and per share amounts)	
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$266,762	$ 191,296
Investments—short-term	272,533	242,208
Receivables, net	292,223	233,590
Contract assets	8,230	—
Inventory	90,196	93,275
Prepaid expenses and other current assets	53,308	48,475
Total current assets	983,252	808,844
PROPERTY, PLANT AND EQUIPMENT, NET	309,987	284,736
INTANGIBLE ASSETS, NET	191,001	256,168
INVESTMENTS—LONG-TERM	80,744	157,212
GOODWILL	92,873	92,873
CONTINGENT CONSIDERATION	65,200	84,800
DEFERRED TAX ASSETS	85,807	98,560
OTHER ASSETS	16,143	14,034
TOTAL ASSETS	$1,825,007	$ 1,797,227
LIABILITIES AND SHAREHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Accounts payable and accrued expenses	$333,762	$ 286,166
Contract liabilities—short-term	3,169	1,956
Long-term debt—short-term	2,843	3,000
Total current liabilities	339,774	291,122
LONG-TERM DEBT	276,465	278,436
OTHER LONG-TERM LIABILITIES	27,958	19,204
CONTRACT LIABILITIES—LONG-TERM	9,525	5,657
Total liabilities	653,722	594,419
COMMITMENTS AND CONTINGENT LIABILITIES (Note 16)		
SHAREHOLDERS' EQUITY:		
Preferred shares, par value, $0.01 per share; 50,000,000 shares authorized; zero issued and outstanding at December 31, 2018 and 2017, respectively	—	—
Ordinary shares, par value, $0.01 per share; 450,000,000 shares authorized; 158,180,833 and 156,057,632 shares issued; 155,757,344 and 154,009,456 shares outstanding at December 31, 2018 and 2017, respectively	1,579	1,557
Treasury shares, at cost (2,423,489 and 2,048,176 shares at December 31, 2018 and 2017, respectively)	(108,969)	(89,347)
Additional paid-in capital	2,467,323	2,338,755
Accumulated other comprehensive loss	(3,280)	(3,792)

Accumulated deficit	(1,185,368)	(1,044,365)
Total shareholders' equity	1,171,285	1,202,808
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	$1,825,007	$ 1,797,227

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

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ALKERMES PLC AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

Years Ended December 31, 2018, 2017 and 2016

	Year Ended December 31,		
	2018	2017	2016
	(In thousands, except per share amounts)		
REVENUES:			
Manufacturing and royalty revenues	$526,675	$505,308	$487,247
Product sales, net	450,334	362,834	256,146
Research and development revenue	68,895	7,232	2,301
License revenue	48,370	28,000	—
Total revenues	1,094,274	903,374	745,694
EXPENSES:			
Cost of goods manufactured and sold (exclusive of amortization of acquired intangible assets shown below)	176,420	154,748	132,122
Research and development	425,406	412,889	387,148
Selling, general and administrative	526,408	421,578	374,130
Amortization of acquired intangible assets	65,168	62,059	60,959
Total expenses	1,193,402	1,051,274	954,359
OPERATING LOSS	(99,128)	(147,900)	(208,665)
OTHER (EXPENSE) INCOME, NET:			
Interest income	9,238	4,649	3,752
Interest expense	(15,437)	(12,008)	(14,889)
Change in the fair value of contingent consideration	(19,600)	21,600	7,900
Other expense, net	(2,040)	(9,615)	(2,485)
Total other (expense) income, net	(27,839)	4,626	(5,722)
LOSS BEFORE INCOME TAXES	(126,967)	(143,274)	(214,387)
INCOME TAX PROVISION (BENEFIT)	12,344	14,671	(5,943)
NET LOSS	$(139,311)	$(157,945)	$(208,444)
LOSS PER ORDINARY SHARE:			
Basic and diluted	$(0.90)	$(1.03)	$(1.38)
WEIGHTED AVERAGE NUMBER OF ORDINARY SHARES OUTSTANDING:			
Basic and diluted	155,112	153,415	151,484
COMPREHENSIVE LOSS:			
Net loss	$(139,311)	$(157,945)	$(208,444)
Holding gain, net of a tax provision (benefit) of $159, $(295) and $237, respectively	512	(518)	522
COMPREHENSIVE LOSS	$(138,799)	$(158,463)	$(207,922)

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

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ALKERMES PLC AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF SHAREHOLDERS' EQUITY

Years Ended December 31, 2018, 2017 and 2016

	Ordinary Shares		Additional Paid-In	Accumulated Other Comprehensive	Accumulated	Treasury Stock		
	Shares	Amount	Capital	Loss	Deficit	Shares	Amount	Total
	(In thousands, except share data)							
BALANCE — December 31, 2015	152,128,941	$1,518	$2,114,711	$(3,795)	$(739,498)	(1,427,952)	$(58,661)	$1,314,275
Issuance of ordinary shares under employee stock plans	2,027,571	20	20,288	—	—	—	—	20,308
Receipt of Alkermes' shares for the purchase of stock options or to satisfy minimum tax withholding obligations related to share based awards	34,769	1	510	—	—	(332,815)	(13,978)	(13,467)
Share-based compensation expense	—	—	94,458	—	—	—	—	94,458
Excess tax benefit from share-based compensation	—	—	1,830	—	—	—	—	1,830
Unrealized gain on marketable securities, net of tax provision of $237	—	—	—	521	—	—	—	521
Net loss	—	—	—	—	(208,444)	—	—	(208,444)
BALANCE — December 31, 2016	154,191,281	$1,539	$2,231,797	$(3,274)	$(947,942)	(1,760,767)	$(72,639)	$1,209,481
Issuance of ordinary shares under employee stock plans	1,850,084	16	23,501	—	—	—	—	23,517
Receipt of Alkermes' shares for the purchase of stock options or to satisfy minimum tax withholding obligations related to	16,267	2	273	—	—	(287,409)	(16,708)	(16,433)

share based awards								
Share-based compensation expense	—	—	83,184	—	—	—	—	83,184
Unrealized loss on marketable securities, net of tax benefit of $(295)	—	—	—	(518)	—	—	—	(518)
Cumulative effect adjustment related to change in accounting for excess tax benefits	—	—	—	—	61,522	—	—	61,522
Net loss	—	—	—	—	(157,945)	—	—	(157,945)
BALANCE — December 31, 2017	156,057,632	$1,557	$2,338,755	$(3,792)	$(1,044,365)	(2,048,176)	$(89,347)	$1,202,808
Issuance of ordinary shares under employee stock plans	1,087,815	11	20,866	—	—	—	—	20,877
Receipt of Alkermes' shares for the purchase of stock options or to satisfy minimum tax withholding obligations related to share based awards	1,035,386	11	(11)	—	—	(375,313)	(19,622)	(19,622)
Share-based compensation expense	—	—	107,713	—	—	—	—	107,713
Unrealized loss on marketable securities, net of tax provision of $159	—	—	—	512	—	—	—	512
Cumulative effect adjustment related to the adoption of new accounting standards	—	—	—	—	(1,692)	—	—	(1,692)
Net loss	—	—	—	—	(139,311)	—	—	(139,311)
BALANCE — December 31, 2018	158,180,833	$1,579	$2,467,323	$(3,280)	$(1,185,368)	(2,423,489)	$(108,969)	$1,171,285

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

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ALKERMES PLC AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF CASH FLOWS

Years Ended December 31, 2018, 2017 and 2016

	Year Ended December 31,		
	2018	2017	2016
	(In thousands)		
CASH FLOWS FROM OPERATING ACTIVITIES:			
Net loss	$(139,311)	$(157,945)	$(208,444)
Adjustments to reconcile net loss to cash flows from operating activities:			
Depreciation and amortization	103,660	98,523	94,256
Share-based compensation expense	105,357	83,917	94,396
Deferred income taxes	10,623	7,234	(9,689)
Change in the fair value of contingent consideration	19,600	(21,600)	(7,900)
Impairment of property, plant and equipment	5,746	—	—
Loss on debt refinancing	2,298	—	2,075
Payment made for debt refinancing	(2,251)	—	—
Impairment of investment in Synchronicity Pharma, Inc.	—	10,471	—
Excess tax benefit from share-based compensation	—	—	(4,229)
Other non-cash charges	979	3,471	2,936
Changes in assets and liabilities:			
Receivables	(58,632)	(42,489)	(35,616)
Contract assets	880	—	—
Inventory	(2,665)	(30,191)	(26,381)
Prepaid expenses and other assets	(5,990)	(9,506)	(15,014)
Accounts payable and accrued expenses	46,739	72,658	45,870
Contract liabilities	3,252	(1,447)	(649)
Other long-term liabilities	8,996	6,094	4,587
Cash flows provided by (used in) operating activities	99,281	19,190	(63,802)
CASH FLOWS FROM INVESTING ACTIVITIES:			
Additions of property, plant and equipment	(69,431)	(51,300)	(43,657)
Proceeds from the sale of equipment	507	162	194
Purchases of investments	(397,727)	(431,712)	(375,099)
Sales and maturities of investments	444,456	464,494	560,805
Investment in Synchronicity Pharma, Inc.	—	—	(15,000)
Cash flows (used in) provided by investing activities	(22,195)	(18,356)	127,243
CASH FLOWS FROM FINANCING ACTIVITIES:			
Proceeds from the issuance of ordinary shares under share-based compensation arrangements	20,877	23,517	20,308
Employee taxes paid related to net share settlement of equity awards	(19,622)	(16,433)	(13,467)
Payment made for debt refinancing	(743)	—	(65,813)
Excess tax benefit from share-based compensation	—	—	4,229
Principal payments of long-term debt	(2,132)	(3,000)	(3,429)
Cash flows (used in) provided by financing activities	(1,620)	4,084	(58,172)
NET INCREASE IN CASH AND CASH EQUIVALENTS	75,466	4,918	5,269

CASH AND CASH EQUIVALENTS—Beginning of period	191,296	186,378	181,109
CASH AND CASH EQUIVALENTS—End of period	$266,762	$191,296	$186,378
SUPPLEMENTAL CASH FLOW DISCLOSURE:			
Cash paid for interest	$12,526	$11,143	$12,458
Cash paid for taxes	$754	$2,992	$5,531
Non-cash investing and financing activities:			
Purchased capital expenditures included in accounts payable and accrued expenses	$11,720	$11,151	$5,766

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

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ALKERMES PLC AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

1. DESCRIPTION OF BUSINESS AND BASIS OF PRESENTATION

Alkermes plc (the "Company") is a fully integrated, global biopharmaceutical company that applies its scientific expertise and proprietary technologies to research, develop and commercialize, both with partners and on its own, pharmaceutical products that are designed to address unmet medical needs of patients in major therapeutic areas. The Company has a diversified portfolio of commercial drug products and a clinical pipeline of product candidates 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

Principles of Consolidation

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

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 its 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 and Cash Equivalents

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

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.”

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ALKERMES PLC AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

For securities with unrealized losses, the Company performs an analysis to assess whether it intends to sell or whether it would more likely than not be required to sell the security before the expected recovery of its amortized cost basis. If the Company intends to sell a security, or may be required to do so, the security's decline in fair value is deemed to be other-than-temporary and the full amount of the unrealized loss is recorded within earnings as an impairment loss. Regardless of the Company's intent to sell a security, the Company performs additional analysis on all securities with unrealized losses to evaluate losses associated with the creditworthiness of the security. Credit losses are identified where the Company does not expect to receive cash flows sufficient to recover the amortized cost basis of a security. The Company's held-to-maturity investments are restricted investments held as collateral under letters of credit related to certain of the Company's agreements and are included in "Investments—long-term," in the accompanying consolidated balance sheets.

Fair Value of Financial Instruments

The Company's financial assets and liabilities are recorded at fair value and are classified as Level 1, 2 or 3 within the fair value hierarchy, as described in the accounting standards for fair value measurement. The Company's financial assets and liabilities consist of cash equivalents, investments, contingent consideration and warrants to purchase the common stock of a publicly traded company 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 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 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, assets utilizing Level 3 inputs included contingent consideration, 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 and cash equivalents, accounts receivable, other current assets, accounts payable and accrued expenses approximate fair value due to their short term nature.

Inventory

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

Property, Plant and Equipment

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

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

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ALKERMES PLC AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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.

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

The Company's finite-lived intangible assets, consisting of core developed technology and collaboration agreements acquired as part of the acquisition of EDT, were recorded at fair value at the time of their acquisition and are stated within the Company’s consolidated balance sheets net of accumulated amortization and impairments. The finite-lived intangible assets are amortized over their estimated useful lives using the economic use method, which reflects the

pattern that the economic benefits of the intangible assets are consumed as revenue is generated from the underlying patent or contract. The useful lives of the Company's intangible assets are primarily based on the legal or contractual life of the underlying patent or contract, which does not include additional years for the potential extension or renewal of the contract or patent.

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.

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ALKERMES PLC AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Revenue 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 revenue, 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:

	Topic 606
(In thousands)	Adjustment
Contract assets	$ 9,110
Inventory	(8,209)
Deferred tax asset	109
Contract liabilities—short-term	(1,104)
Contract liabilities—long-term	(724)
Accumulated deficit	818
	$ —

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 revenue 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 revenue recognition guidance ("Topic 605"). The quantitative impacts of 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.

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ALKERMES PLC AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

ADJUSTED CONDENSED CONSOLIDATED BALANCE SHEET

	December 31, 2018		
(In thousands)	As Reported	Adjustment	Balances Without Adoption of Topic 606
ASSETS			
Contract assets	$8,230	$ (8,230) [1]	$ —
Inventory	90,196	8,847 [2]	99,043
Deferred tax asset	85,807	(133) [3]	85,674
LIABILITIES			
Contract liabilities—short-term	$3,169	$ (3,169) [4]	$ —
Deferred revenue—short-term	—	1,224 [4]	1,224
Contract liabilities—long-term	9,525	(9,525) [4]	—
Deferred revenue—long-term	—	8,852 [4]	8,852
SHAREHOLDERS' EQUITY			
Accumulated deficit	$(1,185,368)	$ 2,156 [5]	$ (1,183,212)

The adjustments are a result of the following:

(1) Adjustment to contract assets to reverse revenue recognized over time under Topic 606.
(2) Adjustment to inventory to add back the cost of goods manufactured related to the revenue transactions summarized in item (1), above.
(3) Adjustment to deferred tax asset to apply the tax impact of the revenue transactions summarized in item (1), above.
(4) Adjustments to contract liabilities—short-term and contract liabilities—long-term is to reclassify amounts previously classified as deferred revenue—short-term and deferred revenue—long-term under Topic 605.
(5) Adjustment to accumulated deficit for the net impact of the transactions noted in items (1) through (4) above.

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ALKERMES PLC AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

ADJUSTED CONDENSED CONSOLIDATED STATEMENTS

OF OPERATIONS AND COMPREHENSIVE LOSS

	Year Ended December 31, 2018			
(In thousands, except per share amounts)	As Reported	Adjustment		Balances Without Adoption of Topic 606
REVENUES:				
Manufacturing and royalty revenues	$526,675	$1,911	(1)	$528,586
Product sales, net	450,334	—		450,334
Research and development revenue	68,895	48,473	(2)	117,368
License revenue	48,370	(48,370)	(3)	—
Total revenues	1,094,274	2,014		1,096,288
EXPENSES:				
Cost of goods manufactured and sold	176,420	(640)	(4)	175,780
Research and development	425,406	—		425,406
Selling, general and administrative	526,408	—		526,408
Amortization of acquired intangible assets	65,168	—		65,168
Total expenses	1,193,402	(640)		1,192,762
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)
Income tax provision (benefit)	12,344	24		12,368
Net loss	$(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		155,112

The adjustments are a result of the following:

(1) Adjustments to manufacturing and royalty revenues to recognize revenue under Topic 605 in the year ended December 31, 2018 that was recognized under Topic 606.
(2) Adjustments to research and development revenue during the year ended December 31, 2018 to recognize revenue under Topic 605 that was recognized under Topic 606.
(3) Adjustments to license revenue during the year ended December 31, 2018 to recognize revenue 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.

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ALKERMES PLC AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Collaborative Arrangements

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 Revenue

The Company recognizes manufacturing revenues from the sale of products it manufactures for resale by its licensees. Manufacturing revenues 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 revenue 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 revenue 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 revenue 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 revenues is based on the end-market sales price earned by its licensees. As end-market sales generally occur after the Company has recorded manufacturing revenue, 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 revenues and estimated manufacturing revenues 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 revenues has not been material to date.

Royalty Revenue

The Company recognizes royalty revenues 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 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 revenues section, above, as the terms of such agreements entitle the Company to royalty revenue 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 revenues 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 revenues and estimated royalty revenues 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 revenues has not been material to date.

Research and Development Revenue

R&D revenue consists of funding that compensates the Company for formulation, pre clinical and clinical testing under R&D arrangements with its 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. Revenue is recognized as the obligations under the R&D arrangements are performed.

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ALKERMES PLC AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

License Revenue

The Company recognizes revenue 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.

Revenues 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 revenues 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;
- 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.

Receivables, net

Receivables, net, include amounts billed and currently unconditionally due from customers. The amounts due are stated at their net estimated realizable value. The Company maintains an allowance for doubtful accounts to provide for the estimated amounts of receivables that will not be collected. The allowance is based upon an assessment of customer creditworthiness, historical payment experience, the age of outstanding receivables and collateral to the extent applicable. The Company's allowance for doubtful accounts was $0.2 million at December 31, 2018 and 2017.

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ALKERMES PLC AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Contract Assets

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
Contract assets at January 1, 2018	$9,110
Additions	57,617
Transferred to receivables, net	(58,497)
Contract assets at December 31, 2018	$8,230

Contract Liabilities

The Company's contract liabilities consist of contractual obligations related to deferred revenue.

Contract liabilities consisted of the following:

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

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 statements of operations and comprehensive loss. During the years ended December 31, 2018, 2017 and 2016 the Company recorded a (loss) gain on foreign currency translation of $(2.3) million, $3.7 million and $0.1 million, respectively.

Concentrations

Financial instruments that potentially subject the Company to concentrations of credit risk are receivables and marketable securities. Billings to large pharmaceutical companies account for the majority of the Company's receivables, and collateral is generally not required from these customers. To mitigate credit risk, the Company monitors the financial performance and credit worthiness of its customers. The following represents revenue and receivables from the Company's customers exceeding 10% of the total in each category as of, and for the years ended, December 31, 2018, 2017 and 2016:

	Year Ended December 31,					
	2018		2017		2016	
Customer	Receivables	Revenue	Receivables	Revenue	Receivables	Revenue
Janssen	27 %	29 %	31 %	33 %	33 %	36 %
Acorda	15 %	10 %	14 %	13 %	17 %	15 %
Cardinal Health	*	13 %	*	*	*	*
Biogen	*	10 %	*	*	*	*

* Indicates the revenues 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, 2017 and 2016, 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.

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ALKERMES PLC AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Geographic Information

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

	Year Ended December 31,		
(In thousands)	2018	2017	2016
Revenue by region:			
U.S.	$884,600	$700,090	$557,312
Ireland	4,915	9,706	4,407
Rest of world	204,759	193,578	183,975
Assets by region:			
Current assets:			
U.S.	$546,533	$402,481	$382,168
Ireland	433,837	403,167	407,761
Rest of world	2,882	3,196	749
Long-term assets:			
U.S.:			
Other	$312,243	$360,641	$236,175
Ireland:			
Intangible assets	$191,001	$256,168	$318,227
Goodwill	92,873	92,873	92,873
Other	245,638	278,701	288,470

Research and Development Expenses

For each of its R&D programs, the Company incurs both external and internal expenses. External R&D expenses include costs related to clinical and non clinical activities performed by contract research organizations, consulting fees, laboratory services, purchases of drug product materials and third party manufacturing development costs. Internal R&D expenses include employee related expenses, occupancy costs, depreciation and general overhead. The Company tracks external R&D expenses for each of its development programs, however, internal R&D expenses, with the exception of those expenses related to BIIB098, are not tracked by individual program as they benefit multiple programs or its technologies in general.

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, 2017 and 2016, advertising costs totaled $54.7 million, $34.4 million and $24.0 million, respectively.

Share Based Compensation

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

Stock Options

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

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ALKERMES PLC AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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

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

	Year Ended December 31,		
	2018	2017	2016
Expected option term	5 - 8 years	5 - 8 years	5 - 7 years
Expected stock volatility	44 % - 49 %	43 % - 47 %	39 % - 53 %
Risk-free interest rate	2.25 % - 3.10 %	1.69 % - 2.38 %	0.95 % - 2.14 %
Expected annual dividend yield	—	—	—

Time Vested Restricted Stock Units

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

Performance-Based Restricted Stock Units

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

Income Taxes

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

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.

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ALKERMES PLC AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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, 2017 and 2016, the Company contributed $12.1 million, $9.8 million and $8.1 million, respectively, to match employee deferrals under the 401(k) Plan.

Defined Contribution Plan

The Company maintains a defined contribution plan for its Ireland based employees (the "Defined Contribution Plan"). The Defined Contribution Plan provides for eligible employees to contribute up to the maximum of 40%, depending upon their age, of their total taxable earnings subject to an earnings cap of €115,000. The Company provides a match of up to 18% of taxable earnings depending upon an individual's contribution level. During the years ended December 31, 2018, 2017 and 2016, the Company contributed $4.0 million, $3.7 million and $3.2 million, respectively, in contributions to the Defined Contribution Plan.

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

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ALKERMES PLC AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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.

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 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.

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ALKERMES PLC AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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. REVENUE FROM CONTRACTS WITH CUSTOMERS

During the years ended December 31, 2018, 2017 and 2016, the Company recorded manufacturing and royalty revenues from its collaboration arrangements as follows:

	Year Ended December 31, 2018		
(In thousands)	Manufacturing Revenue	Royalty Revenue	Total
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
	$133,028	$393,647	$526,675

	Year Ended December 31, 2017		
(In thousands)	Manufacturing Revenue	Royalty Revenue	Total
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
	$152,821	$352,487	$505,308

	Year Ended December 31, 2016		
(In thousands)	Manufacturing Revenue	Royalty Revenue	Total
INVEGA SUSTENNA/XEPLION & INVEGA TRINZA/TREVICTA	$—	$184,233	$184,233
AMPYRA/FAMPYRA	53,406	60,787	114,193
RISPERDAL CONSTA	64,914	22,316	87,230
Other	33,641	67,950	101,591
	$151,961	$335,286	$487,247

During the years ended December 31, 2018, 2017 and 2016, the Company recorded product sales, net, as follows:

	Year Ended December 31,		
(In thousands)	2018	2017	2016
VIVITROL	$302,609	$269,321	$208,982
ARISTADA	147,725	93,513	47,164
Total product sales, net	$450,334	$362,834	$256,146

Research and Development Revenue and License Revenue

The research and development revenue and license revenue recorded during the years ended December 31, 2018 and 2017 primarily related to revenue 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

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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 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 amounts allocated to the development services and clinical supply will be recognized over the course of the development work and as clinical supply is delivered to Biogen, which is expected to continue through 2019.

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 revenue 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 revenue under this agreement with Biogen through 2021.

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

4. INVESTMENTS

Investments consist of the following:

		Gross Unrealized Losses			
December 31, 2018	Amortized Cost	Gains	Less than One Year	Greater than One Year	Estimated Fair Value
Short-term investments:					
Available-for-sale securities:					
Corporate debt securities	$120,197	$57	$(62)	$(274)	$119,918
U.S. government and agency debt securities	80,055	115	(11)	(87)	80,072
International government agency debt securities	72,091	85	(8)	(117)	72,051
	272,343	257	(81)	(478)	272,041
Held-to-maturity securities:					
Corporate debt securities	492	—	—	—	492
Total short-term investments	272,835	257	(81)	(478)	272,533
Long-term investments:					
Available-for-sale securities:					
Corporate debt securities	53,505	—	(185)	(93)	53,227
U.S. government and agency debt securities	18,474	—	(21)	(12)	18,441
International government agency debt securities	5,457	—	(4)	—	5,453
	77,436	—	(210)	(105)	77,121
Held-to-maturity securities:					
Certificates of deposit	1,820	—	—	—	1,820
Fixed term deposit account	1,667	136	—	—	1,803
	3,487	136	—	—	3,623
Total long-term investments	80,923	136	(210)	(105)	80,744
Total investments	$353,758	$393	$(291)	$(583)	$353,277
December 31, 2017					
Short-term investments:					
Available-for-sale securities:					
U.S. government and agency debt securities	$150,673	$1	$(130)	$(233)	$150,311
Corporate debt securities	56,552	3	(48)	(10)	56,497
International government agency debt securities	35,478	1	(54)	(25)	35,400
Total short-term investments	242,703	5	(232)	(268)	242,208
Long-term investments:					
Available-for-sale securities:					
Corporate debt securities	83,924	—	(300)	(34)	83,590
U.S. government and agency debt securities	48,948	—	(270)	(71)	48,607

International government agency debt securities	21,453	—	(118)	—	21,335
	154,325	—	(688)	(105)	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	(688)	(105)	157,212
Total investments	$400,486	$227	$(920)	$(373)	$399,420

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

	Year Ended December 31,		
(In thousands)	2018	2017	2016
Proceeds from the sales and maturities of marketable securities	$444,456	$464,494	$560,805
Realized gains	$4	$9	$206
Realized losses	$268	$3	$28

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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.

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 year ended December 31, 2018 the Company recorded an increase in its investment in Fountain of $0.5 million and during the years ended December 31, 2017 and 2016, the Company recorded a reduction in its investment in Fountain of $0.1 million and $0.4 million, respectively, which represented the Company's proportional share of Fountain's net gains (losses) for the period, respectively. The Company's $5.5 million and $3.7 million net investment in Fountain at December 31, 2018 and 2017, respectively, was included within "Other assets" in the accompanying consolidated balance sheets.

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

5. FAIR VALUE

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

(In thousands)	December 31, 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

	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)

Decrease 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 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.

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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 increases of $21.6 million and $7.9 million during the years ended December 31, 2018, 2017 and 2016, respectively, within "Change in the fair value of contingent consideration" in the accompanying consolidated statements of operations and comprehensive loss.

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:

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

The decrease of $0.2 million, the increase of less than $0.1 million and the decrease of $0.4 million in the fair value of the warrants during the years ended December 31, 2018, 2017 and 2016, respectively, was recorded within "Other (expense) income, net" in the accompanying consolidated statements of operations and comprehensive loss.

The carrying amounts reflected in the consolidated balance sheets for cash and cash equivalents, accounts receivable, contract assets, other current assets, accounts payable and accrued expenses approximate fair value due to their short-term nature.

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”).

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. Please refer to Note 10, Long-Term Debt within these “Notes to Consolidated Financial Statements” in this Annual Report.

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ALKERMES PLC AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

6. INVENTORY

Inventory 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 inventory	$ 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 inventory located at its third party warehouse and shipping service provider.

7. PROPERTY, PLANT AND EQUIPMENT

Property, plant and equipment consist of the following:

(In thousands)	December 31, 2018	December 31, 2017
Land	$ 6,486	$ 6,293
Building and improvements	157,053	155,198
Furniture, fixtures and equipment	314,831	289,455
Leasehold improvements	20,105	19,578
Construction in progress	88,983	54,270
Subtotal	587,458	524,794
Less: accumulated depreciation	(277,471)	(240,058)
Total property, plant and equipment, net	$ 309,987	$ 284,736

Depreciation expense was $38.5 million, $36.5 million and $33.3 million for the years ended December 31, 2018, 2017 and 2016, respectively. Also, during the years ended December 31, 2018, 2017 and 2016, the Company wrote off furniture, fixtures and equipment that had a carrying value of $0.5 million, $0.1 million and $0.9 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.

8. GOODWILL AND INTANGIBLE ASSETS

Goodwill and intangible assets consist of the following:

		December 31, 2018			December 31, 2017		
(In thousands)	Weighted Amortizable Life (Years)	Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount	Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount
Goodwill		$92,873	$ —	$92,873	$92,873	$ —	$92,873
Finite-lived intangible assets:							
Collaboration agreements	12	$465,590	$ (319,311)	$146,279	$465,590	$ (269,392)	$196,198
NanoCrystal technology	13	74,600	(38,942)	35,658	74,600	(31,283)	43,317
OCR technologies	12	42,560	(33,496)	9,064	42,560	(25,907)	16,653
Total		$582,750	$ (391,749)	$191,001	$582,750	$ (326,582)	$256,168

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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, $62.1 million and $61.0 million of amortization expense related to its finite lived intangible assets during the years ended December 31, 2018, 2017 and 2016, respectively. Based on the Company's most recent analysis, amortization of intangible assets included within its consolidated balance sheets at December 31, 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. Although the Company believes such available information and assumptions are reasonable, given the inherent risks and uncertainties underlying its expectations regarding such future revenues, there is the potential for the Company's actual results to vary significantly from such expectations. If revenues are projected to change, the related amortization of the intangible assets will change in proportion to the change in revenues.

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

9. ACCOUNTS PAYABLE AND ACCRUED EXPENSES

Accounts payable and accrued expenses consist of the following:

(In thousands)	December 31, 2018	December 31, 2017
Accounts payable	$ 39,767	$ 55,526
Accrued compensation	67,613	54,568
Accrued sales discounts, allowances and reserves	152,911	111,137
Accrued other	73,471	64,935
Total accounts payable and accrued expenses	$ 333,762	$ 286,166

10. LONG TERM DEBT

Long term debt consists of the following:

(In thousands)	December 31, 2018	December 31, 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

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 Ending December 31:	
2019	$2,843
2020	2,843
2021	2,843
2022	2,843
2023	270,746
Total	$282,118

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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, 2017 and 2016, the Company had amortization expense of $0.7 million, $0.8 million and $0.9 million, respectively, related to deferred financing costs and original issue discount.

11. 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, 2017 and 2016, as the Company was in a net loss position, the diluted loss per share did not assume conversion or exercise of stock options and 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	2016
Stock options	11,331	9,540	10,166
Restricted stock units	2,592	2,119	1,320
Total	13,923	11,659	11,486

12. SHAREHOLDERS' EQUITY

Share Repurchase Program

On September 16, 2011, the board of directors authorized the continuation of the Alkermes, Inc. share repurchase program to repurchase up to $215.0 million of the Company's ordinary shares at the discretion of management from time to time in the open market or through privately negotiated transactions. At December 31, 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.

13. SHARE BASED COMPENSATION

Share based Compensation Expense

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

	Year Ended December 31,		
(In thousands)	2018	2017	2016
Cost of goods manufactured and sold	$9,174	$7,596	$8,633
Research and development	32,943	22,635	24,023
Selling, general and administrative	63,240	53,686	61,740
Total share-based compensation expense	$105,357	$83,917	$94,396

During the years ended December 31, 2018, 2017 and 2016, $2.7 million, $0.4 million and $1.1 million, respectively, of share based compensation expense was capitalized and recorded as "Inventory" in the accompanying consolidated balance sheets.

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ALKERMES PLC AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Share Based Compensation Plans

The Company has one share-based compensation plan pursuant to which awards are currently being made: the 2011 Stock Option and Incentive Plan (the “2011 Plan”). The Company has one share-based 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 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 counted against the total number of shares available under the plan in a 1.8-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, 2017 and 2016 was $30.47, $25.81 and $17.11, respectively. The aggregate intrinsic value of stock options exercised during the years ended December 31, 2018, 2017 and 2016 was $35.5 million, $40.4 million and $35.0 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, 2017 and 2016 was $20.9 million, $23.5 million and $20.3 million, respectively.

Time Vested Restricted Stock Units

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

	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

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

The weighted average grant date fair value of time vested RSUs granted during the years ended December 31, 2018, 2017 and 2016 were $63.01, $54.85 and $32.27, respectively. The total fair value of time vested RSUs that vested during the years ended December 31, 2018, 2017 and 2016, was $34.5 million, $31.5 million and $26.0 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 performance-based RSU 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
Forfeited	(176,637)	$ 54.64
Vested	(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.

14. COLLABORATIVE ARRANGEMENTS

The Company has entered into several collaborative arrangements to develop and commercialize products and, in connection with such arrangements, to access technologies, financial, marketing, manufacturing and other resources. Refer to the “Patents and Proprietary Rights” section in “Part I, Item 1— Business” of this Annual Report for information with respect to intellectual property protection for these products. The collaboration revenue the Company has earned in the years ended December 31, 2018, 2017 and 2016 is summarized in Note 3, Revenue from Contracts with Customers within the notes to the consolidated financial statements in this Annual Report.

The Company’s significant collaborative arrangements are described below:

Janssen

INVEGA SUSTENNA/XEPLION and INVEGA TRINZA/TREVICTA

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

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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

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

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 revenues when product 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%.

Acorda

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

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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;
- 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.

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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.

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.

15. INCOME TAXES

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

	Year Ended December 31,		
(In thousands)	2018	2017	2016
Current income tax provision:			

U.S. federal	$(53)	$6,964	$3,163
U.S. state	1,774	350	480
Rest of world	—	123	103
Deferred income tax provision (benefit):			
U.S. federal	10,624	8,188	(9,278)
U.S. state	62	(933)	(269)
Ireland	(63)	(21)	(142)
Total tax provision (benefit)	$12,344	$14,671	$(5,943)

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

The income tax provision in 2018 and 2017 and the income tax benefit in 2016 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. The unfavorable change in income taxes in 2017, as compared to 2016, was primarily due to the enactment of Tax Reform and an increase in income earned in the U.S., partially offset by the recognition of excess tax benefits related to share-based compensation. A $4.2 million benefit was recorded to additional paid-in capital in the year ended December 31, 2016 with a corresponding reduction to current taxes payable. This was primarily due to the utilization of current year tax benefits and NOL carryforwards derived from the exercise of employee stock options and vesting of restricted stock units.

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 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 (benefit) for income taxes by geographical area consisted of the following:

	Year Ended December 31,		
(In thousands)	2018	2017	2016
Ireland	$(180,195)	$(172,363)	$(212,198)
U.S.	53,287	2,414	(18,935)
Rest of world	(59)	26,675	16,746
Loss before provision (benefit) for income taxes	$(126,967)	$(143,274)	$(214,387)

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 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.

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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

(In thousands)	Balance at Beginning of Period	Additions [1]	Balance at End of Period
Deferred tax asset valuation allowance for the year ended December 31, 2016	$(106,746)	$ (35,113)	$(141,859)
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.

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ALKERMES PLC AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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

	Year Ended December 31,		
(In thousands, except percentage amounts)	2018	2017	2016
Statutory tax rate	12.5 %	12.5 %	12.5 %
Income tax provision at statutory rate	$(15,871)	$(17,909)	$(26,798)
Change in valuation allowance	28,371	26,771	35,290
Federal tax law change[1]	—	21,453	—
Impairment on equity method investment	—	1,662	—
Foreign rate differential[2]	5,405	(682)	2,723
Share-based compensation	1,163	(1,205)	2,072
U.S. state income taxes, net of U.S. federal benefit	1,732	(558)	(2)
Intercompany amounts[3]	(751)	(5,041)	(5,209)
Irish rate differential[4]	(2,350)	(2,675)	(5,231)
R&D credit	(7,698)	(9,326)	(10,572)
Other permanent items[5]	2,343	2,181	1,784
Income tax provision (benefit)	$12,344	$14,671	$(5,943)
Effective tax rate	(9.7)%	(10.2)%	2.8 %

(1) Represents a $21.5 million deferred tax expense recorded as a discrete item during the three months ended December 31, 2017, as a result of the reduction in the U.S. federal tax rate from 35% to 21%.

(2) Represents income or losses of non-Irish subsidiaries, including U.S. subsidiaries, subject to tax at a rate other than the Irish statutory rate.

(3) Intercompany amounts include cross-territory eliminations, the pre-tax effect of which has been eliminated in arriving at the Company's consolidated loss before taxes.

(4) Represents income or losses of Irish companies subject to tax at a rate other than the Irish statutory rate.

(5) Other permanent items include, but are not limited to, non-deductible meals and entertainment expenses, non-deductible lobbying expenses and non-deductible compensation of senior officers of the Company.

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

(In thousands)	Unrecognized Tax Benefits
Balance, December 31, 2015	$ 3,778
Reductions based on tax positions related to prior periods	(7)
Additions based on tax positions related to the current period	917
Balance, December 31, 2016	$ 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

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.

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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

16. 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
	$53,601

Rent expense related to operating leases charged to operations was $10.8 million, $9.4 million and $8.1 million for the years ended December 31, 2018, 2017 and 2016, 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 “Part I, Item 1A—Risk Factors” of this Annual 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.”

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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 “Part I, Item 1A—Risk Factors” of this Annual 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.”

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 "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."

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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 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 "Part I, Item 1A—Risk Factors" of this Annual 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 "Part I, Item 1A—Risk Factors" of this Annual 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."